



SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_.

COMMISSION FILE NUMBER: 000-1029142

DYNAVAX TECHNOLOGIES CORPORATION

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

**DELAWARE**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**33-0728374**  
(IRS Employer Identification No.)

**2929 Seventh St., Suite 100**  
**Berkeley, CA 94710-2753**  
(Address Of The Registrant's Principal Executive Offices)

Registrant's Telephone Number, Including Area Code: **(510) 848-5100**

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

The number of shares of the Registrant's Common Stock outstanding as of April 30, 2005 was 24,747,207.

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## FORWARD-LOOKING STATEMENTS

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements, including statements about our business strategy, 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 variations or comparable terminology, or by discussions of strategy.*

*Actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in “Item 2— Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this document. No assurance can be given that the risk factors described in this Quarterly Report on Form 10-Q are all of the factors that could cause actual results to vary materially from the forward-looking statements. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Readers should not place undue reliance on these forward-looking statements and are cautioned that any such forward-looking statements are not guarantees of future performance. We assume no obligation to update any forward-looking statements.*

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

## PART I. FINANCIAL STATEMENTS

## ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**Dynavax Technologies Corporation**  
**Condensed Consolidated Balance Sheets**  
**(In thousands, except per share amounts)**

	March 31, 2005 <u>(unaudited)</u>	December 31, 2004 <u>(Note 1)</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,401	\$ 16,590
Marketable securities	46,023	49,254
Restricted cash	408	408
Accounts receivable	8,957	3,131
Prepaid expenses and other current assets	2,117	1,396
Total current assets	<u>68,906</u>	<u>70,779</u>
Property and equipment, net	2,344	2,465
Other assets	—	402
Total assets	<u>\$ 71,250</u>	<u>\$ 73,646</u>
<b>Liabilities, minority interest, convertible preferred stock, and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 729	\$ 1,391
Accrued liabilities	4,240	4,371
Deferred revenues	—	1,000
Total current liabilities	<u>4,969</u>	<u>6,762</u>
Deferred revenues, noncurrent	750	6,750
Other long-term liabilities	240	258
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at March 31, 2005 and December 31, 2004	—	—
Common stock: \$0.001 par value; 100,000 shares authorized at March 31, 2005 and December 31, 2004; 24,745 and 24,627 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	25	25
Additional paid-in capital	159,120	159,074
Deferred stock compensation	(3,029)	(3,366)
Notes receivable from stockholders	(394)	(419)
Accumulated other comprehensive loss:		
Unrealized loss on marketable securities available-for-sale	(161)	(102)
Cumulative translation adjustment	(4)	—
Accumulated deficit	(90,266)	(95,336)
Total stockholders' equity	<u>65,291</u>	<u>59,876</u>
Total liabilities and stockholders' equity	<u>\$ 71,250</u>	<u>\$ 73,646</u>

*See accompanying notes.*

**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements of Operations**  
**(In thousands, except per share amounts)**  
**(Unaudited)**

	Three Months Ended March 31,	
	2005	2004
Revenues:		
Collaboration revenue	\$ 12,199	\$ 2,744
Grant revenue	499	461
Total revenues	<u>12,698</u>	<u>3,205</u>
Operating expenses:		
Research and development	5,655	5,271
General and administrative	2,340	1,919
Total operating expenses	<u>7,995</u>	<u>7,190</u>
Income (loss) from operations	4,703	(3,985)
Interest income, net	367	119
Net income (loss)	<u>\$ 5,070</u>	<u>\$ (3,866)</u>
Basic net income (loss) per share	<u>\$ 0.21</u>	<u>\$ (0.36)</u>
Shares used to compute basic net income (loss) per share	<u>24,722</u>	<u>10,847</u>
Diluted net income (loss) per share	<u>\$ 0.20</u>	<u>\$ (0.36)</u>
Shares used to compute diluted net income (loss) per share	<u>24,837</u>	<u>10,847</u>

*See accompanying notes.*

**Dynavax Technologies Corporation**  
**Condensed Consolidated Statements Cash Flows**  
**(In thousands)**  
**(Unaudited)**

	Three Months Ended March 31,	
	2005	2004
<b>Operating activities</b>		
Net income (loss)	\$ 5,070	\$ (3,866)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	184	119
Loss on disposal of property and equipment	—	17
Accretion and amortization on marketable securities	318	54
Interest accrued on notes receivable from stockholders	(7)	(10)
Amortization of stock-based compensation expense	317	626
Changes in operating assets and liabilities:		
Accounts receivable	(5,826)	(2,560)
Prepaid expenses and other current assets	(721)	231
Other assets	402	(417)
Accounts payable	(662)	626
Accrued liabilities	(131)	590
Deferred revenues	(7,000)	7,750
Net cash (used in) provided by operating activities	<u>(8,056)</u>	<u>3,160</u>
<b>Investing activities</b>		
Purchases of marketable securities	(15,691)	—
Maturities and sales of marketable securities	18,545	2,019
Purchases of property and equipment	(81)	(42)
Net cash provided by investing activities	<u>2,773</u>	<u>1,977</u>
<b>Financing activities</b>		
Proceeds from issuance of common stock, net of issuance costs	—	46,432
Proceeds from employee stock purchase plan	66	—
Repayment of notes receivable from stockholders	32	52
Restricted cash	—	(77)
Net cash provided by financing activities	<u>98</u>	<u>46,407</u>
Effect of exchange rate on cash and cash equivalents	<u>(4)</u>	<u>—</u>
Net (decrease) increase in cash and cash equivalents	(5,189)	51,544
Cash and cash equivalents at beginning of period	16,590	23,468
Cash and cash equivalents at end of period	<u>\$ 11,401</u>	<u>\$ 75,012</u>
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Net unrealized loss on marketable securities	<u>\$ (59)</u>	<u>\$ —</u>
Change in cumulative translation adjustment	<u>\$ (4)</u>	<u>\$ —</u>
Exercise of stock options	<u>\$ 200</u>	<u>\$ —</u>
Repurchase of common stock for exercise of stock options	<u>\$ (200)</u>	<u>\$ —</u>
Conversion of preferred stock upon initial public offering	<u>\$ —</u>	<u>\$ 83,635</u>
Conversion of ordinary shares in Dynavax Asia upon initial public offering	<u>\$ —</u>	<u>\$ 14,733</u>

*See accompanying notes.*

**Dynavax Technologies Corporation**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Organization**

Dynavax Technologies Corporation (“Dynavax”, the “Company”, “we” or “us”) is a biopharmaceutical company that discovers, develops, and intends to commercialize innovative products to treat and prevent allergies, infectious diseases, and chronic inflammatory diseases. The Company was originally incorporated in California on August 29, 1996 and reincorporated in Delaware on March 26, 2001.

In February 2004, the Company sold a total of 6,900,000 shares of its common stock, after adjusting for a one-for-three reverse stock split, in an underwritten initial public offering, raising net proceeds of approximately \$46.5 million. The effect of the reverse stock split is reflected in the Condensed Consolidated Financial Statements for all periods presented.

**Subsidiaries**

In October 2003, the Company formed Dynavax Asia Pte. Ltd. (Dynavax Asia), a 100% owned subsidiary in Singapore which focuses on the Company’s clinical and preclinical hepatitis B programs. In October 2003, the Company completed a sale of 15,200,000 ordinary shares in Dynavax Asia, which reduced the Company’s ownership in Dynavax Asia from 100% to 50%. The sale raised net proceeds of \$14.7 million, which were recorded as a minority interest liability in the Consolidated Financial Statements as of December 31, 2003. In addition, the Company recorded a deemed dividend of \$0.6 million for the year ended December 31, 2003 on the difference between the estimated fair value of the common stock at the issuance date and the conversion price of the ordinary shares. In connection with the February 2004 initial public offering, the ordinary shares in Dynavax Asia were converted to 2,111,111 shares of common stock and Dynavax Asia became a wholly owned subsidiary.

In December 2004, the Company formed Ryden Therapeutics KK (Ryden), a 100% owned Japan subsidiary, to explore development and commercialization options for ISS-based immunotherapies for cedar tree allergy in Japan.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

Our accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited Condensed Consolidated Financial Statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period. The balance sheet at December 31, 2004 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles for complete financial statements.

These unaudited Condensed Consolidated Financial Statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2004 as filed with the Securities and Exchange Commission (SEC) on March 18, 2005.

The Condensed Consolidated Financial Statements include the accounts of Dynavax, Dynavax Asia and Ryden. All significant intercompany accounts and transactions have been eliminated. The Company operates in one business segment, which is the development of biopharmaceutical products.

Certain reclassifications of prior year amounts related to legal costs have been made to conform with the current year presentation. These reclassifications, specifically from research and development to general and administrative expenses, did not have an impact on our financial position or results of operations.



## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Actual results may differ from these estimates.

## Critical Accounting Policies

The Company believes that there have been no significant changes in its critical accounting policies during the three months ended March 31, 2005 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2004, except as described below.

### *Revenue Recognition*

Certain of our contractual arrangements may involve multiple deliverables or elements. Under Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables," multiple elements should be divided into separate units of accounting if certain criteria are met, including whether the delivered elements have stand alone value to the customer and whether there is objective reliable evidence of the fair value of the undelivered elements. Consideration should be allocated among the separate units of accounting based on their fair values, and each of the separate units of accounting should be evaluated for appropriate revenue recognition. We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectibility is reasonably assured.

## Recent Accounting Pronouncements

On March 29, 2005, the SEC published Staff Accounting Bulletin (SAB) No. 107 regarding the interaction between Financial Accounting Standard (FAS) No. 123R (revised 2004), "Share-Based Payment" and certain SEC rules and regulations. The Financial Accounting Standards Board (FASB) issued FAS No. 123R on December 16, 2004, that requires all share-based payments to employees, including grants of employee stock options, to be recognized based on their fair values. Pro forma disclosure is no longer an alternative. FAS No. 123R supersedes Accounting Principles Board (APB) No. 25, "Accounting for Stock Issued to Employees," and amends FAS No. 95, "Statement of Cash Flows."

Under FAS No. 123R, share-based payments result in a cost that will be measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest. Compensation cost for awards that vest would not be reversed if the awards expire without being exercised. When measuring fair value, companies can choose an option-pricing model (e.g., Black-Scholes or binomial models) that appropriately reflects their specific circumstances and the economics of their transactions. Public companies are allowed to select from three alternative transition methods, each having different reporting implications. FAS No. 123R is effective for the fiscal year beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date.

We will adopt FAS No. 123R as of January 1, 2006. The adoption of FAS No. 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because we are in the process of reevaluating our methodology used to determine fair value, including consideration of an option-pricing model and related assumptions. In addition, the impact of adoption will depend on levels of share-based payments granted in the future.

## Stock-Based Compensation

As permitted under FAS No. 123, "Accounting for Stock-Based Compensation" as amended by FAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," we continue to recognize employee stock compensation under the intrinsic value method of accounting as prescribed by APB No. 25 and its interpretations. Under APB No. 25, compensation expense is based on the difference, if any, between the estimated fair value of our common stock and the option exercise price on the date of grant. We account for stock compensation to non-employees in accordance with FAS No. 123, as amended by FAS No. 148 and EITF Issue 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services."

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The following table illustrates the pro forma effect on our net income (loss) and net income (loss) per share as if we had applied the fair value recognition provisions of FAS No. 123 to employee stock compensation (in thousands, except per share amounts):

	Three months ended March 31,	
	2005	2004
Net income (loss) attributable to common stockholders, as reported	\$ 5,070	\$ (3,866)
Add: Stock-based employee compensation expense included in net income (loss)	332	626
Less: Stock-based employee compensation expense determined under the fair value based method	(702)	(762)
Net income (loss) attributable to common stockholders, pro forma	\$ 4,700	\$ (4,002)
Net income (loss) per share attributable to common stockholders:		
Basic net income (loss), as reported	\$ 0.21	\$ (0.36)
Diluted net income (loss), as reported	\$ 0.20	\$ (0.36)
Basic net income (loss), pro forma	\$ 0.19	\$ (0.37)
Diluted net income (loss), pro forma	\$ 0.19	\$ (0.37)

Such pro forma disclosure may not be representative of future stock-based compensation expense because such options vest over several years and additional grants may be made each year.

The estimated fair value of each option and employee purchase right is estimated on the date of grant using the Black-Scholes option-pricing model, assuming no expected dividends and the following weighted-average assumptions:

	Employee Stock Options		Employee Stock Purchase Plan	
	March 31,		March 31,	
	2005	2004	2005	2004
Weighted-average fair value	\$4.17	\$6.11	\$6.25	—
Risk-free interest rate	3.5% to 3.6%	2.3% to 2.8%	3.0%	—
Expected life (in years)	4	4	0.5	—
Volatility	0.7	1.0	0.7	—

### 3. Commitments and Contingencies

The Company leases its facility under an operating lease that expires in September 2014. The lease can be terminated at no cost to the Company in September 2009 but otherwise extends automatically until September 2014.

Our facility lease agreement provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our lease agreement provides a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the Condensed Consolidated Balance Sheets as of March 31, 2005 and December 31, 2004. The lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2009. Total net rent expense related to this operating lease for the quarter ended March 31, 2005 was \$0.3 million. Deferred rent was \$0.1 million as of March 31, 2005.

We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to the Company of \$339,990 annually through 2007. This sublease agreement includes an option for early termination in August 2006 but otherwise extends automatically until August 2007.

Future minimum payments under the non-cancelable portion of our operating lease at March 31, 2005, excluding payments from the sublease agreement, are as follows (in thousands):

Year ending December 31,	
2005	\$ 1,241
2006	1,698
2007	1,749
2008	1,802
2009	1,225
	\$ 7,715

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During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our property lease in the amount of \$0.4 million. The letter of credit remained outstanding as of March 31, 2005 and is collateralized by a certificate of deposit which has been included in restricted cash in the Condensed Consolidated Balance Sheets as of March 31, 2005 and December 31, 2004. Under the terms of the lease agreement, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We rely on research institutions and contract research organizations that conduct and manage clinical trials on our behalf. As of March 31, 2005, under the terms of an agreement with a contract research organization (CRO), we are obligated to make future payments as services are provided of up to \$7.6 million through 2006. This agreement is terminable by us upon written notice to the CRO and we are only liable for actual effort expended by the CRO at any point in time during the contract, regardless of payment status.

The Company, as permitted under Delaware law and in accordance with its bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officers or directors are or were serving at the Company's request in such capacity. The term of the indemnification period is for each officer or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that limits its exposure up to \$10 million and may enable the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2005.

The Company enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2005.

#### **4. Collaborative Research, Development, and License Agreements**

##### **UCB Farchim, S.A.**

In February 2004, the Company entered into a development and commercialization collaboration with UCB Farchim, S.A. (UCB) in which the Company licensed the technology, know-how and preclinical and clinical data related to its AIC and grass allergy programs to UCB on an exclusive, worldwide basis. UCB was also granted an option to license the Company's peanut allergy program. The Company received an \$8.0 million upfront payment from UCB when the collaboration was established.

In March 2005, the Company agreed to end its collaboration with UCB and regained full rights to its allergy program. This agreement provided for cash payment to the Company in satisfaction of outstanding receivables due from UCB and obligations owed by UCB under the collaboration. In addition, UCB assigned to the Company the rights and title to certain laboratory equipment and clinical materials used in undertaking specific development activities for AIC clinical trials. The Company was not obligated to make any cash payments to UCB in connection with the execution of the March 2005 agreement to end the collaboration.

In accordance with the provisions of EITF 00-21, the Company accounted separately for each of the elements of consideration provided under the March 2005 agreement. During the quarter ended March 31, 2005, the Company accelerated the recognition of \$7.0 million in deferred revenue from the upfront payment related to the collaboration, as the Company had no ongoing obligations under the collaboration. During the quarter ended March 31, 2005, the Company also recognized revenue associated with the agreed-upon cash payment which was received in April 2005. The equipment and clinical materials assigned were neither capitalized nor expensed as of the end of the period, due to the Company's estimate of the useful life of those assets at less than one year and the Company's estimate of a nominal fair value for those assets based on their potential resale value.

## University of California

The Company entered into a series of exclusive license agreements with the Regents of the University of California (UC) in March 1997 and October 1998. These agreements provide the Company with certain technology and related patent rights and materials. Under the terms of the agreements, the Company pays annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. The agreements will expire on either the expiration date of the last-to-expire patent licensed under the agreements or the date upon which the last patent application licensed under the agreements is abandoned. In connection with these license agreements, the Company incurred license fees of \$20,000 during the first quarters of 2005 and 2004 which was recorded as research and development expense, and the Company incurred patent expenses of \$0.2 million and \$42,000 during the first quarters of 2005 and 2004, respectively, which was recorded as general and administrative expense.

The Company also incurred a \$0.4 million one-time charge to UC due upon the closing of the Company's initial public offering as partial consideration for the technology licenses, which was recorded as research and development expense in the first quarter of 2004. Additionally, as partial consideration for the technology licenses, the Company prepaid \$0.2 million to UC related to the \$8.0 million upfront payment from UCB and was amortizing the amount to research and development expense over the initial term of the UCB collaboration. During the quarter ended March 31, 2005, in conjunction with the termination of the UCB collaboration, the Company incurred \$0.1 million in research and development expense from the accelerated amortization of the prepaid technology licenses fee.

## BioSeek, Inc.

In June 2003, the Company entered into a development collaboration agreement with BioSeek, Inc. to analyze and characterize the activity of certain compounds using BioSeek's technology with the objective of advancing the development of such compounds. Under this agreement, the Company will make various payments to BioSeek based on the success and timing of the Company's signing of a third party partnering agreement where the Company grants to the third party, directly or indirectly, any right or option to market, sell, distribute or otherwise commercialize a thiazolopyrimidine (TZP) product in any geographic territory. The agreement may be terminated by either party. During the quarter ended March 31, 2005, the Company paid BioSeek \$0.3 million associated with the achievement of a contractual milestone.

## Other Agreements

In the third quarter of 2003, the Company was awarded government grants totaling \$8.4 million to be received over as long as three and one-half years, assuming annual review criteria are met, to fund research and development of certain biodefense programs. Grant revenue associated with these awards is recognized as the related expenses are incurred. In the fourth quarter of 2004, the Company was awarded \$0.5 million from the Alliance for Lupus Research to be received during 2005 and 2006 to fund research and development of new treatment approaches for lupus. For each of the quarters ended March 31, 2005 and 2004, the Company recognized grant revenue of approximately \$0.5 million.

## 5. Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) for the period by the weighted-average shares outstanding for that period. Diluted net income (loss) per share takes into account the effect of diluted instruments, such as stock options and warrants, and uses the average share price for the period in determining the number of incremental shares that are to be added to the weighted-average number of shares outstanding.

	Three Months Ended March 31,	
	2005	2004
Shares used to compute basic net income (loss) per share	24,721,829	10,846,894
Shares used to compute diluted net income (loss) per share	24,836,870	10,846,894

Certain potentially dilutive shares were excluded from the shares used to compute diluted net income (loss) per share since their inclusion would have been anti-dilutive, either because the options' exercise prices exceeded the average fair market value of the stock during the period or due to the loss for the period.

## 6. Stockholders' Equity

At March 31, 2005, there were 24,745,201 shares of our common stock issued and outstanding.

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Activity under stock option plans is set forth below:

	<u>Options Available for Grant</u>	<u>Number of Options Outstanding</u>	<u>Weighted-Average Price Per Share</u>
Balance at December 31, 2004 (1,527,989 exercisable at \$2.55 weighted-average price per share)	3,342,976	1,828,314	\$ 3.17
Options granted	(615,000)	615,000	\$ 7.35
Options exercised	—	(133,498)	\$ 1.50
Options canceled	8,535	(8,535)	\$ 5.87
Shares repurchased	27,817	—	\$ 7.19
Shares retired	(27,817)	—	\$ 7.19
Balance at March 31, 2005 (1,411,838 exercisable at \$2.72 weighted-average price per share)	<u>2,736,511</u>	<u>2,301,281</u>	\$ 4.38

During the three months ended March 31, 2005, the Company issued 133,498 shares of common stock resulting from option exercises, of which 27,817 shares were surrendered to the Company in lieu of cash payment for the option exercise.

Employee and director stock-based compensation expense and non-employee stock-based compensation expense for the three months ended March 31, 2005 and 2004 were as follows (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2005</u>	<u>2004</u>
Employees and directors stock-based compensation expense	\$ 332	\$ 626
Non-employees stock-based compensation expense (recovery)	(15)	—
Total	<u>\$ 317</u>	<u>\$ 626</u>

During the quarter ended March 31, 2005, employees acquired 12,374 shares of our common stock under the 2004 Employee Stock Purchase Plan (the "Purchase Plan"). At March 31, 2005, 224,929 shares of our common stock remained available for future purchases under the Purchase Plan.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements under federal securities laws. Forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to those set forth under this Item, as well as those discussed elsewhere in this document and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.*

*This discussion should be read in conjunction with the Condensed Consolidated Financial Statements and related Notes included in Item 1 of this quarterly report and the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 18, 2005.*

### Overview

We discover, develop, and intend to commercialize innovative products to treat and prevent allergies, infectious diseases, 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 that enhance the ability of the immune system to fight disease and control chronic inflammation. ISS are being developed in three initial indications: a ragweed allergy immunotherapeutic, a hepatitis B vaccine, and an asthma immunotherapeutic.

We have developed a novel injectable product candidate to treat ragweed allergy that we call AIC. AIC has completed Phase II trials, and is currently completing a two-year Phase II/III clinical trial. At the end of 2004, we reported that the one-year interim analysis of this Phase II/III trial showed a clear positive trend relative to the trial's major endpoint of nasal symptom scores, as well as other secondary endpoints, following the 2004 ragweed season. We intend to complete the Phase II/III clinical trial. We initiated a supportive Phase III clinical trial in ragweed allergic children. Pending the outcome of discussions with the US Food and Drug Administration (FDA) in 2005 and the results of the Phase II/III study, we plan to initiate a pivotal Phase III clinical program in early 2006.

We have developed a product candidate for hepatitis B prophylaxis. A Phase II/III trial in subjects who are more difficult to immunize with conventional vaccines is currently underway in Singapore. Results from an interim analysis of the Phase II/III trial showed that our vaccine demonstrated statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations when compared to GlaxoSmithKline's Engerix-B® vaccine. Results from a Phase II clinical trial in healthy adults conducted earlier in 2004 showed that our vaccine induced a more robust and durable antibody response than Engerix-B. We anticipate initiating a pivotal Phase III trial in the older, more difficult to immunize population in Asia by mid-year 2005, followed by a second pivotal trial in younger adults in Canada and Europe in early 2006. We believe that strategic opportunities for our vaccine exist in selected countries worldwide. Our initial commercialization strategies will likely target these markets and focus on high-value, underserved populations. These populations include pre-hemodialysis patients, HIV positive patients, other populations with compromised immune systems as well as professionals in healthcare and law enforcement for whom achieving seroprotection quickly is critical.

We have an inhaled therapeutic product candidate for treatment of asthma, which has completed a Phase IIa trial in Canada. Results from a Phase IIa asthma challenge study confirmed the preliminary safety of inhaled immunostimulatory sequences in mild asthmatic patients, and showed substantial and statistically significant pharmacological activity, based upon the induction of genes associated with a reprogrammed immune response. Consistent with our decision to focus clinical and financial resources on our two lead programs in ragweed allergy and hepatitis B prophylaxis, anticipated additional clinical trials in asthma will be postponed. We will, however, perform additional preclinical work to optimize the route of administration and regimen for the asthma clinical program.

For the quarter ended March 31, 2005, our net income was \$5.1 million, compared to a net loss of \$3.9 million in the first quarter of 2004. Our operating results for the first quarter of 2005 primarily reflect the financial impact resulting from the termination of our development and commercialization collaboration with UCB Farchim, S.A. (UCB) that occurred in March 2005. Total revenues for the quarter ended March 31, 2005 were \$12.7 million, compared to \$3.2 million for the first quarter of 2004. 96% of our first quarter

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2005 revenues were derived from our collaboration activities and the termination of the collaboration with UCB, while the remaining revenues were earned from government and private agency grants.

As of March 31, 2005, we had an accumulated deficit of \$90.3 million. We do not have any products that generate revenue. We expect to incur substantial and increasing losses as we continue the development of our lead product candidates and preclinical and research programs. If we were to receive regulatory approval for any of our product candidates, we would be required to invest significant capital to develop, or otherwise secure through collaborative relationships, commercial scale manufacturing, marketing and sales capabilities. Even if we are able to obtain approval for our product candidates, we are likely to incur increased operating losses until product sales grow sufficiently to support the organization.

For the year ended December 31, 2005, excluding the potential impact of any business collaborations or other transactions that may be entered into, we anticipate that our operating expenses will increase as compared to prior year in connection with our clinical development activities and overall organizational growth.

### **Critical Accounting Policies and the Use of Estimates**

The Company believes that there have been no significant changes in its critical accounting policies during the three months ended March 31, 2005 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2004, except as described below.

#### ***Revenue Recognition***

Certain of our contractual arrangements may involve multiple deliverables or elements. Under Emerging Issues Task Force (EITF) Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables," multiple elements should be divided into separate units of accounting if certain criteria are met, including whether the delivered elements have stand alone value to the customer and whether there is objective reliable evidence of the fair value of the undelivered elements. Consideration should be allocated among the separate units of accounting based on their fair values, and each of the separate units of accounting should be evaluated for appropriate revenue recognition. We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectibility is reasonably assured.

### **Results of Operations**

The following table sets forth the results of operations for the quarters ended March 31, 2005 and 2004 (in thousands, except percentages):

<b>Results of Operations:</b>	<b>Three Months Ended March 31,</b>		<b>Increase (Decrease) from 2005 to 2004</b>	
	<b>2005</b>	<b>2004</b>	<b>\$</b>	<b>%</b>
<b>Revenues:</b>				
Collaboration revenue	\$ 12,199	\$ 2,744	\$ 9,455	345%
Grant revenue	499	461	38	8%
Total revenues	<u>\$ 12,698</u>	<u>\$ 3,205</u>	<u>\$ 9,493</u>	296%
<b>Operating expenses:</b>				
Research and development	\$ 5,655	\$ 5,271	\$ 384	7%
General and administrative	2,340	1,919	421	22%
Total operating expenses	<u>\$ 7,995</u>	<u>\$ 7,190</u>	<u>\$ 805</u>	11%
Interest income, net	\$ 367	\$ 119	\$ 248	208%

#### ***Revenues***

Total revenues for the quarter ended March 31, 2005 were \$12.7 million, consisting of \$12.2 million from our collaboration activities and the termination of our collaboration with UCB and \$0.5 million from government and private agency grants.

In March 2005, we agreed to end our collaboration with UCB and regained full rights to our allergy program. This agreement provided for cash payment to us in satisfaction of outstanding receivables due from UCB and obligations owed by UCB under the



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collaboration. In addition, UCB assigned to us the rights and title to certain laboratory equipment and clinical materials used in undertaking specific development activities for AIC clinical trials. We were not obligated to make any cash payments to UCB in connection with the execution of the March 2005 agreement to end the collaboration. During the quarter ended March 31, 2005, we accelerated the recognition of \$7.0 million in deferred revenue related to the collaboration, as we had no ongoing obligations. During the quarter ended March 31, 2005, we also recognized revenue associated with the agreed-upon cash payment which we received in April 2005. The equipment and clinical materials assigned were neither capitalized nor expensed as of the end of the period, due to our estimate of the useful life of those assets at less than one year and our estimate of a nominal fair value for those assets based on their potential resale value.

Our ability to generate future collaboration revenue and obtain additional capital will be dependent on our ability to enter into new collaborative relationships.

### **Research and Development**

Research and development expense consists primarily of outside services related to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates for our preclinical experiments and clinical trials; compensation and related personnel costs which include benefits, recruitment, travel and supply costs; and allocated facility costs. We expense our research and development costs as they are incurred.

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

	Three Months Ended March 31,		Increase (Decrease) from 2005 to 2004	
	2005	2004	\$	%
<b>Research and development:</b>				
Compensation and related personnel costs	\$ 2,336	\$ 1,518	\$ 818	54%
Outside services	2,500	3,098	(598)	(19)%
Facility costs	680	276	404	146%
Non-cash stock-based compensation	139	379	(240)	(63)%
Total research and development	<u>\$ 5,655</u>	<u>\$ 5,271</u>	<u>\$ 384</u>	<u>7%</u>

Research and development expenses of approximately \$5.7 million for the quarter ended March 31, 2005 increased by \$0.4 million, or 7%, from the same period in 2004. The increase over the prior year was primarily due to increased compensation and related personnel costs of \$0.8 million attributed to organizational growth. Research and development full-time headcount increased from 40 employees as of March 31, 2004 to 49 employees as of March 31, 2005. In addition, allocated rent and operating costs for our facility rose by \$0.4 million from the prior year. These increases in expenses were partially offset by a \$0.6 million decline in outside costs for research, clinical trial and clinical manufacturing primarily associated with our ragweed allergy and hepatitis B vaccine programs which incurred higher costs for start-up activities in early 2004, as well as expenses incurred to license technology from the Regents of the University of California.

During 2005, we anticipate that our research and development expense will increase as compared to prior year, in connection with our growing clinical development programs, including our Phase III AIC trial in a pediatric population and our Phase III clinical trials for our hepatitis B vaccine which we expect to initiate in mid-2005.

### **General and Administrative**

General and administrative expense consists primarily of compensation and related personnel costs, outside services such as accounting, consulting, public relations and insurance, legal and patent costs, and allocated facility costs.

The following is a summary of our general and administrative expense (in thousands):

	Three Months Ended March 31,		Increase (Decrease) from 2005 to 2004	
	2005	2004	\$	%
<b>General and administrative:</b>				
Compensation and related personnel costs	\$ 1,123	\$ 685	\$ 438	64%
Outside services	578	526	52	10%
Legal and patent costs, net	335	300	35	12%
Facility costs	126	161	(35)	(22)%
Non-cash stock-based compensation	178	247	(69)	(28)%
Total general and administrative	<u>\$ 2,340</u>	<u>\$ 1,919</u>	<u>\$ 421</u>	<u>22%</u>



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General and administrative expenses of \$2.3 million for the quarter ended March 31, 2005 increased by \$0.4 million, or 22%, from the same period in 2004, reflecting higher compensation and related benefits associated with the expansion of our management team and overall organizational growth. General and administrative full-time headcount increased from 11 employees as of March 31, 2004 to 22 employees as of March 31, 2005. Legal and patent-related costs during the first quarter 2005 were net of \$0.1 million in reimbursable patent interference costs.

During 2005, we expect general and administrative expenses to increase as compared to prior year, primarily resulting from the full year impact of organizational growth that occurred in 2004.

### ***Interest Income, Net***

Interest income, net of interest expense and amortization on marketable securities, was \$0.4 million for the quarter ended March 31, 2005 compared to \$0.1 million for the same period in 2004. The increase was primarily due to the investment of proceeds from our initial public offering in marketable securities in February 2004.

### **Recent Accounting Pronouncements**

On March 29, 2005, the SEC published Staff Accounting Bulletin (SAB) No. 107 regarding the interaction between Financial Accounting Standard (FAS) No. 123R (revised 2004), "Share-Based Payment" and certain SEC rules and regulations. The Financial Accounting Standards Board (FASB) issued FAS No. 123R on December 16, 2004, that requires all share-based payments to employees, including grants of employee stock options, to be recognized based on their fair values. Pro forma disclosure is no longer an alternative. FAS No. 123R supersedes Accounting Principles Board (APB) No. 25, "Accounting for Stock Issued to Employees," and amends FAS No. 95, "Statement of Cash Flows."

Under FAS No. 123R, share-based payments result in a cost that will be measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest. Compensation cost for awards that vest would not be reversed if the awards expire without being exercised. When measuring fair value, companies can choose an option-pricing model (e.g., Black-Scholes or binomial models) that appropriately reflects their specific circumstances and the economics of their transactions. Public companies are allowed to select from three alternative transition methods, each having different reporting implications. FAS No. 123R is effective for the fiscal year beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date.

We will adopt FAS No. 123R as of January 1, 2006. The adoption of FAS No. 123R's fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because we are in the process of reevaluating our methodology used to determine fair value, including consideration of an option-pricing model and related assumptions. In addition, the impact of adoption will depend on levels of share-based payments granted in the future.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of shares of our common stock, shares of our convertible preferred stock, and ordinary shares in a subsidiary, which have yielded a total of approximately \$144.8 million in net cash proceeds and, to a lesser extent, through amounts received under collaborative agreements and government grants for biodefense programs. We completed an initial public offering in February 2004, raising net proceeds during fiscal 2004 of approximately \$46.5 million from the sale of 6,900,000 shares of common stock. As of March 31, 2005, we had \$57.4 million in cash, cash equivalents and marketable securities. Our funds are currently invested in a variety of securities, including highly liquid institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

Cash used in operating activities of \$8.1 million during the quarter ended March 31, 2005 compared to cash provided by operating activities of \$3.0 million during the quarter ended March 31, 2004. The variance from the prior year was due primarily to the one-time \$8.0 million upfront payment made to us by UCB and a decline in working capital.

Cash provided by investing activities of \$2.8 million during the quarter ended March 31, 2005 compared to \$2.0 million for the same period in 2004. The increase in cash provided by investing activities was due primarily to maturities and net sales of investments.

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Cash provided by financing activities of \$0.1 million during the quarter ended March 31, 2005 compared to \$46.6 million for the same period in 2004. Cash provided by financing activities during the first quarter of 2004 resulted primarily from the issuance of common stock in our initial public offering.

Excluding the potential impact of any equity offerings, business collaborations or other transactions that may be entered into, we expect our cash, cash equivalents and marketable securities to decline by December 31, 2005, primarily due to cash used for 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 it will take for any of our product candidates to complete the clinical trials process, be approved by regulatory authorities and successfully commercialized, we may require substantial additional capital resources. We may raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations.

Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions that are outside of our control. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, scale back or eliminate some or all of our research or development programs, to lose rights under existing licenses or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose or may adversely affect our ability to operate as a going concern.

### ***Contractual Obligations***

The following summarizes our significant contractual obligations as of March 31, 2005 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<b>Contractual Obligations:</b>	<b>Payments Due by Period</b>			
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>
Future minimum payments under our operating lease	\$ 7,715	\$ 1,241	\$ 3,447	\$ 3,027
Total	\$ 7,715	\$ 1,241	\$ 3,447	\$ 3,027

We lease our facility under an operating lease that expires in September 2014. The lease can be terminated at no cost to us in September 2009 but otherwise extends automatically until September 2014. We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to us of \$339,990 annually through 2007. This sublease agreement includes an option for early termination in August 2006 but otherwise extends automatically until August 2007.

The table above excludes certain commitments that are contingent upon future events. The most significant of these contractual commitments that we consider to be contingent obligations are summarized below.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our property lease in the amount of \$0.4 million. The letter of credit remained outstanding as of March 31, 2005 and is collateralized by a certificate of deposit which has been included in restricted cash in the Condensed Consolidated Balance Sheets as of March 31, 2005 and December 31, 2004. Under the terms of the lease agreement, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

We rely on research institutions and contract research organizations that conduct and manage clinical trials on our behalf. As of March 31, 2005, under the terms of an agreement with a contract research organization (CRO), we are obligated to make future payments as services are provided of up to \$7.6 million through 2006. This agreement is terminable by us upon written notice to the CRO and we are only liable for actual effort expended by the CRO at any point in time during the contract, regardless of payment status.

In March 2005, we agreed to end our development and commercialization collaboration with UCB and regained full rights to our allergy program. We assume financial responsibility for all further clinical, regulatory, manufacturing and commercial activities related to AIC and for preclinical development programs in grass and in peanut allergy. The March 2005 agreement provided for cash

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payment to us in satisfaction of outstanding receivables due from UCB and obligations owed by UCB under the collaboration, which we received in April 2005. The March 2005 agreement also provides for the continued partial reimbursement of certain patent interference fees and expenses, if and as incurred by the Company, subject to a maximum amount.

Under the terms of the exclusive license agreements with the Regents of the University of California, we are obligated to pay milestones and royalties on net sales of products originating from the licensed technologies. As partial consideration for the technology licenses, during the first quarter of 2004 we paid one-time charges of \$0.4 million upon the closing of the Company's initial public offering and \$0.2 million related to the upfront payment from UCB. No other milestones were achieved as of March 31, 2005.

Under the development collaboration agreement with BioSeek, Inc., we will make various payments based on the success and timing of the Company's signing of a third party partnering agreement where the Company grants to the third party, directly or indirectly, any right or option to market, sell, distribute or otherwise commercialize a thiazolopyrimidine (TZP) product in any geographic territory. During the quarter ended March 31, 2005, we paid BioSeek \$0.3 million associated with the achievement of a contractual milestone.

Under the terms of an agreement with Berna Biotech, we agreed to make certain commercialization and sales milestone payments to Berna regarding the Company's hepatitis B vaccine. None of these milestones were achieved as of March 31, 2005.

### **Risk Factors**

*Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future products, 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 revenue.**

We have experienced significant operating losses in each year since our inception in August 1996. Currently, our revenue results from a collaboration agreement and government and private agency grants. The UCB collaboration agreement ended in March 2005. The grants are subject to annual review based on the achievement of milestones and other factors and will terminate in 2006 at the latest. Our accumulated deficit was \$90.3 million as of March 31, 2005, and we anticipate that we will incur substantial additional operating losses for the foreseeable future. These losses have been, and will continue to be, principally the result of the various costs associated with our research and development activities. We expect our losses to increase primarily as a consequence of our continuing product development efforts. Specifically, in 2004, we began Phase II/III trials for AIC, an immunotherapy for ragweed allergy, and Phase II/III trials for our hepatitis B vaccine and in 2005, we initiated a Phase III trial of AIC in ragweed allergic children and plan to initiate a pivotal Phase III trial for our hepatitis B vaccine in mid-2005.

We do not have any products that generate revenue. Our product candidates may never be commercialized, and we may never generate product-related revenue. Our ability to generate product revenue depends upon:

- demonstrating in clinical trials that our product candidates are safe and effective, in particular, in the planned Phase III trials for AIC and our hepatitis B vaccine;
- obtaining regulatory approvals for our product candidates in the U.S. and international markets;
- entering into collaborative relationships on commercially reasonable terms for the development, manufacturing, sales and marketing of our product candidates, and then successfully managing these relationships; and
- commercial acceptance of our products, in particular AIC and our hepatitis B vaccine.

If we are unable to generate revenues or achieve profitability, we may be required to significantly reduce or discontinue our operations or raise additional capital under adverse circumstances.

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

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We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations. Because of the significant time and resources it will take to develop our product candidates, potentially commercialize them and generate revenues, we may require substantial additional capital resources in order to continue our operations, and any such funding may not cover our costs of operations. We may also need to secure more funding than currently anticipated because we may change our product development plans or clinical programs.

We may be unable to obtain additional capital from financing sources or from agreements with collaborators on acceptable terms, or at all. If at any time sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate some or all of our research, preclinical or clinical programs or discontinue our operations.

**All of our product candidates are unproven, and our success depends on our product candidates being approved through uncertain and time-consuming regulatory processes. Failure to prove our products safe and effective in clinical trials and obtain regulatory approvals could require us to discontinue operations.**

None of our product candidates has been proven safe and effective in clinical trials or approved for sale in the U.S. or any foreign market. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the U.S., including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for AIC, our ragweed allergy product candidate, and our hepatitis B vaccine product candidate. We intend to commercialize our hepatitis B vaccine initially outside the U.S., which will require us to seek approval from foreign regulatory agencies. Approval processes in the U.S. and in other countries are uncertain, take many years and require the expenditure of substantial resources. Product development failure can occur at any stage of clinical trials and as a result of many factors, many of which are not under our control.

We will need to demonstrate in clinical trials that each product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. We initiated a two-year, multi-site Phase II/III trial in the first quarter of 2004 in the U.S. for AIC. Pending the outcome of discussions with the FDA in 2005 and the results of the Phase II/III study, we plan to initiate a pivotal Phase III AIC clinical program in early 2006. We also anticipate initiating a pivotal Phase III trial for our hepatitis B vaccine in 2005. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval in their jurisdictions.

Many new drug candidates, including many drug candidates that have completed Phase III 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 never guaranteed. Failure to complete clinical trials and prove that our products are safe and effective would have a material adverse effect on our ability to eventually generate revenues and could require us to reduce the scope of or discontinue our operations.

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

We may 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 and concerns regarding health risks to test subjects. In addition, our ability to conduct clinical trials for some of our product candidates, notably AIC, is limited due to the seasonal nature of ragweed allergy. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the next appropriate season, which could result in a delay of an entire year. Consequently, we may experience additional delays in obtaining regulatory approval for these product candidates.

Suspension, termination or unanticipated delays of our clinical trials for AIC, hepatitis B, or asthma may:

- adversely affect our ability to commercialize or market any product candidates we may develop;
- impose significant additional costs on us;
- potentially diminish any competitive advantages that we may attain;

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- 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; and
- 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, which may be costly and subject us to various enforcement actions.**

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, resulting in limitations on our labeling indications or marketing claims, or withdrawn completely if problems occur after commercialization. Thus, even if we receive FDA and other regulatory approvals, our product candidates may later exhibit qualities that limit or prevent their widespread use or that force us to withdraw those products from the market.

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 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 product candidates in clinical trials are based on 1018 ISS, 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 1018 ISS, potential collaborators may also be reluctant to establish collaborations for our products in distinct therapeutic areas due to the common safety risk across therapeutic areas. If adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to discontinue our operations.

**A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may be unsuccessful in establishing and managing collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.**

We will have 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. We have established a collaborative relationship with Berna Biotech for our hepatitis B vaccine and hepatitis B therapeutic product candidates. Our collaboration agreement with UCB for AIC and grass allergy immunotherapy ended in March 2005. As a result, we recognized revenue associated with the agreed-upon cash payment from UCB which we received in April 2005 and accelerated the recognition of \$7.0 million in deferred revenue during the quarter ended March 31, 2005. Future collaboration revenue will be dependent on our ability to enter into new collaborative relationships.

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

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

**We rely on third parties to supply component materials necessary for our clinical product candidates and manufacture product candidates for our clinical trials. Loss of these suppliers or manufacturers, or failure to replace them may delay our clinical trials and research and development efforts and may result in additional costs, which would preclude us from producing our product candidates on commercially reasonable terms.**

We rely on contract relationships with third parties to obtain the component materials that are necessary for our clinical product candidates and to manufacture our product candidates for clinical trials. Termination or interruption of these relationships may occur due to circumstances that are outside our control, resulting in higher costs or delays in our product development efforts.

In particular, we have relied on a single supplier to produce our ISS for clinical trials. ISS is a critical component of both of our AIC and hepatitis B vaccine product candidates. 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 an in-house ISS manufacturing capability, incurring increased capital and operating costs and delays in 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.

In addition, we do not currently have a contract manufacturer for AIC or sufficient AIC to supply our potential commercial needs. We believe that our existing supplies of AIC are sufficient for us to conduct our current Phase III clinical trial in ragweed allergic children. We intend to enter into manufacturing agreements with one or more new commercial-scale contract manufacturers to produce additional supplies of AIC as required for new clinical trials and commercialization. If we are unable to complete such agreements, we would have to establish an internal commercial scale manufacturing capability for AIC, incurring increased capital and operating costs, delays in the commercial development of AIC and higher manufacturing costs than we have experienced to date.

**We have or intend to contract with one or more third parties to conduct our Phase II/III clinical trials for AIC and Phase II/III trials for our hepatitis B vaccine. If these third parties do not carry out 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 AIC or our hepatitis B vaccine.**

We are unable to independently conduct our planned clinical trials for AIC or our hepatitis B vaccine, and we have or intend to contract with third party contract research organizations to manage and conduct these trials. If these third parties do not carry out their contractual duties or obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to failure to adhere to our clinical protocols or for other reasons, our planned clinical trials may be extended, delayed or terminated. Any extension, delay or termination of our trials would delay our ability to commercialize AIC or our hepatitis B vaccine and generate revenues.

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

We do not anticipate that any of our product candidates will be commercially available until 2008 at the earliest, if at all. Furthermore, even if we obtain regulatory approval for our product candidates and are able to successfully commercialize them, our product candidates 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 constrain our marketing claims, reducing our or our collaborators' ability to market the benefits of our products to particular patient populations. If we are unable to successfully market any approved product candidates, or are limited in our marketing efforts by regulatory limits on labeling indications or marketing claims, our ability to generate revenues could be significantly impaired.

In particular, treatment with AIC, if approved, will require a series of injections, and we expect that some of the patients that currently take oral or inhaled pharmaceutical products to treat their allergies would not consider our product. We believe that market acceptance of AIC will also depend on our ability to offer competitive pricing, increased efficacy and improved ease of use as compared to existing or potential new allergy treatments.



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While we may seek partners for purposes of commercialization of our hepatitis B vaccine in selected markets worldwide in addition to or as a replacement for our current collaborative partner, which has an exclusive option to commercialize our hepatitis B vaccine and therapeutic product candidates, marketing challenges vary by market and could limit or delay acceptance in any particular country. We believe that market acceptance of our hepatitis B vaccine will depend on our ability to offer increased efficacy and improved ease of use as compared to existing or potential new hepatitis B vaccine products.

**We face uncertainty related to coverage, pricing and reimbursement due to health care reform 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 generate revenues from the sales of any approved product candidates in excess of the costs of producing the product candidates will depend in part on the availability of 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. Significant uncertainty therefore exists as to coverage and reimbursement levels for newly approved health care products, including pharmaceuticals. 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 the considerable capital resources we have spent and will continue to spend on product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investment in product development. If it becomes apparent, due to changes in coverage or pricing of pharmaceuticals in our market or a lack of reimbursement, that it will be difficult, if not impossible, for us to generate revenues in excess of costs, we will need to alter our business strategy significantly. This could result in significant unanticipated costs, harm our future prospects and reduce our stock price.

**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 many companies and institutions, including pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing alternative therapies to treat or prevent allergy, infectious diseases, 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.

AIC, if approved, will compete directly with conventional allergy shots and indirectly with antihistamines, corticosteroids and anti-leukotriene agents, which manage seasonal allergy symptoms, including those produced by GlaxoSmithKline Plc, Merck & Co., Inc. and AstraZeneca Plc. Since our AIC ragweed allergy treatment would require a series of injections, we expect that some patients that currently take oral or inhaled pharmaceutical products to treat their allergies would not consider our product.

Our hepatitis B vaccine, if approved, will compete with existing vaccines produced by GlaxoSmithKline Plc and Merck & Co., Inc., among others.

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 with existing and potential competitors we may not be able to obtain financing, sell our product candidates or generate revenues.

**We intend to develop, seek regulatory approval for and market our product candidates outside the U.S., 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 hepatitis B vaccine and therapeutic product candidates.**

We plan to introduce our hepatitis B vaccine in various markets outside the U.S. Developing, seeking regulatory approval for and marketing our product candidates outside the U.S. could impose substantial burdens on our resources and divert management's attention from domestic operations. We may also conduct operations in other foreign jurisdictions.

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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;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- difficulties and costs associated with complying with a wide variety of complex international laws and treaties;
- 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
- geopolitical risks.

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 hepatitis B vaccine and therapeutic product candidates, as well as other product candidates that we may choose to commercialize internationally, which would impair our ability to generate revenues.

**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 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.

**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.

**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;



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- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. Legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved. The biopharmaceutical patent environment outside the U.S. is even more uncertain. We may be particularly affected by this uncertainty, given that several of our product candidates may address market opportunities outside the U.S. For example, we expect to market our hepatitis B vaccine, if approved, in foreign countries with high incidences of hepatitis B, particularly in Asia. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we might not have been the first to file patent applications for these inventions;
- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;
- our issued patents may not provide a basis for commercially viable products 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 companies, universities or research institutions may harm our ability to do business;
- other companies, universities or research institutions may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other companies, universities or research institutions 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 leak of confidential data into 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.

**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 of our product candidates.**

We may be exposed to future litigation by third parties based on claims that our product candidates, proprietary technologies or the licenses on which we rely, 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 another party's proprietary rights. If we become involved in any litigation, interference or other administrative proceedings related to our intellectual property or the intellectual property of others, we will incur substantial expenses and it will divert the efforts of our technical and management personnel. Others may succeed in challenging the validity of our issued and pending claims. If we are unsuccessful in defending or prosecuting any such claim we could be required to pay substantial damages and we may be unable to commercialize our product candidates or use these proprietary technologies unless we obtain a license from the third party. A license may require us to pay substantial royalties, require us to grant a cross-license to our technology or may not be available to us on acceptable terms. In addition, we may be required to redesign our

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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 may require us to change our business strategy and could reduce the value of our business.

In particular, one of our potential competitors, Coley Pharmaceutical Group (Coley), has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, that, if held to be valid, could require us to obtain a license in order to commercialize one or more of our formulations of ISS in the U.S., including AIC. In December 2003 the U.S. Patent and Trademark Office declared an interference to resolve first-to-invent disputes between a patent application filed by the Regents of the University of California, which is exclusively licensed to us, and an issued U.S. patent owned by Coley relating to immunostimulatory DNA sequences. The declaration of interference names the Regents of the University of California as senior party, indicating that a patent application filed by the Regents of the University of California and licensed to us was filed prior to a patent application owned by Coley that led to an issued U.S. patent. The interference provides the first forum to challenge the validity and priority of certain of Coley's patents. If successful, the interference action would establish our founders as the inventors of the inventions in dispute. On March 10, 2005, the U.S. Patent and Trademark Office issued a decision in the interference which did not address the merits of the case, but dismissed it on a legal technicality related to the timing of Dynavax's filing of its claims and request for interference. Dynavax has appealed this non-final decision. If we do not prevail in the interference proceeding, we may not be able to obtain patent protection on the subject matter of the interference, which would have a material adverse impact on our business. In addition, if Coley prevails in the interference, it may seek to enforce its rights under issued claims, including, for example, by suing us for patent infringement. Consequently, we may need to obtain a license to issued and/or pending claims held by Coley by paying cash, granting royalties on sales of our products or offering rights to our own proprietary technologies. Such a license may not be available to us on acceptable terms, if at all.

### **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 success depends upon our license arrangements with the Regents of the University of California. These licenses are critical to our research and product development efforts. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the invention and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us and the Regents of the University of California, or scientific collaborators. Additionally, our agreements with the Regents of the University of California generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow the Regents of the University of California to terminate any of these licensing agreements or convert them to non-exclusive licenses. In addition, our license agreements with the Regents of the University of California 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.

### **We expect that our stock price will be volatile, 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 may be 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, in particular any announcements regarding the progress or results of our planned Phase III trials for AIC and our hepatitis B vaccine;
- progress of regulatory approval of our product candidates, in particular AIC and our hepatitis B vaccine, and compliance with ongoing regulatory requirements;
- our ability to establish collaborations for the development and commercialization of our product candidates;
- market acceptance of our product candidates;
- our ability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;

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- 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 form strategic partnerships or joint ventures;
- maintenance of our existing licensing agreements with the Regents of the University of California;
- changes in government regulations;
- issuance of new or changed securities analysts' reports or recommendations;
- general economic conditions and other external factors;
- actual or anticipated fluctuations in our quarterly financial and operating results; and
- degree of trading liquidity 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. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, divert management's attention and resources and disrupt our business operations.

**If the ownership of our common stock continues to be highly concentrated, it may prevent stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.**

Our executive officers, directors and their affiliates beneficially owned or controlled approximately 22% of our outstanding common stock as of March 31, 2005. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

**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

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- 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.

### **Being a public company increases our administrative costs.**

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as new rules subsequently implemented by the SEC and new listing requirements subsequently adopted by Nasdaq in response to Sarbanes-Oxley, have required changes in corporate governance practices of public companies. These new rules, regulations, and listing requirements have increased our legal and financial compliance costs, and made some activities more time consuming and costly. For example, as a result of becoming a public company, we have created several board committees, adopted additional internal controls and disclosure controls and procedures, retained a transfer agent and a financial printer, adopted an insider trading policy, and have all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws. These new rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance. These new rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee, and qualified executive officers.

### **We are currently reviewing and testing our internal control systems, processes and procedures in compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 which may result in the identification of significant control deficiencies or result in an adverse opinion with respect to the report on internal controls from our independent auditors.**

Sarbanes-Oxley Section 404 requires us to review and test our internal control systems, processes and procedures to ensure compliance. There can be no assurance that our review and testing of internal control systems, processes and procedures will not result in the identification of significant control deficiencies or result in an adverse opinion with respect to the report on internal controls from our independent auditors.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments.

*Interest Rate Risk.* We do not use derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents and marketable securities, we do not expect any material loss with respect to our investment portfolio.

*Foreign Currency Risk.* We have no significant investments outside the U.S. and have nominal transactional foreign currency risk because nearly all of our business is transacted in U.S. dollars. As a result, we have little exposure to foreign exchange rate fluctuations.

### **ITEM 4A. CONTROLS AND PROCEDURES**

#### **(a) Evaluation of disclosure controls and procedures**

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the CEO and CFO concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

#### **(b) Changes in internal controls**

Timothy G. Henn, Vice President, Finance and Administration, was appointed Chief Accounting Officer in January 2005. Deborah A. Smeltzer was appointed Vice President, Operations and Chief Financial Officer in January 2005. No other changes in the Company's internal control over financial reporting occurred during the Company's last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 2. USE OF PROCEEDS FROM SALES OF REGISTERED SECURITIES**

On February 24, 2004, we completed our initial public offering of 6,900,000 shares of common stock, including 900,000 shares subject to the underwriters' over-allotment option (which was exercised in full) at a public offering price of \$7.50 per share and realized an aggregate offering price of \$51.8 million. Our registration statement on Form S-1 (Reg. No. 333-109965) was declared effective by the SEC on February 11, 2004. The underwriters for the initial public offering were Bear, Stearns & Co. Inc., Deutsche Bank Securities Inc. and Piper Jaffray & Co.

We received net proceeds from the offering of approximately \$46.5 million. These proceeds are net of \$3.6 million in underwriting discounts and commissions, \$1.4 million in legal, accounting and printing fees and \$0.3 million in other expenses. We used \$0.4 million of the net proceeds to make a one-time cash payment to the University of California pursuant to the terms of several license agreements with them. During 2004, the net proceeds were used for research and development activities and general corporate purposes. We will retain broad discretion over the use of the net proceeds received from our offering. The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product candidate development and commercialization efforts and the amount of cash used by our operations.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K****(a) Exhibits**

<b>Exhibit Number</b>	<b>Document</b>
10.19*	Management Continuity and Severance Agreement, dated as of January 4, 2005, between Dynavax Technologies Corporation and Deborah A. Smeltzer
31.1**	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2**	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Incorporated by reference to our Report on Form 8-K, dated January 5, 2005

\*\* Filed herewith

**(b) Reports on Form 8-K**

<b>Date</b>	<b>Item Reported</b>
January 5, 2005	We filed a Current Report on Form 8-K on January 5, 2005, announcing the appointment of Deborah A. Smeltzer as Vice President, Operations and Chief Financial Officer.
January 26, 2005	We filed a Current Report on Form 8-K on January 26, 2005, announcing the appointment of Timothy G. Henn as Chief Accounting Officer.
February 15, 2005	We furnished a Current Report on Form 8-K on February 15, 2005, announcing our financial results for the fourth quarter and year ended December 31, 2004.
March 18, 2005	We filed a Current Report on Form 8-K on March 18, 2005, announcing the termination of the collaboration agreement with UCB Farchim, S.A.

**SIGNATURES**

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

DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ DINO DINA, M.D.  
Dino Dina, M.D.  
President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: May 9, 2005

By: /s/ DEBORAH A. SMELTZER  
Deborah A. Smeltzer  
Vice President, Operations and  
Chief Financial Officer  
(Principal Financial Officer)

Date: May 9, 2005

By: /s/ TIMOTHY G. HENN  
Timothy G. Henn  
Vice President, Finance and Administration and  
Chief Accounting Officer  
(Principal Accounting Officer)

Date: May 9, 2005

**Rule 13a-14(a) Certification of Chief Executive Officer**CERTIFICATIONS

I, Dino Dina, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably like to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 9, 2005

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

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Dino Dina, M.D.  
President, Chief Executive Officer and Director  
(Principal Executive Officer)



**Rule 13a-14(a) Certification of Chief Financial Officer****CERTIFICATIONS**

I, Deborah A. Smeltzer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably like to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 9, 2005

By: /s/ DEBORAH A. SMELTZER

Deborah A. Smeltzer  
Vice President, Operations and  
Chief Financial Officer  
(Principal Financial Officer)

**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

I, Dino Dina, M.D., hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

- (i) The Quarterly Report of the Company on Form 10-Q for the period ended March 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and
- (ii) The information contained in the Report fairly represents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2005

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

Dino Dina, M.D.

President, Chief Executive Officer and Director

(Principal Executive Officer)

**Certification Pursuant to Section 1350 of Chapter 63  
of Title 18 of the United States Code**

I, Deborah A. Smeltzer, hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

- (iii) The Quarterly Report of the Company on Form 10-Q for the period ended March 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and
- (iv) The information contained in the Report fairly represents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2005

By: /s/ DEBORAH A. SMELTZER \_\_\_\_\_

Deborah A. Smeltzer  
Vice President, Operations and  
Chief Financial Officer  
(Principal Financial Officer)