

DYNAVAX TECHNOLOGIES CORP

Form 10-Q

November 08, 2004

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**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 SEPTEMBER 30, 2004  
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** **33-0728374**  
(State or Other Jurisdiction of (IRS Employer Identification No.)  
Incorporation or Organization)

**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 October 31, 2004 was 24,623,438.

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Exhibit 32.1

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Table of Contents**PART I. FINANCIAL STATEMENTS****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

|  | <b>September 30,<br/>2004</b> | <b>December 31,<br/>2003</b> |
|--|-------------------------------|------------------------------|
|  | (Unaudited)                   | (Note 1)                     |
| <b>Assets</b>  |                               |                              |
| Current assets:  |                               |                              |
| Cash and cash equivalents  | \$ 71,514                     | \$ 23,468                    |
| Restricted cash  | 408                           |                              |
| Marketable securities  |                               | 5,629                        |
| Accounts receivable  | 3,544                         | 220                          |
| Prepaid expenses and other current assets  | 1,043                         | 1,422                        |
|  | <hr/>                         | <hr/>                        |
| Total current assets   | 76,509                        | 30,739                       |
| Property and equipment, net  | 2,157                         | 828                          |
| Other assets   | 407                           | 18                           |
|  | <hr/>                         | <hr/>                        |
| Total assets   | \$ 79,073                     | \$ 31,585                    |
|  | <hr/>                         | <hr/>                        |
| <b>Liabilities, minority interest, convertible preferred stock,<br/>and stockholders' equity (net capital deficiency)</b>  |                               |                              |
| Current liabilities:   |                               |                              |
| Accounts payable   | \$ 2,059                      | \$ 1,410                     |
| Accrued liabilities  | 4,885                         | 2,989                        |
| Deferred revenue   | 1,750                         | 750                          |
|  | <hr/>                         | <hr/>                        |
| Total current liabilities  | 8,694                         | 5,149                        |
| Deferred revenue, noncurrent   | 6,250                         |                              |
| Minority interest in Dynavax Asia  |                               | 14,733                       |
| Convertible preferred stock: \$0.001 par value; no shares<br>authorized at September 30, 2004 and 61,767 shares<br>authorized at December 31, 2003; no shares outstanding at |                               | 83,635                       |

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September 30, 2004 and 39,514 shares outstanding at  
December 31, 2003

Commitments and contingencies

Stockholders' equity (net capital deficiency):

Preferred stock: \$0.001 par value; 5,000 shares authorized  
and no shares issued and outstanding at September 30, 2004  
or December 31, 2003

Common stock: \$0.001 par value; 100,000 and 28,333 shares  
authorized at September 30, 2004 and December 31, 2003,  
respectively; 24,625 and 1,884 shares issued and outstanding  
at September 30, 2004 and December 31, 2003, respectively

|                                    |                   |                   |
|------------------------------------|-------------------|-------------------|
|                                    | 25                | 2                 |
| Additional paid-in capital         | 158,691           | 12,762            |
| Deferred stock compensation        | (3,783)           | (4,677)           |
| Notes receivable from stockholders | (631)             | (654)             |
| Accumulated deficit                | (90,173)          | (79,365)          |
|                                    | <u>          </u> | <u>          </u> |

|   |               |                 |
|---|---------------|-----------------|
| Total stockholders' equity (net capital deficiency) | <u>64,129</u> | <u>(71,932)</u> |
|---|---------------|-----------------|

|   |                  |                  |
|---|------------------|------------------|
| Total liabilities, minority interest, convertible preferred stock,<br>and stockholders' equity (net capital deficiency) | <u>\$ 79,073</u> | <u>\$ 31,585</u> |
|---|------------------|------------------|

*See accompanying notes.*

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

|  | <b>Three Months Ended<br/>September 30,</b> |                   | <b>Nine Months Ended<br/>September 30,</b> |                   |
|--|---|-------------------|--|-------------------|
|  | <b>2004</b>                                 | <b>2003</b>       | <b>2004</b>                                | <b>2003</b>       |
| Revenues:  |   |                   |  |                   |
| Collaboration revenue  | \$ 3,769                                    | \$                | \$ 11,644                                  | \$                |
| Grant revenue  | (109)                                       | 23                | 713  | 119               |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |
| Total revenues   | 3,660                                       | 23                | 12,357                                     | 119               |
| Operating expenses:  |   |                   |  |                   |
| Research and development                                       | 5,928                                       | 2,935             | 17,709                                     | 9,528             |
| General and administrative                                     | 2,017                                       | 1,315             | 6,013                                      | 3,732             |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |
| Total operating expenses                                       | 7,945                                       | 4,250             | 23,722                                     | 13,260            |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |
| Loss from operations   | (4,285)                                     | (4,227)           | (11,365)                                   | (13,141)          |
| Interest income, net   | 252   | 88                | 557  | 329               |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |
| Net loss   | \$ (4,033)                                  | \$ (4,139)        | \$ (10,808)                                | \$ (12,812)       |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |
| Basic and diluted net loss per share                           | \$ (0.16)                                   | \$ (2.30)         | \$ (0.54)                                  | \$ (7.20)         |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |
| Shares used to compute basic and<br>diluted net loss per share | 24,609                                      | 1,803             | 20,034                                     | 1,780             |
|  | <u>          </u>                           | <u>          </u> | <u>          </u>                          | <u>          </u> |

*See accompanying notes.*

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

|   | <b>Nine Months Ended September 30,</b> |             |
|---|--|-------------|
|   | <b>2004</b>                            | <b>2003</b> |
| <b>Operating activities</b>   |  |             |
| Net loss  | \$ (10,808)                            | \$ (12,812) |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |             |
| Depreciation and amortization   | 307                                    | 453         |
| Loss on disposal of property and equipment                                  | 18                                     |             |
| Accretion and amortization on investments                                   | 80                                     | 493         |
| Interest accrued on notes receivable from stockholders                      | (28)                                   | (30)        |
| Amortization of stock-based compensation expense                            | 1,944                                  | 1,150       |
| Changes in operating assets and liabilities:                                |  |             |
| Accounts receivable   | (3,324)                                |             |
| Prepaid expenses and other current assets                                   | 379                                    | 110         |
| Other assets  | (389)                                  | 33          |
| Accounts payable  | 649                                    | (912)       |
| Accrued liabilities   | 1,896                                  | 246         |
| Deferred revenue  | 7,250                                  |             |
|   | <hr/>                                  | <hr/>       |
| Net cash used in operating activities                                       | (2,026)                                | (11,269)    |
| <b>Investing activities</b>   |  |             |
| Purchase of marketable securities   |  | (7,022)     |
| Maturities and sale of marketable securities                                | 5,549                                  | 18,000      |
| Purchases of property and equipment   | (1,654)                                | (111)       |
|   | <hr/>                                  | <hr/>       |
| Net cash provided by investing activities                                   | 3,895                                  | 10,867      |
| <b>Financing activities</b>   |  |             |
| Proceeds from issuance of common stock, net of issuance costs               | 46,534                                 | (23)        |
| Repayment of notes receivable from stockholders                             | 51                                     | 88          |
| Restricted cash   | (408)                                  |             |
|   | <hr/>                                  | <hr/>       |
| Net cash provided by financing activities                                   | 46,177                                 | 65          |
| Net increase (decrease) in cash and cash equivalents                        | 48,046                                 | (337)       |
| Cash and cash equivalents at beginning of the period                        | 23,468                                 | 5,171       |
|   | <hr/>                                  | <hr/>       |



|  |                   |                   |
|--|-------------------|-------------------|
| Cash and cash equivalents at end of the period | \$ 71,514         | \$ 4,834          |
|  | <u>          </u> | <u>          </u> |

*See accompanying notes.*

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**Dynavax Technologies Corporation  
Notes to Condensed Consolidated Financial Statements  
September 30, 2004  
(Unaudited)**

**1. Basis of Presentation and Summary of Significant Accounting Policies**

**Basis of Presentation**

The terms Dynavax, the Company, we and us as used in this report refer to Dynavax Technologies Corporation. The accompanying unaudited condensed consolidated balance sheet as of September 30, 2004 and condensed consolidated statements of operations for the three and nine month periods ended September 30, 2004 and 2003 have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of the management of the Company, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ended December 31, 2004 or any other period. The condensed consolidated balance sheet at December 31, 2003 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. These unaudited condensed financial statements and the notes accompanying them should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2003.

Certain reclassifications of prior year amounts have been made to conform with the current year presentation. Patent legal expenses in the prior year have been reclassified from research and development expenses to general and administrative expenses.

**Dynavax Asia**

In October 2003, the Company formed Dynavax Asia Pte. Ltd., or Dynavax Asia, a 100% owned Singapore subsidiary, which focuses on the Company's clinical and preclinical hepatitis B programs. Also 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 Company recorded the sale of the ordinary shares as a minority interest liability in the consolidated financial statements. In February 2004, the ordinary shares of Dynavax Asia were converted into 2,111,111 shares of common stock of the Company and Dynavax Asia became a wholly owned subsidiary.

**Principles of Consolidation**

The consolidated financial statements include the accounts of Dynavax and Dynavax Asia, its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

**Critical Accounting Policies**

The Company believes that there have been no significant changes in its critical accounting policies during the nine months ended September 30, 2004 as compared with those previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2003 filed with the SEC on March 30, 2004.

## **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 consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

**Table of Contents****Revenue Recognition**

The Company recognizes collaboration, upfront and other revenue based on the terms specified in the agreements, generally as work is performed or approximating the straight-line basis over the period of the collaboration. Any amounts received in advance of performance are recorded as deferred revenue. Revenue from milestones with substantive performance risk is recognized upon achievement of the milestone. All revenues recognized to date under these collaborations and milestones are nonrefundable.

Revenues related to government grants are recognized as the related research expenses are incurred. Additionally, we recognize revenue based on the facilities and administrative cost rate reimbursable per the terms of the grant awards. Any amounts received in advance of performance are recorded as deferred revenue until earned.

Payments by collaborators for the option to license technology or product rights in the future are deferred when received. When an option is exercised, revenue is recognized on a straight-line basis over the term of the resulting license agreement. In the event that an option expires without exercise, the payment is recognized in full at the expiration of the option.

**Restricted Cash**

At September 30, 2004, the Company held \$408,304 in a certificate of deposit account as collateral for an irrevocable standby letter of credit, which is required under the new operating lease the Company entered into in January 2004.

**Net Loss Per Share**

Basic loss per share is computed based on the number of weighted average shares outstanding. The calculation of diluted net loss per share excludes shares of potential common stock, consisting of stock options and warrants, because their effect is anti-dilutive.

|   | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|---|---|-------------|--|-------------|
|   | <b>2004</b>                                 | <b>2003</b> | <b>2004</b>                                | <b>2003</b> |
|   | (In thousands, except per share amounts)    |             |  |             |
| Numerator:  |   |             |  |             |
| Net loss  | \$ (4,033)                                  | \$ (4,139)  | \$ (10,808)                                | \$ (12,812) |
| Denominator:  |   |             |  |             |
| Weighted-average common shares outstanding                          | 24,617                                      | 1,851       | 20,050                                     | 1,844       |
| Less: Weighted-average unvested common shares subject to repurchase | (8)   | (48)        | (16)                                       | (64)        |
|   | 24,609                                      | 1,803       | 20,034                                     | 1,780       |

Denominator for basic and diluted net loss  
per share

|                                      |                   |                   |                   |                   |
|--------------------------------------|-------------------|-------------------|-------------------|-------------------|
|                                      | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Basic and diluted net loss per share | \$ (0.16)         | \$ (2.30)         | \$ (0.54)         | \$ (7.20)         |
|                                      | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |

### Stock-Based Compensation

The Company has adopted the pro forma disclosure requirements of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( SFAS 148 ). As permitted, the Company continues to recognize employee stock compensation under the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25 ( APB 25 ) and its interpretations. Under APB 25,

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compensation expense is based on the difference, if any, on the date of grant, between the deemed fair value of the Company's common stock and the option exercise price, and is amortized over the respective vesting period of the options using the straight-line method. The pro forma effects of applying SFAS 123, as amended by SFAS 148, on the Company's net loss had compensation cost for options granted to employees been determined based on the fair value at grant date as prescribed by SFAS 123, would be as follows (in thousands, except per share amounts):

|   | <b>Three Months Ended<br/>September 30,</b> |                   | <b>Nine Months Ended<br/>September 30,</b> |                    |
|---|---|-------------------|--|--------------------|
|   | <b>2004</b>                                 | <b>2003</b>       | <b>2004</b>                                | <b>2003</b>        |
| Net loss:   |   |                   |  |                    |
| As reported   | \$ (4,033)                                  | \$ (4,139)        | \$ (10,808)                                | \$ (12,812)        |
| Add:  |   |                   |  |                    |
| Stock-based employee<br>compensation expense included<br>in net loss                            | 727   | 501               | 1,944                                      | 1,150              |
| Less:   |   |                   |  |                    |
| Stock-based employee<br>compensation expense<br>determined under the fair value<br>based method | (745)                                       | (551)             | (2,242)                                    | (1,390)            |
| Pro forma   | <u>\$ (4,051)</u>                           | <u>\$ (4,189)</u> | <u>\$ (11,106)</u>                         | <u>\$ (13,052)</u> |
| Net loss per share  |   |                   |  |                    |
| Basic and diluted, as reported  | <u>\$ (0.16)</u>                            | <u>\$ (2.30)</u>  | <u>\$ (0.54)</u>                           | <u>\$ (7.20)</u>   |
| Basic and diluted, pro forma  | <u>\$ (0.16)</u>                            | <u>\$ (2.32)</u>  | <u>\$ (0.55)</u>                           | <u>\$ (7.33)</u>   |

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 method, assuming no expected dividends and the following weighted average assumptions:

| <b>Employee Stock Options</b> |                     | <b>Employee Stock Purchase<br/>Plan</b> |
|-------------------------------|---------------------|---|
| <b>For the Three</b>          | <b>For the Nine</b> | <b>For the Nine</b>                     |

|                          | <b>Months Ended</b>  |             | <b>Months Ended</b>  |             | <b>For the<br/>Three<br/>Months<br/>Ended</b> | <b>Months<br/>Ended</b> |                         |
|--------------------------|----------------------|-------------|----------------------|-------------|---|-------------------------|-------------------------|
|                          | <b>September 30,</b> |             | <b>September 30,</b> |             | <b>September 30,</b>                          |                         |                         |
|                          | <b>2004</b>          | <b>2003</b> | <b>2004</b>          | <b>2003</b> | <b>2004</b>                                   | <b>2003</b>             | <b>2004</b> <b>2003</b> |
| Risk-free interest rate  | 3.1%                 | 2.4%        | 3.0%                 | 2.5%        | 2.0%  |                         | 2.0%                    |
| Expected life (in years) | 4                    | 4           | 4                    | 4           | 0.5   |                         | 0.5                     |
| Volatility               | 1.0                  | 1.0         | 1.0                  | 1.0         | 1.0   |                         | 1.0                     |

The weighted-average fair value per share of employee stock options granted during the three months ended September 30, 2004 and 2003 was \$4.75 and \$11.52, respectively. The weighted-average estimated fair value per share of employee stock options granted during the nine months ended September 30, 2004 and 2003 was \$5.54 and \$7.34, respectively.

For options granted to non-employees, the Company determined the estimated fair value of the options using the Black-Scholes option-pricing model. Compensation expense is being recognized over the option-vesting period ranging up to 4 years. The Company recorded compensation expense of approximately \$179,000 and \$191,000 for the three and nine months ended September 30, 2004, respectively, in connection with options granted to non-employees. There was no compensation expense for the nine months ended September 30, 2003.

**Table of Contents****2. Commitments and Contingencies****Operating Lease**

The Company leases its facility under an operating lease that expires in September 2014. Under this operating lease, the Company had an option through May 2004 to expand the amount of office and laboratory space it occupies. In May 2004, the Company exercised that option. This lease can be terminated at no cost to the Company in September 2009 but extends automatically until September 2014 if the Company chooses not to exercise the option to terminate the lease.

Future minimum payments under the non-cancelable portion of the operating lease at September 30, 2004 are as follows (in thousands):

|                          |         |
|--------------------------|---------|
| Year ending December 31, |         |
| 2004                     | \$ 408  |
| 2005                     | 1,650   |
| 2006                     | 1,699   |
| 2007                     | 1,750   |
| 2008                     | 1,803   |
| Thereafter               | 1,225   |
|                          | <hr/>   |
|                          | \$8,535 |
|                          | <hr/>   |

We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to us of \$50,179 (in 2004) and \$334,525 (thereafter through 2006). This sublease agreement includes an option for early termination in September 2006 and an option for extension of the sublease term through February 2009.

**3. Collaborative Research, Development, and License Agreements****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. The Company incurred license and milestone fees of \$20,000 for the nine months ended September 30, 2004. There was no license and milestone fee for the three months ended September 30, 2004. The Company incurred patent expenses of approximately \$240,000 and \$45,000 for the three months ended September 30, 2004 and 2003, respectively, and \$352,000 and \$152,000 for the nine months ended September 30, 2004 and 2003, respectively, in connection with these license agreements. The Company incurred a \$375,000 one-time charge to UC due upon the closing of the Company's initial public offering as partial consideration for the technology licenses. The Company recorded this charge as research and development expense in the first quarter of 2004. Also as partial consideration for the technology licenses, the Company incurred a one-time charge of \$150,000 to UC related to the \$8.0 million upfront



payment from UCB Farchim S.A., which is being amortized over the development period of the licensed programs, currently estimated to be eight years.

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### **License and Development Agreement with UCB**

In February 2004, the Company entered into an agreement with UCB Farchim, S.A., or UCB, a subsidiary of UCB, S.A. a publicly traded multi-national company based in Brussels, Belgium, in which the Company licensed the technology, know-how and preclinical and clinical data related to its AIC and grass allergy programs on an exclusive, worldwide basis. UCB was also granted an option to license the Company's peanut allergy program. According to terms of the agreement, the Company received an \$8.0 million upfront payment and may earn up to \$40.0 million in milestone payments based on achieving defined clinical and regulatory objectives. The Company is amortizing the \$8.0 million upfront payment from UCB over the development period of the licensed programs, currently estimated to be eight years. In addition, UCB agreed to fund ongoing development costs of the licensed programs, as well as costs relating to regulatory filings, potential launch, sales and marketing, and reasonable administrative support. The Company is accounting for such funding as collaboration revenue, which is generally recognized in the period in which expenses related to the licensed programs are incurred. The Company records the development costs and costs relating to regulatory filings, which account for substantially all of the costs as research and development expenses. The remaining costs are recorded as general and administrative expenses on the statement of operations. If any of the licensed product candidates are successfully developed and approved for sale, the Company will receive royalties on sales. The Company has retained an option to co-promote any approved product in the United States, in which case the Company would recognize revenue from sales in lieu of receiving royalty payments. UCB may terminate the agreement at any time on 60 days' advance notice either in its entirety or with respect to one or more licensed programs, but may not terminate the agreement as to our ragweed allergy program prior to February 2006 except for safety or efficacy reasons, in which case it may not terminate the agreement prior to February 2005. Either party may terminate the UCB agreement if a default occurs and is not resolved. Otherwise, the agreement does not terminate until the later to occur of the date when the last valid issued patent claim covering any of the licensed programs expires or June 2018. Total revenue recognized during the three month period ended September 30, 2004, related to the UCB agreement was \$3.8 million. Total revenue recognized during the nine month period ended September 30, 2004, related to the UCB agreement was \$11.6 million, making up 94% of total revenues. Total accounts receivables at September 30, 2004, related to the UCB agreement was \$3.5 million, making up 98% of total accounts receivables balances.

### **4. Initial Public Offering**

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 \$46.4 million. As a result of the initial public offering, all outstanding shares of Preferred Stock with a net value of \$83.6 million converted to 13,712,128 shares of common stock and the 15,200,000 shares of ordinary stock in Dynavax Asia with a net value of \$14.7 million converted into 2,111,111 shares of common stock making Dynavax Asia a wholly-owned subsidiary as of that date.

### **5. New Accounting Pronouncement**

In March 2004 the Financial Accounting Standard Board ( FASB ) issued an exposure draft entitled Share-Based Payment, an amendment of FASB Statements No. 123 and 95. This exposure draft would require stock-based compensation to employees to be recognized as a cost in the financial statements and that such cost be measured according to the fair value of the stock options. In the absence of an observable market price for the stock awards, the fair value of the stock options would be based upon a valuation methodology that takes into consideration various factors, including the exercise price of the option, the expected term of the option, the current price of the underlying shares, the expected volatility of the underlying share price, the expected dividends on the underlying shares and the risk-free interest rate. The proposed requirements in the exposure draft would be effective for interim or annual periods beginning after June 15, 2005. The Company will continue to monitor communications on this subject from

the FASB in order to determine the impact on the Company's consolidated financial statements.

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

This 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 the safe harbor created by those sections. These forward-looking statements include, but are not limited to: 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 on our recognition of revenue, uncertainty regarding our future operating results and our profitability, anticipated sources of funds and all plans, objectives, expectations and intentions contained in this report that are not historical facts. We usually use words such as may, will, should, expect, plan, anticipate, believe, estimate, predict, future, intend, or certain or the negative of these terms or similar expressions to identify forward-looking statements. Discussions containing such forward-looking statements may be found throughout the document. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. We disclaim any obligation to update these forward-looking statements as a result of subsequent events. The business risks discussed in Item 2 of this Report on Form 10-Q, among other things, should be considered in evaluating our prospects and future financial performance.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. The discussion should be read in conjunction with our consolidated financial statements and notes thereto.

**Overview**

We discover, develop and intend to commercialize innovative products to treat and prevent allergies, infectious diseases and chronic inflammatory diseases. 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. Our most advanced clinical programs include:

AIC, an immunotherapy product candidate for treatment of ragweed allergy that has completed Phase II trials, and is currently completing a Phase II/III clinical trial. A confirmatory Phase III clinical trial is anticipated to begin in 2005.

Hepatitis B vaccine, for which a Phase II program in adolescents conducted in Canada has been completed, and for which a Phase II/III trial in patients who are less responsive to conventional vaccine is currently underway in Singapore. We anticipate initiating Phase III trials in Canada, Europe and Asia in 2005. Our intention is to commercialize our Hepatitis B vaccine outside of the United States.

An inhaled therapeutic product candidate for treatment of asthma, which has recently completed a pilot Phase II trial. We plan to advance the asthma program into a broader clinical program focused on direct measurement of efficacy.

Preclinical programs focused on chronic inflammation, antiviral therapies and improved, next-generation vaccines using ISS and other technologies.

**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 nine months ended September 30, 2004 as compared with those previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2003 filed with the SEC on March 30, 2004.



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*Comparison of Three Months and Nine Months Ended September 30, 2004 and 2003 (In thousands, except percentages)*

|                                     | <b>Three Months<br/>Ended<br/>September 30,</b> |             | <b>Increase/<br/>(Decrease)</b> |          | <b>Nine Months<br/>Ended<br/>September 30,</b> |             | <b>Increase/<br/>(Decrease)</b> |          |
|-------------------------------------|---|-------------|---------------------------------|----------|--|-------------|---------------------------------|----------|
|                                     | <b>2004</b>                                     | <b>2003</b> | <b>\$</b>                       | <b>%</b> | <b>2004</b>                                    | <b>2003</b> | <b>\$</b>                       | <b>%</b> |
| <b><u>Results of Operations</u></b> |   |             |                                 |          |  |             |                                 |          |
| Revenues:                           |   |             |                                 |          |  |             |                                 |          |
| Collaboration revenue               | \$3,769   | \$          | \$3,769                         | n/a      | \$11,644                                       | \$          | \$11,644                        | n/a      |
| Grant revenue                       | (109)   | 23          | (132)                           | n/a      | 713  | 119         | 594                             | n/a      |
| Total revenues                      | 3,660   | 23          | 3,637                           | n/a      | 12,357   | 119         | 12,238                          | n/a      |
| Research and development expenses   | 5,928   | 2,935       | 2,993                           | 102%     | 17,709   | 9,528       | 8,181                           | 86%      |
| General and administrative expenses | 2,017   | 1,315       | 702                             | 53%      | 6,013  | 3,732       | 2,281                           | 61%      |
| Total operating expenses            | 7,945   | 4,250       | 3,695                           | 87%      | 23,722   | 13,260      | 10,462                          | 79%      |
| Interest income, net                | \$ 252  | \$ 88       | \$ 164                          | 186%     | \$ 557   | \$ 329      | \$ 228                          | 69%      |

Total revenues for the three and nine months ended September 30, 2004 were \$3.7 million and \$12.4 million, respectively, compared to \$23,000 and \$119,000 for the three and nine months ended September 30, 2003, respectively. Total revenues for the three and nine month periods ended September 30 2004, consisted of \$3.8 million and \$11.6 million, respectively, from a collaborative agreement with UCB in ragweed and grass allergies, which was initiated in the first quarter of 2004, as well as grant revenue of \$(109,000) and \$713,000, respectively, from government grants for biodefense programs awarded by the National Institutes of Health (NIH). The \$(109,000) in net revenue from government grants for biodefense programs for the three months ended September 30, 2003 includes a one-time adjustment of \$(303,000). This one-time adjustment reflects the minimum cost overhead rate allowable under the grant awards until such time as the final rate is determined. Revenues of \$23,000 and \$119,000 for the three and nine months ended September 30, 2003, respectively, consisted solely of a government grant awarded by the NIH. We expect revenues from our collaboration with UCB and from government grants for biodefense programs to be consistent with or increase moderately through the remainder of 2004 as these programs progress.

Research and development expenses were \$5.9 million for the three months ended September 30, 2004, an increase of 102% from \$2.9 million for the three months ended September 30, 2003, and \$17.7 million for the nine months ended September 30, 2004, an increase of 86% from \$9.5 million for the nine months ended September 30, 2003. The increases for the three and nine month periods ended September 30, 2004 compared to the same periods in 2003 were primarily the result of increased clinical trial activities in our ragweed allergy, hepatitis B vaccine and asthma programs, as well as preclinical works associated with government grants for biodefense programs, being conducted during the three and nine months ended September 30, 2004. Non-cash stock-based compensation expense included in

research and development expenses was approximately \$344,000 and \$379,000 for the three months ended September 30, 2004 and 2003, respectively, and approximately \$1.1 million and \$790,000 for the nine months end September 30, 2004 and 2003, respectively. We expect research and development expenses in future periods generally to be consistent with or increase moderately from levels experienced in the three and nine month periods ended September 30, 2004 as our clinical and preclinical programs progress.

General and administrative expenses were \$2.0 million for the three months ended September 30, 2004, an increase of 53% as compared to \$1.3 million for the three months ended September 30, 2003, and \$6.0 million for the nine months ended September 30, 2004, an increase of 61% as compared to \$3.7 million for the nine months ended September 30, 2003. The increases for the three and nine month periods ended September 30, 2004 compared to the same periods in 2003 reflect higher compensation and benefits associated primarily with the expansion of our management team and higher expenditures for consulting and professional services. Non-cash stock-based compensation expense

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included in general and administrative expenses was approximately \$383,000 and \$121,000 for the three months ended September 30, 2004 and 2003, respectively, and approximately \$877,000 and \$360,000 for the nine months ended September 30, 2004 and 2003, respectively. We expect general and administrative expenses to increase from levels experienced in the three and nine month periods ended September 30, 2004 as a result of our organizational growth and increased costs of operating as a public company.

Interest income, net, was \$252,000 for the three months ended September 30, 2004, an increase of 186% as compared to \$88,000 for the three months ended September 30, 2003, and \$557,000 for the nine months ended September 30, 2004, an increase of 69% as compared to \$329,000 for the nine months ended September 30, 2003. The increases for both the three and nine month periods compared to the same periods in 2003 were primarily due to higher average cash and marketable securities balances during the three and nine months ended September 30, 2004.

**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. As of September 30, 2004, we had \$71.5 million in cash and cash equivalents. Our funds are currently invested in highly liquid, institutional money market funds.

Our operating activities used cash of \$2.0 million during the nine months ended September 30, 2004, compared to cash used in operating activities of \$11.3 million during the nine months ended September 30, 2003. The decrease of approximately \$9.3 million was due primarily to an \$8.0 million upfront payment made to us by UCB and a narrower loss from operations.

Our investing activities provided cash of \$3.9 million during the nine months ended September 30, 2004, compared to \$10.9 million during the nine months ended September 30, 2003. Cash provided by investing activities during the nine months ended September 30, 2004 consisted primarily of maturities of investments of approximately \$5.5 million offset by an investment of approximately \$1.7 million in property and equipment. Cash provided by investing activities during the nine months ended September 30, 2003 consisted primarily of net sales and maturities of investments of approximately \$11.0 million.

Our financing activities provided cash of approximately \$46.2 million during the nine months ended September 30, 2004, primarily from the issuance of 6,900,000 shares of common stock in our initial public offering in February 2004 and the repayment of notes receivable from stockholders, offset by restricted cash held in a certificate of deposit used as collateral. Cash provided by financing activities of approximately \$65,000 during the nine months ended September 30, 2003 consisted primarily of repayment of notes receivable from stockholders of approximately \$88,000.

**Long-term Debt and Operating Leases**

We have no long-term debt. As of September 30, 2004, we had contractual obligations related to non-cancelable portion of the operating leases as follows (in thousands):

| <b>Payments Due by Period</b> |                  |                  |                          |
|-------------------------------|------------------|------------------|--------------------------|
| <b>Total</b>                  |                  |                  |                          |
|                               | <b>1-3 years</b> | <b>4-5 years</b> | <b>After<br/>5 years</b> |



|                  |         | <b>Less than<br/>1 year</b> |         |         |         |
|------------------|---------|-----------------------------|---------|---------|---------|
| Operating leases | \$8,535 | \$ 408                      | \$3,349 | \$3,553 | \$1,225 |

The Company leases its facility under an operating lease that expires in September 2014. Under this operating lease, the Company had an option through May 2004 to expand the amount of office and laboratory space it occupies. In May 2004, the Company exercised that option. This lease can be terminated at no cost to the Company in September 2009 but extends automatically until September 2014 if the Company

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chooses not to exercise the option to terminate the lease. We have entered into a sublease agreement for a certain portion of the leased space with scheduled payments to us of \$50,179 (in 2004) and \$334,525 (thereafter through 2006). This sublease agreement includes an option for early termination in September 2006 and an option for extension of the sublease term through February 2009.

We believe our existing cash and cash equivalents, together with the payments due to us under the terms of our collaboration agreement with UCB, will be sufficient to meet our anticipated cash requirements through 2006. 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. To the extent that we raise additional funds by issuing equity securities, our stockholders will experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators, government agencies and other licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may significantly harm our future capital position. UCB may terminate the agreement at any time on 60 days advance notice either in its entirety or with respect to one or more licensed programs, but may not terminate the agreement as to our ragweed allergy program prior to February 2006 except for safety or efficacy reasons, in which case it may not terminate the agreement prior to February 2005. Either party may terminate the UCB agreement if a default occurs and is not resolved. Otherwise, the agreement does not terminate until the later to occur of the date when the last valid issued patent claim covering any of the licensed programs expires or June 2018.

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, reduce the scope of, eliminate or divest one or more of our research, preclinical or clinical programs or discontinue our business.

## **ADDITIONAL FACTORS THAT MAY AFFECT FUTURE RESULTS**

*Various discussions in this Quarterly Report on Form 10-Q contain forward-looking statements concerning our future products, expenses, revenue, 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 payments made under a collaboration agreement and payments received under government grants for biodefense programs. The collaboration agreement is subject to termination under specified circumstances. 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 approximately \$90.2 million as of September 30, 2004, 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.

We do not have any products that generate revenue. We began Phase II/III trials for AIC, an immunotherapy for ragweed allergy, and began Phase II/III trials for our hepatitis B vaccine in 2004. Our product candidates may never be commercialized, and we may never generate product-related revenue. Our ability to generate revenue depends upon:

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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 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.**

We believe our existing capital resources, will be sufficient to meet our anticipated cash requirements through 2006. We do not believe that we will have product revenue until 2007, at the earliest. 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 revenue, 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, eliminate or divest one or more 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 Food and Drug Administration, or 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 only 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.

Currently, only three of our product candidates have advanced to Phase II clinical trials: AIC, our hepatitis B vaccine and our inhaled therapeutic for treatment of asthma. We have only limited clinical data for these product candidates, some of which may not be supportive of ultimate regulatory approval. In particular, in one of our Phase II trials for AIC, which was conducted in Canada in 2001 and 2002, there was no impact on clinical symptom scores or medication use in the first year of the two-year trial. We will need to demonstrate in Phase III clinical trials that each

product candidate is safe and effective before we can obtain 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. We anticipate initiating a confirmatory Phase III trial for AIC in 2005. We also anticipate initiating Phase III trials for our hepatitis B vaccine in Canada, Europe and Asia in 2005. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval in their jurisdictions.

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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 revenue 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 revenue.**

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 and our asthma product candidate, is limited due to the seasonal nature of ragweed allergy and allergic asthma. Even a small delay in a trial for any of these product candidates 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 or our hepatitis B vaccine 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;

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.

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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 revenue 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. Currently we have established two collaborative relationships, one with Berna Biotech for our hepatitis B vaccine and hepatitis B therapeutic product candidates and the second with UCB Farchim, S.A., or UCB, for AIC and grass allergy immunotherapy. The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Moreover, even if we do establish collaborative relationships, our collaborators may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of 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 potential 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 is available from our current third-party supplier.

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In addition, we do not currently have a contract manufacturer for AIC or enough AIC to supply ongoing clinical and, potentially, commercial needs. We believe that our existing supplies of AIC are only sufficient for us to conduct the two-year Phase II/III clinical trial we initiated in February 2004. We intend to qualify and enter into manufacturing agreements with one or more new commercial-scale contract manufacturers to produce additional supplies of AIC as required for completion of 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 revenue.

**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 revenue, if any.**

We do not anticipate that any of our product candidates will be commercially available until 2007, 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.

We expect that Asia will be the primary target market for our hepatitis B vaccine, if approved. While we may seek partners for purposes of commercializing this product candidate in Asian and other non-U.S. markets 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 heightened scrutiny from 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

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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 revenue 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 revenue 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, steroid hormones called corticosteroids and anti-leukotriene agents, which block symptoms caused by inflammatory molecules, 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 of the 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 three-shot vaccines produced by GlaxoSmithKline Plc and Merck & Co., Inc., among others, as well as potentially with a two-shot vaccine in clinical development by GlaxoSmithKline Plc.

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 currently intend to conduct certain operations relating to our hepatitis B vaccine and therapeutic product candidates through Dynavax Asia Pte. Ltd., or Dynavax Asia, our subsidiary based in Singapore. We intend to commercialize our hepatitis B vaccine only outside the U.S. due to the presence of third-party patents in the U.S. covering hepatitis B surface antigen, a key component of our hepatitis B vaccine, that extend until as late as 2019. 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.

International operations are subject to risk, including:

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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 revenue.

**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.

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

Our success depends on our ability to:

obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;

operate without infringing upon the proprietary rights of others; and

prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting U.S. and foreign patent applications. 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 revenue or maintain any advantage we may have with respect to existing or potential competitors.

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**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 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, or 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 United States 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. 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.

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**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;

technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;

changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;

our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;

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 you and other 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 42.9% of our outstanding common stock as of October 31, 2004. 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

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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

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 Securities and Exchange Commission 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.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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

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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 current investments, 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 the high quality and conservative nature of our longer-term investments, which are generally held to maturity, we do not expect any material loss with respect to our investment portfolio.

***Foreign Currency Risk.*** All of our business is currently transacted in U.S. dollars. As a result, we have no exposure to foreign exchange rate fluctuations.

**ITEM 4. CONTROLS AND PROCEDURES**

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer (CEO) who also serves as Acting Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of September 30, 2004. Based on that evaluation, the CEO concluded that the Company's disclosure controls and procedures were effective as of such date to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. William J. Dawson, the former Vice President, Finance & Operations and Chief Financial Officer, stepped down from that role in late June to pursue other professional opportunities. Mr. Dawson has agreed to remain as a consultant to the Company for an additional six months until the Company hires a suitable replacement. In the meantime, Dr. Dino Dina, President and Chief Executive Officer, has assumed the role of Acting Chief Financial Officer. Timothy G. Henn was appointed Vice President, Finance and Administration in August 2004. There were no other changes in the Company's internal control over financial reporting that 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. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

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 gross proceeds of \$51.8 million. Our registration statement on Form S-1 (Reg. No. 333-109965) was declared effective by the Securities and Exchange Commission 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 \$46.4 million. These proceeds are net of \$3.6 million in underwriting discounts and commissions, \$1.4 million in legal, accounting and printing fees and \$315,000 in other expenses. We used a portion of the net proceeds to make a one-time cash payment of \$375,000 to the University of California pursuant to the terms of several license agreements with them. We intend to use the remaining net proceeds for 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.

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**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<br/>Number</b> | <b>Document</b>   |
|---------------------------|---|
| 31.1                      | Certification of Chief Executive Officer and Acting Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1                      | Certification of Chief Executive Officer and Acting Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

(b) Reports on Form 8-K:

On August 27, 2004, the Registrant filed a report on Form 8-K, announcing the appointment of Timothy G. Henn as Vice President, Finance and Administration.

On August 6, 2004, the Registrant filed a report on Form 8-K, announcing the Company's financial results for the second quarter ended June 30, 2004.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 8, 2004

**DYNAVAX TECHNOLOGIES CORPORATION**

/s/ Dino Dina

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Dino Dina  
President, Chief Executive  
Officer, Acting Chief  
Financial Officer, and Director  
*(Principal Executive Officer  
and Principal Financial and  
Accounting Officer)*