CANCERVAX CORP
Form 10-Q
August 13, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

[x] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 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: 0-50440

CANCERVAX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**52-2243564**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2110 Rutherford Road, Carlsbad, CA	**92008**
(Address of principal executive offices)	(Zip Code)

(760) 494-4200
(Registrant s telephone number, including area code)

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. [X] Yes [ ] No

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

The number of outstanding shares of the registrant s common stock, par value $0.00004 per share, as of August 1, 2004 was 26,764,827.

CANCERVAX CORPORATION

FORM 10-Q QUARTERLY REPORT
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

CancerVax Corporation

Condensed Consolidated Balance Sheets
(In thousands, except par value)

	June 30, 2004	December 31, 2003
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 24,819	$ 101,681
Securities available-for-sale	54,418	5,411
Restricted cash		1,000
Other current assets	1,233	917
Total current assets	80,470	109,009
Property and equipment, net	11,155	10,529
Goodwill	5,381	5,381
Intangibles, net	495	519
Restricted cash	1,000	1,000
Other assets	473	569
Total assets	$ 98,974	$ 127,007
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 6,343	$ 5,650
Current portion of long-term debt	2,838	6,091
Total current liabilities	9,181	11,741
Long-term debt, net of current portion	631	1,811
Deferred rent	800	682
Commitments		
Stockholders equity:		
Common stock, $.00004 par value; 75,000 shares authorized; 26,756 and 26,736 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	1	1
Additional paid-in capital	245,376	245,314
Accumulated other comprehensive income (loss)	(130)	3

Deferred compensation	(2,108)	(3,353)
Accumulated deficit	(154,777)	(129,192)
Total stockholders equity	88,362	112,773
Total liabilities and stockholders equity	$ 98,974	$ 127,007

See accompanying notes to condensed consolidated financial statements.

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CancerVax Corporation

Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Operating expenses:				
Research and development	$ 9,638	$ 6,310	$ 19,210	$ 12,521
General and administrative	2,709	1,502	5,429	2,834
Amortization of employee stock-based compensation	504	639	1,102	794
Total operating expenses	12,851	8,451	25,741	16,149
Interest income (expense), net	97	(151)	156	(269)
Net loss	(12,754)	(8,602)	(25,585)	(16,418)
Accretion to redemption value of redeemable convertible preferred stock		(2,150)		(4,300)
Net loss applicable to common stockholders	$(12,754)	$(10,752)	$(25,585)	$(20,718)
Basic and diluted net loss per share (1)	$ (0.48)	$ (24.83)	$ (0.96)	$ (52.25)
Weighted average shares used to compute basic and diluted net loss per share (1)	26,685	433	26,673	396
The allocation of employee stock-based compensation is as follows:				
Research and development	$ 146	$ 206	$ 311	$ 235
General and administrative	358	433	791	559
	$ 504	$ 639	$ 1,102	$ 794

(1) As a result of the conversion of our preferred stock into 20.1 million shares of our common stock upon completion of our initial public offering on November 4, 2003, there is a lack of comparability in the basic and diluted net loss per

share amounts for the periods presented above. Please reference Note 2 for an unaudited pro forma basic and diluted net loss per share calculation for the periods presented.

See accompanying notes to condensed consolidated financial statements.

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CancerVax Corporation

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (25,585)	$(16,418)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	1,245	892
Amortization of premium on securities available-for-sale	177	86
Interest receivable on securities available-for-sale	(99)	42
Depreciation	1,016	921
Amortization of intangibles	110	122
Deferred rent	118	25
Changes in operating assets and liabilities:		
Other assets	(292)	31
Accounts payable and accrued liabilities	693	(238)
Net cash used in operating activities	(22,617)	(14,537)
Cash flows from investing activities:		
Purchases of property and equipment	(1,643)	(332)
Purchases of securities available-for-sale	(56,722)	(2,943)
Maturities of securities available-for-sale	7,505	998
Sales of securities available-for-sale		5,481
Increase in intangibles	(86)	(123)
Decrease in restricted cash	1,000	
Net cash (used in) provided by investing activities	(49,946)	3,081
Cash flows from financing activities:		
Payments on long-term debt, net	(4,433)	(1,233)
Proceeds from stock plans, net	134	86
Net cash used in financing activities	(4,299)	(1,147)
Decrease in cash and cash equivalents	(76,862)	(12,603)
Cash and cash equivalents at beginning of period	101,681	26,083
Cash and cash equivalents at end of period	$ 24,819	$ 13,480

See accompanying notes to condensed consolidated financial statements.

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CancerVax Corporation

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

The condensed consolidated financial statements as of June 30, 2004, and for the three and six months ended June 30, 2004 and 2003 are unaudited. We have condensed or omitted certain information and disclosures normally included in financial statements presented in accordance with accounting principles generally accepted in the United States. We believe the disclosures made are adequate to make the information presented not misleading. However, you should read these condensed consolidated financial statements in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2003.

The accompanying unaudited condensed consolidated financial statements include the accounts of our wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires our management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an on-going basis, we evaluate our estimates, including those related to the valuation of goodwill, intangibles and other long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates. Interim results are not necessarily indicative of results for a full year or for any subsequent interim period.

In the opinion of management, these condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of results for the interim periods presented.

Prior to our initial public offering, we issued shares of redeemable convertible preferred stock. We accrued the dividends due on the redeemable convertible preferred stock and accreted the difference between the carrying value and the redemption value of the redeemable convertible preferred stock. Upon conversion of the redeemable convertible preferred stock into common stock in conjunction with our November 2003 initial public offering, we ceased accruing the dividends and accreting the redemption value.

2. Net Loss Per Share

We calculate net loss per share in accordance with Statement of Financial Accounting Standards, or SFAS, No. 128, *Earnings Per Share*. Accordingly, basic and diluted net loss per share is calculated by dividing net loss by the weighted average number of common shares outstanding for the period, reduced by the weighted average unvested common shares subject to repurchase, without consideration for common stock equivalents.

The actual net loss per share amounts for the three and six months ended June 30, 2004 and 2003 were computed based on the shares of common stock outstanding during the respective periods. The net loss per share for the three and six months ended June 30, 2004 includes the full effect of the 6.0 million shares of our common stock issued in our initial public offering on November 4, 2003 and the 20.1 million shares of our common stock issued upon conversion of our preferred stock in conjunction with the initial public offering. As a result of the issuance of these common shares on November 4, 2003, there is a lack of comparability in the basic and diluted net loss per share amounts for the three and six months ended June 30, 2004 and 2003. In order to provide a more relevant measure of

our operating results, the following unaudited pro forma net loss per share calculation has been provided. The shares used to compute unaudited pro forma basic and diluted net loss per share represent the weighted average common shares used to calculate actual basic and diluted net loss per share, increased to include the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as-if converted method as of the beginning of each year presented or the date of issuance, if later.

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(In thousands, except per share amounts)			
Actual:				
Numerator:				
Net loss, as reported	$(12,754)	$ (8,602)	$(25,585)	$(16,418)
Accretion to redemption value of redeemable convertible preferred stock		(2,150)		(4,300)
Net loss applicable to common stockholders, as reported	$(12,754)	$(10,752)	$(25,585)	$(20,718)
Denominator:				
Weighted average common shares outstanding	26,743	551	26,740	523
Weighted average unvested common shares subject to repurchase	(58)	(118)	(67)	(127)
Weighted average common shares used to calculate basic and diluted loss per share	26,685	433	26,673	396
Basic and diluted net loss per share	$ (0.48)	$ (24.83)	$ (0.96)	$ (52.25)
Pro forma:				
Numerator:				
Net loss, as reported	$(12,754)	$ (8,602)	$(25,585)	$(16,418)
Denominator:				
Weighted average common shares used to calculate basic and diluted loss per share	26,685	433	26,673	396
Pro forma adjustments to reflect weighted average effect of assumed conversion of preferred stock		15,431		15,431
Weighted average shares used to compute pro forma basic and diluted net loss per share	26,685	15,864	26,673	15,827
Pro forma basic and diluted net loss per share	$ (0.48)	$ (0.54)	$ (0.96)	$ (1.04)

The following common stock equivalents were excluded from the calculation of actual diluted net loss per share for the three and six months ended June 30, 2004 and 2003 as their effect would be antidilutive (in thousands):

	2004	2003
Preferred stock		15,431
Common stock subject to repurchase	54	112
Stock options	3,209	1,736
Stock warrants	86	100
	3,349	17,379

3. Stock-Based Compensation

The following table illustrates the effect on net loss and net loss per share for the three and six months ended June 30, 2004 and 2003 if we had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-based Compensation*, as amended, to stock-based employee compensation. For purposes of the SFAS No. 123 pro forma disclosures, the estimated fair value of stock options is amortized to expense over the vesting period of the related options using the accelerated method.

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(In thousands, except per share amounts)			
Net loss applicable to common stockholders, as reported	$(12,754)	$(10,752)	$(25,585)	$(20,718)
Add: Stock-based employee compensation expense included in net loss applicable to common stockholders, as reported	504	639	1,102	794
Deduct: Stock-based employee compensation expense determined under the fair value based method for all awards	(1,708)	(840)	(2,865)	(1,088)
Pro forma net loss applicable to common stockholders	$(13,958)	$(10,953)	$(27,348)	$(21,012)
Loss per share:				
Basic and diluted net loss per share, as reported	$ (0.48)	$ (24.83)	$ (0.96)	$ (52.25)
Pro forma basic and diluted net loss per share	$ (0.52)	$ (25.29)	$ (1.03)	$ (53.00)

The fair value of our employee stock options and employee stock purchase plan, or ESPP, purchase rights was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Three Months Ended June 30, 2004		Three Months Ended June 30, 2003	
	Stock Options	ESPP Purchase Rights	Stock Options	ESPP Purchase Rights
Dividend yield	0%	0%	0%	
Expected volatility	70%	70%	70%	
Risk-free interest rate	3.58%	2.00%	2.58%	
Expected life in years	4.76	0.53	4.97	
Per share grant date fair value	$6.16	$ 3.94	$6.83	

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net loss are estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because our employee stock options and ESPP purchase rights have characteristics significantly different

from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, we believe that the existing models do not necessarily provide a reliable measure of the fair value of our stock-based employee compensation.

4. Comprehensive Loss

For the three and six months ended June 30, 2004 and 2003, comprehensive loss consists of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Net loss	$(12,754)	$(8,602)	$(25,585)	$(16,418)
Unrealized gain (loss) on securities available-for-sale	(111)	57	(133)	69
Total comprehensive loss	$(12,865)	$(8,545)	$(25,718)	$(16,349)

5. Segment Information

We operate in one segment, which is the research, development and commercialization of novel biological products for the treatment and control of cancer. The chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

6. Related Party Transactions

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We were founded by Donald L. Morton, M.D., who is currently Medical Director and Surgeon-in-Chief and a member of the board of directors of the John Wayne Cancer Institute, or JWCI, a cancer research institute located in Santa Monica, California. Dr. Morton is a member of our board of directors, a significant stockholder and provides services to us under a consulting agreement that expires in December 2004. Included in long-term debt at June 30, 2004 and December 31, 2003 is $250,000 and $375,000, respectively, representing the remaining amount we owe to JWCI under an installment obligation. Additionally, we paid to JWCI an aggregate of approximately $98,000 and $105,000, respectively, during the three months ended June 30, 2004 and 2003, and approximately $129,000 and $238,000, respectively, during the six months ended June 30, 2004 and 2003, for clinical trial site payments, assays and other research expenses.

7. Guarantees

In the ordinary course of our business, we enter into agreements with third parties, including corporate partners, contractors and clinical sites, which contain standard indemnification provisions. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. Although the maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. Additionally, we have insurance policies that, in most cases, would limit our exposure and enable us to recover a portion of any amounts paid. Therefore, we believe the estimated fair value of these agreements is minimal and accordingly, we have not accrued any liabilities for these agreements as of June 30, 2004.

8. Sublicense Agreement with SemaCo, Inc.

On March 10, 2004, we signed an agreement with SemaCo, Inc. whereby we obtained an exclusive, worldwide sublicense from SemaCo to develop and commercialize novel technology utilizing T-oligonucleotides for the potential treatment or prevention of cancer. In exchange, we made upfront payments totaling $0.5 million for the acquisition of the technology rights and a $0.3 million payment for the reimbursement of certain patent costs. Additionally, we will make research support payments totaling $1.2 million over the three-year period commencing on the effective date of the agreement. We are also obligated to make future milestone payments upon meeting certain regulatory and clinical objectives and royalties on sales of commercial products, if any. The agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreement or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreement. We may terminate the agreement for any reason following 60 days written notice to SemaCo. Due to the early stage of development of the sublicensed technology and since no alternative uses were sublicensed at the time of acquisition, the amounts payable to SemaCo under the sublicense agreement will be charged to research and development expense when due and payable.

9. Subsequent Event

On July 13, 2004, our wholly-owned subsidiaries, Tarcanta, Inc. and Tarcanta, Ltd., signed agreements with CIMAB, S.A., a Cuban corporation, and YM BioSciences, Inc., a Canadian corporation, whereby we obtained the exclusive rights to develop and commercialize in a specific territory, which includes the U.S., Canada, Japan, Australia, New Zealand, Mexico and certain countries in Europe, three specific active immunotherapeutic product candidates that target the epidermal growth factor receptor, or EGFR, signaling pathway for the treatment of cancer. In exchange, we will pay to CIMAB and YM BioSciences technology access and transfer fees totaling $5.7 million, to be paid over the next three years. We will also make future milestone payments to CIMAB and YM BioSciences up to a maximum of $34.7 million upon meeting certain regulatory, clinical and commercialization objectives, and royalties on future sales of commercial products, if any. Prior to the commercialization of any of the product candidates,

payment of the technology transfer fees, technology access fees, and milestones owed to CIMAB under the agreements will be made entirely in U.S.-origin food, medicines and/or medical supplies rather than cash. Upon commercialization of a product candidate in the U.S., payment of milestones and royalties owed to CIMAB under the agreements will be made 50% in cash and 50% in U.S.-origin food, medicines and/or medical supplies. All payments owed to YM BioSciences under the agreement will be made in cash. We anticipate that the amounts payable to CIMAB and YM BioSciences prior to product commercialization will be charged to research and development expense.

The agreements terminate upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreements or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreements. CIMAB may terminate the agreements if we have not used reasonable commercial efforts to file an investigational new drug, or IND, submission to the U.S. Food and Drug Administration, or FDA, for the leading product candidate by July 12, 2006, or if the first regulatory approval for marketing this product candidate within our territory is not obtained by July 12, 2016, provided that

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CIMAB has timely complied with all of its obligations under the agreements, or if CIMAB does not receive timely payment of the initial technology access and transfer fees. In addition, if CIMAB does not receive payments under the agreements due to changes in U.S. law, actions by the U.S. government or by order of any U.S. court for a period of more than one year, CIMAB may terminate our rights to the licensed product candidates in countries within our territory other than the U.S. and Canada. We may terminate the agreement for any reason following 180 days written notice to CIMAB.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption Risk Factors. The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2003 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2004.

Overview

We are a biotechnology company focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. Our lead product candidate, Canvaxin, is one of a new class of products being developed in the area of specific active immunotherapy, also known as therapeutic cancer vaccines. Canvaxin is currently in two Phase 3 clinical trials at 80 sites worldwide for the treatment of advanced-stage melanoma. Canvaxin is based on our proprietary specific active immunotherapy development platform that uses human tumor cell lines that express a broad array of tumor related antigens. Canvaxin has also been studied in a Phase 1/2 clinical trial for advanced-stage colorectal cancer. We are finalizing the design of exploratory Phase 2 clinical trials for patients with other advanced-stage solid tumors.

In July 2004, we in-licensed three specific active immunotherapeutic product candidates targeting the EGFR signaling pathway, including one product candidate that has been evaluated in Phase 2 clinical trials. We plan to initiate our own Phase 2 clinical trial with SAI-EGF, the most advanced of these three new product candidates, in patients with advanced non-small-cell lung cancer in mid-2005, and to continue pre-clinical development of the other two product candidates. We also have a number of other product candidates in research and preclinical development, including four humanized monoclonal antibodies, three human monoclonal antibodies and several peptides that potentially target various solid tumors. We plan to identify and develop new product candidates based on our proprietary specific active immunotherapy, anti-angiogenesis, and T-oligonucleotide technologies, our human monoclonal antibodies and other technologies.

We were incorporated in Delaware in June 1998 and have incurred net losses since our inception. As of June 30, 2004, our accumulated deficit was approximately $154.8 million. We expect to incur substantial and increasing losses for the next several years as we:

- continue the development and prepare for the commercialization of our leading specific active immunotherapy product candidate, Canvaxin;
- complete the development of and commercialize our specific active immunotherapeutic product candidates that target the EGFR signaling pathway;
- advance our preclinical anti-angiogenesis, human monoclonal antibody and T-oligonucleotide product candidates into clinical development;
- scale-up and validate our manufacturing operations and improve our quality systems;
- expand our research and development programs; and

in-license technology and acquire or invest in businesses, products or technologies that are complementary to our own.

We have a limited history of operations. To date, we have funded our operations primarily through sales of equity securities as well as through equipment and leasehold improvement financing.

We have retained worldwide commercialization rights to Canvaxin and intend to market it through our own sales force or with a co-promotion partner in the United States and through strategic collaborations outside of the United States. Agreements with potential collaborators may include joint marketing or promotion arrangements. Alternatively, we may grant exclusive marketing rights to potential collaborators for countries outside the United States in exchange for up-front fees, milestones and royalties on future sales, if any. We manufacture Canvaxin at our biologics manufacturing facility located in the Los Angeles, California area. We have initiated

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an expansion of the production capacity of our biologics manufacturing facility which we anticipate completing in 2005. Total capital expenditures associated with this expansion are estimated to be approximately $16.0 million, of which $0.9 million has been invested through June 30, 2004. We intend to fund a portion of these capital expenditures through new leasehold and equipment financing. Upon completion of this expansion, we believe our biologics manufacturing facility will have the capacity to satisfy commercial demand for Canvaxin for several years after the initial launch.

Our business is subject to significant risks, including the risks inherent in our ongoing clinical trials and the regulatory approval process, the results of our research and development efforts, competition from other products, uncertainties associated with obtaining and enforcing patent rights, and with maintaining our licenses obtained from CIMAB.

Research and Development

Our research and development expenses consist primarily of costs associated with the clinical trials of Canvaxin for advanced-stage melanoma, including costs associated with the production of Canvaxin for use in these clinical trials, and for preclinical research on our other product candidates, manufacturing process and quality systems development for Canvaxin, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, license fees, amortization of purchased technology and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on clinical trials of Canvaxin for advanced-stage melanoma, the development of additional indications for Canvaxin and the development of product candidates based on our proprietary specific active immunotherapy, anti-angiogenesis and T-oligonucleotide technologies. We are also developing several human monoclonal antibodies that target various solid tumors. In July 2004, we in-licensed three specific active immunotherapeutic product candidates targeting the EGFR signaling pathway, including one product candidate that has been evaluated in Phase 2 clinical trials.

From our inception through June 30, 2004, we incurred costs of approximately $85.4 million associated with the research and development of Canvaxin, representing 96% of our total research and development expenses. Included in the costs associated with the research and development of Canvaxin are certain external costs of our Phase 3 clinical trials for Canvaxin, including payments made to clinical sites participating in the trials and payments to third parties for data collection, management and analysis services, clinical trial monitoring services and clinical material collection and storage, all of which are recognized as research and development expenses. While difficult to predict, we estimate that we will incur at least an additional $100 million in costs, including internal costs, prior to the commercialization of Canvaxin.

We are unable to estimate with any certainty the costs we will incur in the continued development of our other product candidates. However, we expect our research and development costs to increase as we continue to develop new applications for our proprietary specific active immunotherapy technologies, refine our manufacturing processes and quality systems and move other product candidates through preclinical and clinical trials.

Clinical development timelines, likelihood of success and total costs vary widely. Although we are currently focused primarily on advancing Canvaxin through Phase 3 clinical trials for advanced-stage melanoma, we anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an on-going basis in response to the scientific and clinical success of each product candidate.

The costs and timing for developing and obtaining regulatory approvals of our product candidates vary significantly for each product candidate and are difficult to estimate. The expenditure of substantial resources will be required for the lengthy process of clinical development and obtaining regulatory approvals as well as to comply with

applicable regulations. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We anticipate launching Canvaxin in the United States in late 2006 and Europe in early 2007 if the FDA and European regulatory authorities accept a positive result in one of our two ongoing Phase 3 clinical trials as sufficient for marketing approval, and if our manufacturing processes and facility are approved by the FDA and European regulatory authorities in connection with our marketing applications. Although the FDA and European regulatory authorities typically require successful results in two Phase 3 clinical trials to support marketing approval, both agencies have, on several occasions, approved products based on a single Phase 3 clinical trial that demonstrates a high level of statistical significance and where there is an unmet medical need for a life-threatening condition. In the event that the FDA or European regulatory authorities require the results of a second Phase 3 clinical trial before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin in the United States or Europe, respectively, would be delayed. We cannot be certain when any net cash inflows from

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Canvaxin or any of our other development projects will commence.

In February 2004, the independent Data and Safety Monitoring Board, or DSMB, with oversight responsibility for the Phase 3 clinical trials of Canvaxin completed its review of the planned, second interim analysis of data from our clinical trial of Canvaxin in Stage III melanoma. The DSMB recommended that we continue the trial as planned. We anticipate that in September 2004 we will complete our planned enrollment of 1,118 patients in our Phase 3 clinical trial in Stage III melanoma and that by the end of 2004, the DSMB will complete its review of data from the second interim analysis of our Phase 3 clinical trial in Stage IV melanoma.

The rate of enrollment in our Phase 3 clinical trials for Canvaxin has increased as new clinical trial sites added in recent months have begun to enroll patients, but we cannot be sure that we will be able to accelerate clinical trial enrollment or enroll an adequate number of patients to complete the Phase 3 clinical trials. In addition, we may not be able to control the amount and timing of resources that the medical institutions that conduct the clinical testing may devote to these Phase 3 clinical trials. If these clinical investigators and medical institutions fail to enroll a sufficient number of patients in our clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for Canvaxin. In addition, the interim and final analyses of the data from these clinical trials may not be performed until a specified number of patients in each of these clinical trials has expired, so a delay in enrollment will adversely impact the timely completion of these clinical trials.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis, including those related to valuation of goodwill, intangibles and other long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the bases for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Our accounting policies are described in more detail in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K. We have identified the following as the most critical accounting policies and estimates used in the preparation of our consolidated financial statements.

Goodwill

In accordance with Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, we do not amortize goodwill. Instead, we review goodwill for impairment at least annually and whenever events or changes in circumstances indicate a reduction in the fair value of the reporting unit to which the goodwill has been assigned. Conditions that would necessitate a goodwill impairment assessment include a significant adverse change in legal factors or in the business climate, an adverse action or assessment by a regulator, unanticipated competition, a loss of key personnel, or the presence of other indicators that would indicate a reduction in the fair value of the reporting unit to which the goodwill has been assigned. SFAS No. 142 prescribes a two-step process for impairment testing of goodwill. The first step of the impairment test is used to identify potential impairment by comparing the fair value of the reporting unit to which the goodwill has been assigned to its carrying amount, including the goodwill. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete in-process projects, projecting regulatory approvals, estimating future cash inflows from product sales and other sources, and developing appropriate discount rates and probability rates by project. If the carrying value of the reporting unit exceeds the fair value, the second step of the impairment test is performed in order to measure the impairment loss.

Our goodwill had a carrying value of $5.4 million at June 30, 2004 and December 31, 2003, respectively, and resulted from our acquisition of Cell-Matrix in January 2002. We have assigned the goodwill to our Cell-Matrix reporting unit. In October 2003, we performed our annual goodwill impairment test in accordance with SFAS No. 142 and determined that the carrying amount of goodwill was recoverable. In determining the fair value of the Cell-Matrix reporting unit, we considered internal risk-adjusted cash flow projections which utilize several key assumptions, including estimated timing and costs to complete development of the anti-angiogenesis technology and estimated future cash inflows from existing collaborations, anticipated future collaborations and projected product sales. Additionally, we reviewed the implied market capitalization of the Cell-Matrix reporting unit, based on the number of shares issued by us in the acquisition, and third party revenue projections for other products and product candidates utilizing similar technology. Our analysis of the fair value of the Cell-Matrix reporting unit assumes the timely and successful completion of development of the anti-angiogenesis technology. The major risks and uncertainties associated with the timely and successful completion of development of the anti-angiogenesis technology include the risk that we will not be able to confirm the

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safety and efficacy of the technology with data from clinical trials and the risk that we will not be able to obtain necessary regulatory approvals. No assurance can be given that the underlying assumptions used to forecast the cash flows or the timely and successful completion of development will materialize as estimated. We cannot assure you that our reviews of goodwill impairment in the future will not result in a material charge.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property and equipment and intangible assets subject to amortization, are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the market price of an asset or asset group, a significant adverse change in the extent or manner in which an asset or asset group is being used, a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset or asset group, or the presence of other indicators that would indicate that the carrying amount of an asset or asset group is not recoverable. Determination of recoverability is based on the undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. The determination of the undiscounted cash flows requires significant estimates and assumptions including, but not limited to: determining the timing and expected costs to complete in-process projects, projecting regulatory approvals and estimating future cash inflows from product sales and other sources. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated fair value. There have been no indications of impairment with respect to our long-lived assets through June 30, 2004.

Results of Operations

Research and Development Expenses. Research and development expenses were $9.6 million and $19.2 million for the three and six months ended June 30, 2004, respectively, compared to $6.3 million and $12.5 million for the comparable periods in 2003. The increase in research and development expenses for the three and six months ended June 30, 2004 primarily reflects additional investment in personnel in the manufacturing, clinical affairs and research and development departments and increased clinical trial expenses associated with increased patient enrollment in our Phase 3 clinical trials of our lead product candidate, Canvaxin, including costs associated with the production of Canvaxin for use in these clinical trials. The increase in research and development expenses for the six months ended June 30, 2004 was also due to payments totaling $0.8 million made under our sublicense agreement with SemaCo, Inc. in the first quarter of 2004, which were recognized as research and development expenses.

Non-cash employee stock-based compensation of $0.1 million and $0.3 million for the three and six months ended June 30, 2004, respectively, compared with $0.2 million for both of the comparable periods in 2003, was excluded from research and development expenses and reported under a separate caption.

General and Administrative Expenses. General and administrative expenses were $2.7 million and $5.4 million for the three and six months ended June 30, 2004, respectively, compared to $1.5 million and $2.8 million for comparable periods in 2003. The increase in general and administrative expenses for the three and six months ended June 30, 2004 was primarily due to additional investment in personnel in the finance and marketing and business development departments, increased directors and officers insurance premiums and other expenses associated with our becoming a publicly-traded company and increased expenses associated with marketing activities. The increase in general and administrative expenses for the six months ended June 30, 2004 was also due to increased legal fees related to business development activities.

Non-cash employee stock-based compensation of $0.4 million and $0.8 million for the three and six months ended June 30, 2004, respectively, and $0.4 million and $0.6 million for the three and six months ended June 30, 2003,

respectively, was excluded from general and administrative expenses and reported under a separate caption.

Amortization of Employee Stock-based Compensation. During the initial public offering process, we re-evaluated the historical estimated fair value of our common stock considering the anticipated initial public offering price. As a result, the exercise price of certain stock options that were previously granted to our employees and directors were deemed to be below the revised estimated fair value of the underlying common stock on the option grant date. We recorded this spread between the exercise price and the revised estimated fair value as deferred employee stock-based compensation. We amortize the deferred employee stock-based compensation as a non-cash charge to operations on an accelerated basis over the vesting period of the options. Amortization of deferred employee stock-based compensation was $0.5 million and $1.1 million for the three and six months ended June 30, 2004, respectively, compared to $0.6 million and $0.8 million for the comparable periods in 2003.

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Interest Income (Expense), Net. Interest income (expense), net for the three and six months ended June 30, 2004 was $0.1 million and $0.2 million of net interest income, respectively, compared to $0.2 million and $0.3 million of net interest expense for the comparable periods in 2003. The increase was primarily attributable to an increase in interest income due to higher average invested balances resulting from the proceeds from the sale of our Series C preferred stock and our initial public offering of common stock in the second half of 2003 as well as a decrease in interest expense due to lower long-term debt balances.

Liquidity and Capital Resources

As of June 30, 2004, we had $79.2 million in cash, cash equivalents and securities available-for-sale as compared to $107.1 million as of December 31, 2003. This decrease was primarily due to the use of cash to fund ongoing operations and payments on long-term debt.

Net cash used in operating activities was $22.6 million during the six months ended June 30, 2004, compared with $14.5 million during the six months ended June 30, 2003. The increase in net cash used in operating activities was primarily due to the increase in our operating expenses as we expanded our research and development activities.

Net cash used in investing activities was $49.9 million during the six months ended June 30, 2004, compared with net cash provided by investing activities of $3.1 million during the six months ended June 30, 2003. Significant components of cash flows from investing activities for the six months ended June 30, 2004 included a $49.2 million net increase in our securities available-for-sale portfolio, a $1.0 million decrease in restricted cash and $1.6 million of purchases of property and equipment. Significant components of cash flows from investing activities for the six months ended June 30, 2003 included a net decrease in our securities available-for-sale portfolio of $3.5 million and $0.3 million of purchases of property and equipment.

Net cash used in financing activities was $4.3 million during the six months ended June 30, 2004, compared with $1.1 million during the six months ended June 30, 2003. Cash flows from financing activities for the six months ended June 30, 2004 and 2003 primarily consisted of payments on long-term debt, including the full repayment in January 2004 of the notes payable that were assumed in the January 2002 acquisition of Cell-Matrix.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include but are not limited to the following:

- the progress of our clinical trials;
- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical development activities;
- our ability to establish and maintain strategic collaborations;
- the costs involved in enforcing or defending patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs of establishing or expanding manufacturing, sales and distribution capabilities;

the success of the commercialization of Canvaxin; and

the extent to which we acquire or invest in other products, technologies and businesses.

We have initiated an expansion of the production capacity of our biologics manufacturing facility located in the Los Angeles, California, area which we anticipate completing in 2005. Total capital expenditures associated with this expansion are estimated to be approximately $16.0 million, of which $0.9 million has been invested through June 30, 2004. We intend to fund a portion of these capital expenditures through new leasehold and equipment financing.

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On July 13, 2004, our wholly-owned subsidiaries, Tarcanta, Inc. and Tarcanta, Ltd., signed agreements with CIMAB, S.A. and YM BioSciences, Inc. under which we will pay to CIMAB and YM BioSciences technology access and transfer fees totaling $5.7 million, to be paid over the next three years. We will also make future milestone payments to CIMAB and YM BioSciences up to a maximum of $34.7 million upon meeting certain regulatory, clinical and commercialization objectives, and royalties on future sales of commercial products, if any.

In August 2004, we intend to sign a seven-year lease for additional office, laboratory, and warehouse space near our biologics manufacturing facility located in the Los Angeles, California area. The lease will include a renewal option for an additional five years. Total rent payments due over the initial term of the lease will be approximately $2.3 million.

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for the next 12 months.

To date, we have funded our operations primarily through the sale of equity securities as well as through equipment and leasehold improvement financing. Through June 30, 2004, we had received aggregate net proceeds of approximately $196.6 million from the sale of equity securities. In addition, through June 30, 2004, we had financed through capital leases and loans the purchase of equipment and leasehold improvements totaling approximately $9.3 million, of which $3.2 million remained outstanding under the loans as of June 30, 2004. These obligations are secured by the purchased equipment and leasehold improvements, bear interest at rates ranging from approximately 9.3% to 14.0% and are due in monthly installments through June 2006. As of December 31, 2003, no further draws may be made under our existing credit facilities.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities and from equipment and leasehold improvement financing. In addition, we may finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that our existing cash and marketable securities resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

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Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue, anticipate, seek, plan, expect, should, or would. Among the factors that could cause actual results to differ materially from t indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, statements about the progress and timing of our clinical trials; difficulties or delays in development, testing, obtaining regulatory approval, producing and marketing our products; unexpected adverse side effects or inadequate therapeutic efficacy of our products that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; the scope and validity of patent protection for our products; competition from other pharmaceutical or biotechnology companies; our ability to obtain additional financing to support our operations; and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2004 and the discussions set forth below under the caption Risk Factors.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Risk Factors

The following information sets forth factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this quarterly report and those we may make from time to time. For a more detailed discussion of the factors that could cause actual results to differ, see the Risk Factors section in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 29, 2004.

Risks Related to Our Business and Industry

We are dependent on the success of our lead product candidate, Canvaxin, and we cannot be certain that it will be approved by regulatory authorities or that it will be commercialized.

We have expended significant time, money and effort in the development of our lead product candidate, Canvaxin, which has not yet received regulatory approval and which may never be commercialized. Before we can market and sell Canvaxin, we will need to demonstrate in Phase 3 clinical trials that the product candidate is safe and effective and will also need to obtain necessary approvals from the FDA and similar foreign regulatory agencies. Canvaxin is currently in two Phase 3 clinical trials for advanced-stage melanoma.

Even if we were to ultimately receive regulatory approval, we may be unable to gain market acceptance of Canvaxin for a variety of reasons, including the treatment regimen. Under this treatment regimen, patients will require 33 doses of Canvaxin over a five-year period and will be advised against the use of other approved treatments during this period that suppress their immune systems, such as chemotherapy. In addition, the success of Canvaxin may be affected by the prevalence and severity of adverse side effects, which include blistering, stinging, itching and redness at the site of injection, flu-like symptoms and a decrease in energy. Side effects, such as a localized skin reaction, may also be associated with bacillus Calmette-Guérin, or BCG, which is the adjuvant we administer to patients with the first two doses of Canvaxin. Furthermore, the availability of alternative treatments and the cost effectiveness of Canvaxin will affect our ability to commercialize Canvaxin. If we fail to commercialize this lead product candidate, our business, financial condition and results of operations will be materially and adversely affected.

We are subject to extensive government regulation that increases the cost and uncertainty associated with gaining regulatory approval of Canvaxin and our other product candidates.

The preclinical development, clinical trials, manufacturing and marketing of our product candidates are all subject to extensive regulation by United States and foreign governmental authorities. It takes many years and significant expense to obtain the required regulatory approvals for biological products. Satisfaction of regulatory requirements depends upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. In particular, the specific active immunotherapy technology on which Canvaxin is based is a relatively new form of cancer therapy that presents novel issues for regulatory authorities

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to consider and, therefore, may be subject to heightened scrutiny in the regulatory process. For example, in 2002, the FDA sent a letter requesting additional information from all holders of Investigational New Drug, or IND, applications for products involving somatic cell or gene therapies, including Canvaxin. We cannot be certain that any of our product candidates will be shown to be safe and effective or that we will ultimately receive approval from the FDA or foreign regulatory authorities to market these products. In addition, even if granted, product approvals and designations such as fast-track and orphan drug may be withdrawn or limited at a later time.

We anticipate launching Canvaxin in the United States in late 2006 and in Europe in early 2007 if the FDA and European regulatory authorities accept a positive result in a single Phase 3 clinical trial as sufficient for marketing approval, and if our manufacturing processes and facility are approved by the FDA and European regulatory authorities in connection with our marketing applications. Although the FDA and European regulatory authorities typically require successful results in two Phase 3 clinical trials to support marketing approval, both agencies have approved products based on a single Phase 3 clinical trial that demonstrates a high level of statistical significance and where there is an unmet medical need for a life-threatening condition. In the event that the FDA or the European regulatory authorities require the results of a second Phase 3 clinical trial before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin in the United States or Europe, respectively, would be delayed.

In addition, manufacturers of biological products, including specific active immunotherapies, must comply with the FDA s current good manufacturing practice regulations, and similar regulations of foreign regulatory authorities in jurisdictions where we may seek to market our products. These regulations apply to our biologics manufacturing facility, located in the Los Angeles, California area, where we currently manufacture Canvaxin. These regulations include quality control, quality assurance and the maintenance of records and documentation. Our manufacturing facility also is subject to the licensing requirements of the California Department of Health Services and may be inspected by the FDA, foreign regulatory authorities and the California Department of Health Services at any time. We and our present or future suppliers may be unable to comply with the applicable good manufacturing practice regulations and with other FDA, state and foreign regulatory requirements. Our suppliers include CIMAB, S.A., which will supply our newly licensed specific active immunotherapeutic product candidates that target the EGFR signaling pathway for Phase 2 clinical trials, and for Phase 3 clinical trials and commercialization in countries in our territory other than the U.S., Canada and Mexico. Failure to maintain a license from the California Department of Health Services or to meet the inspection criteria of the FDA, foreign regulatory authorities and the California Department of Health Services would disrupt our manufacturing processes and would delay our clinical trials and the eventual commercialization of these product candidates. If an inspection by the FDA, California Department of Health Services or a foreign regulatory authority indicates that there are deficiencies, we or our suppliers could be required to take remedial actions or be prohibited from supplying product for our ongoing clinical trials and for commercial sale, or our facilities or those of our suppliers could be closed.

If clinical trials of Canvaxin or any other product candidates that we may develop do not produce successful results, we will be unable to commercialize these product candidates.

In order to receive regulatory approval for the commercial sale of our product candidate Canvaxin or any other product candidates that we may develop, we must conduct, primarily at our own expense, extensive clinical trials to demonstrate safety and efficacy. Clinical testing is expensive, can take many years and has an uncertain outcome. For example, while difficult to predict, we estimate that we will incur at least an additional $100 million in costs, including internal costs, prior to commercialization of Canvaxin. Failure can occur at any phase of clinical testing. While Canvaxin is currently being studied in two Phase 3 clinical trials for advanced-stage melanoma, these trials may not produce positive results and may, under some circumstances, be terminated early. Both Phase 3 clinical trials for Canvaxin in advanced-stage melanoma were designed with three interim analyses prior to the final analysis at the planned completion of the clinical trials. At each interim analysis, an independent data and safety monitoring board, or

DSMB, will review unblinded data from the clinical trials primarily to evaluate the safety of Canvaxin. It is possible that in connection with any of the interim analyses or at any other stage of the trials, the DSMB may determine that there are safety risks associated with Canvaxin or that it is not sufficiently effective to continue the trials, and may, as a result, recommend the discontinuation of these clinical trials.

In February 2004, the independent DSMB responsible for providing oversight of our Phase 3 clinical trials completed its planned, second interim analysis of our Phase 3 clinical trial of Canvaxin in Stage III melanoma. Based upon its review of data from 842 patients enrolled in the trial, the DSMB recommended that we continue both of the Phase 3 clinical trials as planned. We anticipate that in 2004, the DSMB will complete its review of the planned, second interim analysis of our Phase 3 clinical trial of Canvaxin in Stage IV melanoma, and that in the first half of 2005 the DSMB will complete its third interim analysis of our Phase 3 clinical trial of Canvaxin in Stage III melanoma. We also currently anticipate that the third interim analysis of our Phase 3 clinical trial in Stage IV melanoma will be reviewed by the DSMB in late 2005 or early 2006.

We have encountered regulatory delays in our clinical trials in the past and we may encounter significant delays or discontinue our clinical trials in the future.

We or regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate

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our clinical trials if at any time we believe that they present an unacceptable risk to the patients enrolled in our clinical trials. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials. In April 2002, the FDA placed our two Phase 3 clinical trials of Canvaxin in advanced-stage melanoma on partial clinical hold. The FDA s action with respect to our Phase 3 clinical trials was consistent with clinical holds placed on other companies immunotherapy products, and with requests for additional information sent to us and all other holders of IND applications for products involving somatic cell or gene therapies. The partial clinical hold was the result of questions regarding the production, testing and characterization of Canvaxin. During the partial clinical hold, we were allowed to continue treating patients who were already enrolled in our Phase 3 clinical trials but were not allowed to enroll new patients. The FDA removed the partial clinical hold in April 2003 and we resumed enrolling patients in the Phase 3 clinical trials. Our clinical trials of Canvaxin and our other product candidates may be subject to additional clinical holds imposed by the FDA or other regulatory authorities in the future.

Our clinical trial operations are subject to inspection by the FDA and other regulatory authorities at any time, and the FDA has previously noted deficiencies in our clinical trials at these inspections. Any temporary or permanent hold imposed on our clinical trial operations as a result of these inspections or for any other reason would harm the testing and development of Canvaxin and our other product candidates.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting the ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. In April 2002, the FDA inspected our clinical trial operations and three of our clinical trial sites. As a result of the FDA s inspections, we received a report of observations from the FDA. The deficiencies noted in this report included inadequate documentation of the review and approval of clinical site investigators and a contract clinical trial monitoring firm; delays in obtaining formal internal approvals of some of our standard operating procedures; and lack of timeliness in preparing and filing certain reports associated with the clinical trials and in obtaining compliance with corrective action plans by several clinical trial sites. We responded to the FDA s report of observations and, in December 2002, we received an untitled letter from the FDA, requesting additional follow-up information related to the April 2002 inspection. We provided the requested information and have received no further requests from the FDA in that regard. In addition, JWCI and the Medical College of Virginia received reports of observations and formal warning letters from the FDA. The deficiencies noted in these warning letters included the use of an incorrect version of patient informed consent forms, delayed reporting of serious adverse events and failures to rigorously follow the investigational plan. Both sites responded to the FDA s report of observations and, in December 2002, the FDA notified the two clinical trial sites that received the warning letters that it had reviewed their responses and that no further responses were necessary at that time. There were no delays to the clinical trials attributable to these inspections, reports of observations or warning letters. We cannot be sure that the FDA or other regulatory authorities will not request further data or information regarding our clinical trial operations in the future. The FDA may elect to re-inspect our clinical operations for a variety of reasons, including to confirm that we and our clinical trial sites continue to observe the corrective actions taken in response to the initial FDA inquiry. Moreover, if the FDA determines that the deficiencies noted at any of the sites are of sufficient concern, it could require that data from such sites be excluded from our clinical trial results and additional patients be enrolled as part of the protocol, that the Phase 3 studies be redone, or that additional Phase 3 clinical trials be conducted.

Additionally, we may encounter difficulties related to the clinical trials of the specific active immunotherapeutic product candidates that target the epidermal growth factor receptor, or EGFR, signaling pathway that we have licensed from CIMAB, S.A. The U.S. government has maintained an embargo against Cuba for more than forty years. The embargo is administered by the Office of Foreign Assets Control, or OFAC, of the U.S. Department of Treasury. Without a license from OFAC, U.S. individuals and companies may not engage in any transaction in which Cuba or Cubans have an interest. In order to enter into and carry out the licensing agreements with CIMAB we have obtained from OFAC a license authorizing us to carry out all transactions set forth in the license agreements that we have entered into with CIMAB for the development, testing, licensing and commercialization of the three specific active immunotherapeutic product candidates that target the EGFR signaling pathway. In the absence of such a license from OFAC, our performance under the agreement with CIMAB could have exposed us to legal and criminal liability. At any time, there may occur for reasons beyond our control a change in U.S. or Cuban law, or in the regulatory environment in the U.S. or Cuba, or a shift in the political attitudes of either the U.S. or Cuban governments, that could result in the suspension or revocation of our OFAC license or in our inability to carry out part or all of the licensing agreements with CIMAB. There can be no assurance that the U.S. government will not modify existing law or establish new laws or regulations that may adversely affect our ability to develop, test,

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license and commercialize these product candidates. There can be no guarantee that our OFAC license may not be revoked or amended in the future, or that either the U.S. government or the Cuban government may not restrict our ability to carry out all or part of our licensing agreements with CIMAB. In addition, we cannot be sure that the FDA or other regulatory authorities will accept data from the Phase 2 clinical trials of these products that were conducted in Cuba as the basis for our applications to conduct additional Phase 2 or Phase 3 clinical trials, or as part of our application to seek marketing authorizations for such products.

We have undertaken two Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma based on the positive results of the Phase 1 and Phase 2 clinical trials conducted by our founder, Dr. Morton, who has a substantial ownership interest in our common stock and other economic incentives. If the results of these Phase 1 and Phase 2 clinical trials are affected by a bias or conflict of interest and we fail to obtain satisfactory Phase 3 clinical trial results, our development of Canvaxin would be significantly delayed or may be terminated.

There is potential for bias in connection with the Phase 1 and Phase 2 clinical trials of Canvaxin conducted at JWCI and the UCLA School of Medicine because Donald L. Morton, M.D., our founder, served as Medical Director and Surgeon-in-Chief and a member of the board of directors of JWCI and was a professor and Chief of the Division of Surgical Oncology at the UCLA School of Medicine during the time these trials were being conducted.

Of the approximately 2,600 patients who have been administered Canvaxin in Phase 1 and Phase 2 clinical trials, fewer than 50 of those patients received Canvaxin at locations other than JWCI and UCLA. As of March 31, 2004, Dr. Morton beneficially owned approximately 19.4% of our common stock. In addition, pursuant to a cross-license agreement with JWCI, in August 2000 we issued JWCI 284,090 shares of common stock, which represented approximately 4.8% of our common stock at the time of issuance. Moreover, Dr. Morton and JWCI received significant funding from the National Institutes of Health to support the early clinical trials of Canvaxin and this funding was a significant source of revenue for JWCI. We are obligated to pay JWCI 50% of the initial net royalties we receive from any sublicensees from sales of Canvaxin, if any, up to $3.5 million. Subsequently, we are obligated to pay JWCI a 1% royalty on net sales, if any, of Canvaxin to third parties by us, our sublicensees and affiliates. We have undertaken two international Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma based on the positive results of the Phase 1 and Phase 2 clinical trials conducted by Dr. Morton. If it is determined that the results of these Phase 1 and Phase 2 clinical trials are affected by a bias or conflict of interest and we fail to obtain satisfactory Phase 3 clinical trial results, our development of Canvaxin would be significantly delayed or may be terminated.

The results of Phase 1 and Phase 2 clinical trials of Canvaxin may not be predictive of the future results of our ongoing Phase 3 clinical trials. Data from these Phase 1 and Phase 2 clinical trials were evaluated using retrospective survival analyses that may be subject to potential selection biases.

In the Phase 1 and Phase 2 clinical trials of Canvaxin, clinicians and statisticians at JWCI and other institutions used the JWCI database of approximately 11,000 melanoma patients to perform retrospective analyses comparing the survival of the Canvaxin-treated group with the survival of patients who did not receive Canvaxin.

In addition to analyses of survival data from all patients with advanced-stage melanoma in the JWCI database who met certain criteria, matched-pair analyses were performed. These matched-pair analyses were conducted by using prognostic factors to match patients who received Canvaxin with similar patients in the database who did not receive Canvaxin. Median overall survival and five-year survival rates were compared between patients treated with Canvaxin and the matched-pair patient control groups who were not treated with Canvaxin. All clinical data reported regarding the patients in the Phase 1 and Phase 2 clinical trials were obtained from JWCI s database and we have not independently performed any audit or other reconciliation against actual patient medical records. In addition, retrospective analyses of matched-pair data are not generally deemed sufficient by the FDA and most foreign

regulatory authorities as a basis for approval to market a product because they may be subject to potential selection biases that may be minimized in prospective, randomized, double-blind, placebo-controlled clinical trials.

Due to the differences in patient populations and study methodologies, it may be difficult to compare results from the retrospective analyses in our Phase 1 and Phase 2 clinical trials for Canvaxin to any other analyses by other groups. Differences in survival rates between studies in patients with Stage III and Stage IV melanoma are affected by the following factors:

time from which survival of patients is initially calculated, such as the time of diagnosis, the time of surgery or time of treatment;

definitions of mortality, such as all causes mortality or disease-specific mortality;

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diagnosis status of patients, such as initial diagnosis or recurrent disease; and

severity of disease, such as size of tumors and number of metastases.

In particular, specialty cancer centers such as JWCI tend to treat patients with more advanced disease than other types of healthcare facilities. As a result of these factors and the uncertainties affecting the clinical trial process generally, the results of the Phase 1 and Phase 2 clinical trials may not be predictive of the future results of our Phase 3 clinical trials.

We depend on clinical investigators and medical institutions to enroll patients in our clinical trials and other third parties to perform related data collection and analysis, and, as a result, we may face costs and delays outside of our control.

In our Phase 3 clinical trials, we plan to enroll 1,118 patients with Stage III melanoma, and 670 patients with Stage IV melanoma, and we rely on clinical investigators and medical institutions to enroll these patients. As of July 31, 2004, 1,062 patients had been enrolled in our Phase 3 clinical trial in Stage III melanoma and 406 patients had been enrolled in our Phase 3 clinical trial in Stage IV melanoma. We anticipate that in September 2004 we will complete our planned enrollment of 1,118 patients in our Phase 3 clinical trial in Stage III melanoma. From June 1, 2003, through the end of July 2004, the rate of patient enrollment in these trials has been between 18 and 41 patients per month for the clinical trial in Stage III melanoma, and between 4 and 18 patients per month for the clinical trial in Stage IV melanoma. The rate of enrollment has increased as new clinical trials sites added in recent months have begun to enroll patients, but we cannot be sure that we will be able to accelerate clinical trial enrollment or enroll an adequate number of patients to complete the Phase 3 clinical trials. In addition, we may not be able to control the amount and timing of resources that the medical institutions that conduct the clinical testing may devote to these Phase 3 clinical trials. If these clinical investigators and medical institutions fail to enroll a sufficient number of patients in our clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for Canvaxin. In addition, the interim and final analyses of the data from these clinical trials may not be performed until a specified number of patients in each of these clinical trials have died, so a delay in enrollment will adversely impact the timely completion of these clinical trials. A total of 392 patients participating in the Phase 3 clinical trial in Stage III melanoma, and a total of 390 patients participating in the Phase 3 clinical trial in Stage IV melanoma, respectively, must have died before we can perform the final analyses on these clinical trials. Eighty clinical trial sites are currently participating in our two Phase 3 clinical trials. In the event that we are unable to maintain our relationship with any of these clinical trial sites, or elect to terminate the participation of any of these clinical trial sites, we may experience the loss of follow-up information on patients enrolled in the Phase 3 clinical trials unless we are able to transfer the care of those patients to another clinical trial site. Any delays could significantly slow the pace of our patient enrollment activities and the ultimate development of Canvaxin.

We contract with Synteract, Inc. to perform data collection, data management and data analysis for our two Phase 3 clinical trials in advanced-stage melanoma as well as for specified Phase 1 and Phase 2 clinical trials. Our agreement with Synteract requires Synteract to provide these services to us through December 31, 2005. However, this agreement is subject to early termination by either party without cause upon 90 days notice to the other party. This agreement may also be terminated by either party for material breach upon 30 days notice to the other party. In the event that we are unable to maintain our relationship with Synteract, and are required to transfer the data collection, data management and data analysis functions for our clinical trials to another suitable third party, we may experience significant additional expenditures and substantial delays in the completion of our clinical trials. We may not be able to maintain our agreement with Synteract or any of our relationships with other third parties, or establish new ones without undue delays or excessive expenditures.

Our agreements with clinical investigators and medical institutions for clinical testing and with a third party for data management services place substantial responsibilities on these parties, which could result in delays in, or

termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize Canvaxin.

We have limited experience in manufacturing and testing biological products and may encounter problems or delays that could result in delayed development or commercialization of Canvaxin and our other product candidates as well as lost revenue.

We expend significant time, money and effort in production, record keeping and quality systems to assure that Canvaxin will meet FDA-approved product specifications and other regulatory requirements. We are continuing to develop and plan to validate

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specialized assays to enable us to ensure the characterization, potency and consistency of our lead product candidate, Canvaxin. We are also validating our quality systems, manufacturing processes and product container closure systems. However, we have no experience producing commercial quantities of Canvaxin. We previously modified our manufacturing process for Canvaxin and switched from a small volume flask process to a larger scale flask process in an effort to improve our manufacturing process and scale-up our manufacturing capability to produce larger quantities. We introduced Canvaxin that was manufactured using this new process into our two Phase 3 clinical trials for advanced-stage melanoma in 2003.

We have experienced significant delays in connection with our commercial-scale manufacturing processes and may encounter delays in the future. For example, as a result of a sterility concern caused by a third party testing process related to one lot of Canvaxin used in our Phase 3 clinical trials, we initiated a product retrieval from 35 clinical trial sites in June 2003. While we do not believe this voluntary product retrieval was due to our manufacturing process, we may experience other delays in our development programs and commercialization efforts stemming from our manufacturing and testing processes, including testing and other services performed by third parties. Additionally, in March 2004, we reminded the clinical trial sites participating in the Phase 3 clinical trials of Canvaxin of the need to ensure that the storage containers in which vials of Canvaxin and placebo are stored are not over-filled with liquid nitrogen, which could result in the submersion of the vials and could, potentially, damage the container closure system. We also notified the clinical trials sites to take measures to prevent the vials from becoming submerged while being thawed in water baths, and to carefully inspect vials of Canvaxin and placebo to ensure that the vials do not exhibit protruding gaskets, which could indicate damage to the container closure system.

Under the licensing agreements for our specific active immunotherapeutic product candidates that target the EGFR signaling pathway, CIMAB, S.A., has the right and obligation, subject to certain terms and conditions, to supply the quantities of these product candidates that we or our sublicensees may require for Phase 2 clinical trials throughout our territory, and for Phase 3 clinical trials and commercial sales in countries within our territory other than the U.S., Canada and Mexico. There can be no assurance that CIMAB will be able to develop adequate manufacturing capabilities to supply the product needed for our clinical trials or commercial-scale quantities. Production of these product candidates may require raw materials for which the sources and amounts are limited. Any inability to obtain adequate supplies of such raw materials could significantly delay the development, regulatory approval and marketing of these product candidates. In addition, prior to the initiation of Phase 3 clinical trials in the U.S., we will need to transfer the manufacturing and quality assurance processes for these product candidates to a facility outside of Cuba. Our ability to transfer information to CIMAB that might be beneficial in scaling-up such manufacturing processes is significantly limited due to U.S. government restrictions. Difficulties or delays in the transfer of the manufacturing and quality processes related to these product candidates could cause significant delays in the initiation of the Phase 3 clinical trials and in the establishment of our own commercial-scale manufacturing capabilities for these products.

In 2004, we initiated an expansion of our production capacity for Canvaxin, which will continue into 2005. Significant delays in the completion of the expansion of our manufacturing facility could result in an inability to meet the demand for the product upon its commercialization. If we are unable to manufacture sufficient quantities of Canvaxin or our other product candidates using commercial-scale processes in accordance with FDA and foreign regulatory authority regulations, the lack of supply could delay our clinical trials, thereby delaying submission of our product candidates for regulatory approval and commercial launch. Similarly, if we are unable to complete the development and validation of the specialized assays required to ensure the consistency of our product candidates, our quality systems, manufacturing processes and product container closure systems, our ability to manufacture and deliver products in a timely manner could be impaired or precluded. The approval of our manufacturing processes and facility will be a part of the review process performed by FDA and foreign regulatory authorities in connection with our applications to obtain regulatory approvals of Canvaxin and our other product candidates. If the FDA or foreign regulatory authorities have any issues with our manufacturing facilities or processes, we may have to perform additional studies in order to obtain such regulatory approvals.

If we are unable to renew our lease for our sole manufacturing facility in the Los Angeles, California area, or if the facility is damaged or destroyed, our ability to manufacture Canvaxin will be significantly affected, and we will be delayed or prevented from completing our clinical trials and commercializing Canvaxin.

We rely on the availability and condition of our sole biologics manufacturing facility, located in the Los Angeles, California area, to manufacture Canvaxin. Our lease is scheduled to expire on August 14, 2011, although we have the option to renew the terms for an additional five years. After that time, we may not be able to negotiate a new lease for our facility. Our facility is located in a seismic zone, and there is the possibility of an earthquake which could be disruptive to our operations and result in a lack of supply of Canvaxin. Any lack of supply could, in turn, delay our clinical trials and any potential commercial sales. In addition, if the facility or the equipment in the facility is significantly damaged or destroyed for any reason, we may not be able to replace our manufacturing

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capacity, and our business, financial condition and results of operations will be materially and adversely affected.

If we or others identify side effects after our products are on the market, we may be required to perform lengthy additional clinical trials, change the labeling of our products or withdraw our products from the market, any of which would hinder or preclude our ability to generate revenues.

If we or others identify side effects after any of our products are on the market:

- regulatory authorities may withdraw their approvals;
- we may be required to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to or obtain re-approvals of our manufacturing facilities, or recall our products;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

Our efforts to discover, develop and commercialize new product candidates beyond Canvaxin, including the specific active immunotherapeutic product candidates that we have licensed from CIMAB, S.A., are in a very early stage and, therefore, these efforts are subject to a high risk of failure.

Our strategy is to discover, develop and commercialize new products for the treatment of cancer. The process of successfully developing product candidates is very time-consuming, expensive and unpredictable. We have only recently begun to direct significant effort toward the expansion of our scientific staff and research capabilities to identify and develop product candidates in addition to Canvaxin. We do not know whether our planned preclinical development or clinical trials for these other product candidates, including for the specific active immunotherapeutic product candidates that we have licensed from CIMAB, S.A., will begin on time or be completed on schedule, if at all. In addition, we do not know whether these clinical trials will result in marketable products. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials. We do not anticipate that any of our product candidates will reach the market for at least several years.

We may not identify, develop or commercialize any additional new product candidates from our proprietary specific active immunotherapy, anti-angiogenesis, T-oligonucleotide or other technologies. Our ability to successfully develop any of these product candidates depends on our ability to demonstrate safety and efficacy in humans through extensive preclinical testing and clinical trials and to obtain regulatory approval from the FDA and other regulatory authorities. Our development programs for our product candidates will also depend upon our ability to fund our research and development operations.

If we are unable to establish or manage strategic collaborations in the future, our revenue and product development may be limited.

Our strategy includes substantial reliance on strategic collaborations for marketing and commercialization of Canvaxin, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other product candidates. To date, we have not entered into any strategic collaborations with

third parties capable of providing these services. In addition, we have not yet marketed or sold any of our product candidates in the United States or elsewhere and we will need to continue to build our internal marketing and sales capabilities or enter into successful collaborations for these services in order to ultimately commercialize our product candidates. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

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Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

If we enter into research and development collaborations at an early phase of product development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our product candidates. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our product candidates. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, our collaborators may terminate our relationships, and we may be unable to establish additional corporate collaborations in the future on acceptable terms, if at all. For example, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

If our competitors develop and market products that are more effective than our existing product candidates or any products that we may develop, or obtain marketing approval before we do, our commercial opportunity will be reduced or eliminated.

The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. We have many potential competitors, including major drug and chemical companies, large, diversified biotechnology companies, smaller, specialized biotechnology firms, universities and other research institutions. These companies and other institutions may develop technologies and products that are more effective than our product candidates or that would make our technology and product candidates obsolete or non-competitive. Many of these companies and other institutions have greater financial and technical resources and development, production and marketing capabilities than we do. In addition, many of these companies and other institutions have more experience than we do in preclinical testing, human clinical trials and manufacturing of new or improved biological therapeutics, as well as in obtaining FDA and foreign regulatory approvals.

Various companies are developing or commercializing products that are used for the treatment of melanoma, other forms of cancer and other diseases that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. These companies may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their products sooner than we do for ours.

We are aware of a number of competitive products currently available in the marketplace or under development for the prevention and treatment of the diseases we have targeted for product development. Products marketed in the United States and elsewhere for melanoma include Chiron Corporation s Proleukin® (IL-2), Schering-Plough Corporation s IntronA® (interferon alpha) and Bayer AG s chemotherapeutic agent dacarbazine. Despite the side effects associated with these chemotherapy and biotherapy products, these products are currently being used in the treatment of patients with advanced-stage melanoma. In addition, Corixa Corporation s Melacine® has been approved in Canada for the treatment of patients with Stage IV melanoma, however, Corixa recently announced that it is discontinuing the development of Melacine in the United States for melanoma. A number of other potential competitors are developing immunotherapeutics and other approaches for the treatment of advanced-stage melanoma,

including Progenics Pharmaceuticals, Inc. s GMK™, Antigenics, Inc. s Oncophage®, Maxim Pharmaceutical, Inc. s Ceplene™ and Genta, Inc. s Genasense™, which are all in Phase 3 clinical trials. In November 2003, Maxim announced that it has filed for European approval to market Ceplene, in combination with interleukin-2 for the treatment of advanced malignant melanoma in patients with liver metastases. In March 2004, Maxim announced the availability of Ceplene™ through an expanded access program. Expanded access programs are designed to allow patients to be treated with a product candidate that is not approved for marketing but that is under clinical investigation for a serious or immediately life-threatening disease condition for which no satisfactory alternative therapy is available. Also in March 2004, Celgene Corp. announced that it was discontinuing its Phase 3 clinical trial studying Revlimid® as a monotherapy for the treatment of patients with melanoma, but that it plans to conduct clinical trials for Revlimid® in combination with other treatments for melanoma. In May 2004, Genta announced that the FDA s oncologic drug advisory committee determined that the clinical trial results provided to it by Genta did not provide enough evidence of effectiveness to outweigh the increased toxicity of administering the drug in combination with dacarbazine for the treatment of patients with advanced malignant melanoma.

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Oncophage, Ceplene and Genasense are all being studied in patients with metastatic melanoma, but none of these clinical trials require that patients undergo surgical resection to remove all clinically detectable disease prior to the initiation of their treatment. This is contrasted with patients who are being studied in Canvaxin s Phase 3 clinical trials, who have their primary tumors and all clinically detectable metastases resected. If we receive approval to market and sell Canvaxin, we may compete with these companies and their products as well as other products in varying stages of development. In addition, researchers are continually learning more about the treatment of melanoma and other forms of cancer, and new discoveries may lead to new technologies for treatment. As a result, Canvaxin, or any other product candidates that we may develop, may be rendered obsolete and noncompetitive.

Several products that target the EGFR signaling pathway in the treatment of cancer have recently been approved by the FDA or are in the late phases of development. The approved products are AstraZeneca Pharmaceutical LP s Iressa (gefitinib), an EGFR-targeted tyrosine kinase inhibitor for refractory Stage IV non-small-cell lung cancer, and ImClone Systems, Inc. s Erbitux (cetuximab), an EGFR monoclonal antibody for Stage IV refractory colorectal cancer. Recently, Genentech, Inc., OSI Pharmaceuticals, Inc., and Roche Holdings AG, announced positive results from a randomized, Phase 3 clinical trial in late-stage non-small-cell lung cancer for their EGFR-targeted tyrosine kinase inhibitor, Tarceva (erlotinib HCl). Recently published data has shown that treatment with Tarceva increased overall survival in non-small-cell lung cancer patients with late-stage disease. Genentech and OSI Pharmaceuticals recently announced that they had submitted a new drug application for Tarceva as a monotherapy for the treatment of patients with advanced non-small-cell lung cancer for whom chemotherapy has failed. The submission was based on results from a Phase 3 clinical trial, which demonstrated a 42% increase in median survival for patients treated with Tarceva versus patients who received a placebo. Two other products that are currently being evaluated in Phase 3 clinical trials are GlaxoSmithKline s lapatinib (GW572016), a tyrosine kinase dual inhibition compound, which is being studied in patients with advanced metastatic breast cancer whose disease progressed on Herceptin® (trastuzumab) therapies, and Abgenix, Inc. and Agmen, Inc. s panitumumab (ABX-EGF), a fully human monoclonal antibody targeting EGFR, which is being studied in patients with advanced colorectal cancer.

We also face competition from a number of companies working in the fields of anti-angiogenesis and specific active immunotherapy for the treatment of other solid tumors, and working to develop technologies similar to the T-oligonucleotides that use internal cellular mechanisms to regulate cell responses to treat cancer. We expect that competition among such products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent our product candidates commercial success.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect:

our ability to generate revenues and achieve profitability;

the future revenues and profitability of our potential customers, suppliers and collaborators; and

the availability of capital.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. For example, legislation was enacted on December 8, 2003, which provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. While we cannot predict the full effects of the implementation of this new legislation or whether any

legislative or regulatory proposals affecting our business will be adopted, the implementation of this legislation or announcement or adoption of these proposals could have a material and adverse effect on our business, financial condition and results of operations.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate reimbursement levels for the cost of our products and related treatments. Third-party payors are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for our product candidates or exclusion of our product candidates from reimbursement programs. The cost containment measures that

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health care payors and providers are instituting and the effect of any health care reform could materially and adversely affect our results of operations.

If physicians and patients do not accept the products that we may develop, our ability to generate product revenue in the future will be adversely affected.

Canvaxin and other product candidates that we may develop may not gain market acceptance among physicians, healthcare payors, patients and the medical community. Market acceptance of and demand for any product that we may develop will depend on many factors, including:

our ability to provide acceptable evidence of safety and efficacy;

convenience and ease of administration;

prevalence and severity of adverse side effects;

availability of alternative treatments;

cost effectiveness;

effectiveness of our marketing strategy and the pricing of any product that we may develop;

publicity concerning our products or competitive products; and

our ability to obtain third-party coverage or reimbursement.

Even if we receive regulatory approval and satisfy the above criteria for Canvaxin or any of our other product candidates, physicians may be reluctant to recommend, or patients may be reluctant to use, our products. One reason for this reluctance may be concerns about the side effects associated with Canvaxin, which include blistering, stinging, itching and redness at the site of injection, flu-like symptoms and a decrease in energy. Side effects, such as a localized skin reaction, may also be associated with BCG, which we administer to patients with the first two doses of Canvaxin. The treatment protocol for Canvaxin, which includes a total of 33 doses over five years, may limit physician and patient acceptance of the product. During the course of treatment with Canvaxin, patients will be advised not to receive treatment with products, such as chemotherapy, that suppress the immune system because those treatments could reduce the effectiveness of Canvaxin. Patients may be unwilling to forego chemotherapy treatment and their physicians may be unwilling to recommend foregoing such treatment.

In the event Canvaxin does not achieve market acceptance for one indication, such as advanced-stage melanoma, it may be even more difficult to promote Canvaxin for other indications, such as colon cancer. If any product that we may develop fails to achieve market acceptance, we may not be able to successfully market and sell the product, which would limit our ability to generate revenue and could materially and adversely affect our results of operations.

If we are unable to establish our sales, marketing and distribution capabilities, we will be unable to successfully commercialize our product candidates.

To date, we have no experience as a company in selling, marketing or distributing biological products. If we are successful in developing and obtaining regulatory approvals for Canvaxin or our other product candidates, we will need to establish sales, marketing and distribution capabilities. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be

capable of generating demand for Canvaxin or our other product candidates. Although we intend to establish strategic collaborations to market our products outside the United States, if we are unable to establish such collaborations, we may be required to market our product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

We currently plan to distribute Canvaxin from our manufacturing facility in pressurized liquid nitrogen storage containers, which will require that any distribution service we retain to comply with exacting standards and precise specifications in order to preserve

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Canvaxin in the appropriate form for administration to patients. Although there are several distributors that could potentially meet our requirements for the handling, storage and distribution of Canvaxin, we may be unable to obtain distribution services on economically viable terms, or at all. Any failure to comply with the precise handling and storage requirements for Canvaxin by our distribution service or any medical facility that may store Canvaxin prior to administration to patients could adversely affect its quality and, as a result, materially and adversely affect our results of operations.

If we are required to seek alternative sources for bacillus Calmette-Guérin, our clinical trials and/or marketing of Canvaxin could be disrupted.

We are currently dependent on a sole source supplier, Organon Teknika Corporation, for the strain of BCG that we administer to patients with the first two doses of Canvaxin. Our supply agreement with Organon Teknika had an initial term of one year beginning in April 1998, with automatic renewals for successive one-year terms. Under some circumstances, Organon Teknika can terminate the agreement if we fail to purchase BCG for specified periods of time. However, last year we purchased BCG, which should preserve our agreement with Organon Teknika for the foreseeable future. The FDA may require that if the manufacturing source of BCG is changed, comparability be demonstrated before patients may be administered BCG from the alternative source with Canvaxin. If required, the demonstration of comparability may require additional clinical trials to be conducted. There may be similar requirements if we change our suppliers for other components. We may not be able to demonstrate comparability and the effort to do so may require significant expenditures of time and money, which could have a material and adverse effect on our results of operations.

Organon Teknika is also subject to FDA rules and regulations. Therefore, our ability to continue to purchase BCG from Organon Teknika could be significantly delayed or halted completely if Organon Teknika fails to comply with applicable regulatory requirements or if the FDA or another regulatory agency institutes a hold on the manufacture of BCG. The strain of BCG that we purchase from Organon Teknika is not currently approved for use in all countries in which we would eventually plan to market Canvaxin, so we will need to apply for approval to market BCG as an adjuvant for use with Canvaxin. In the countries where it is currently approved, we will need to work with Organon Teknika and the relevant regulatory agencies to modify the product s labeling to permit its use as an adjuvant with Canvaxin. In addition, Organon Teknika may supply BCG to a number of significant purchasers and may in the future experience capacity constraints that would cause it to limit the quantity of BCG that we can purchase. Organon Teknika manufactures BCG at a single location. Any interruption or unavailability of this critical adjuvant used with the first two doses of Canvaxin would delay or prevent us from completing our clinical trials and commercializing Canvaxin.

We may encounter difficulties managing our growth, which could adversely affect our results of operations.

We will need to expand and effectively manage our organization, operations and facilities in order to successfully pursue our research, development and commercialization efforts and secure collaborations to market and distribute our products. We increased the number of our full-time employees from 22 as of December 31, 2000 to 182 as of June 30, 2004, and we expect the number of employees to continue to grow to meet our strategic objectives. If we continue to grow, it is possible that our management and scientific personnel, systems and facilities currently in place may not be adequate. Our need to effectively manage our operations, growth and various projects requires that we continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

If we do not successfully integrate the operations of any future acquisitions, we may incur unexpected costs and disruptions to our business.

In 2002, we acquired Cell-Matrix, Inc., a privately held biotechnology company specializing in the field of angiogenesis. We may acquire additional complementary companies. Future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to developing acquired technologies;
- increased amortization expenses;
- higher than expected acquisition and integration costs;
- difficulty and cost in combining the operations and personnel of acquired businesses with our operations and personnel;

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impairment of relationships with key suppliers or customers of acquired businesses due to changes in management and ownership;

inability to retain key employees of acquired businesses; and

incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions.

Although we periodically engage in preliminary discussions with respect to acquisitions of companies, we are not currently a party to any agreements or commitments and we have no understandings with respect to any such acquisitions.

Changes in the laws or regulations of the United States or Cuba related to the conduct of our business with CIMAB, S.A., may adversely affect our ability to develop and commercialize the specific active immunotherapeutic product candidates that we have licensed from that company.

We have obtained from OFAC a license authorizing us to carry out all transactions set forth in the license agreements that we have entered into with CIMAB and YM BioSciences, Inc., for the development, testing, licensing and commercialization of the three specific active immunotherapeutic product candidates that target the EGFR signaling pathway. In the absence of such a license from OFAC, our performance under these agreements could have exposed us to legal and criminal liability. At any time, there may occur for reasons beyond our control a change in U.S. or Cuban law, or in the regulatory environment in the U.S. or Cuba, or a shift in the political attitudes of either the U.S. government or Cuba, that could result in the suspension or revocation of our OFAC license or in our inability to carry out part or all of the licensing agreements with CIMAB. There can be no assurance that the U.S. or Cuban governments will not modify existing law or establish new laws or regulations that may adversely affect our ability to develop, test, license and commercialize these product candidates. Our OFAC license may be revoked or amended at anytime in the future, or the U.S. or Cuban governments may restrict our ability to carry out all or part of our licensing agreements with CIMAB and YM BioSciences.

A recent significant change to the U.S. embargo against Cuba resulted from congressional passage of the Cuban Liberty and Democratic Solidarity Act, also known as the Helms-Burton Bill. That law authorizes private lawsuits for damages against anyone who traffics in property confiscated, without compensation, by the government of Cuba from persons who at the time were, or have since become, nationals of the U.S. We do not own any property in Cuba and do not believe that any of CIMAB s properties or any of the scientific centers that are or have been involved in the development of the technology that we have licensed from CIMAB were confiscated by the government of Cuba from persons who at the time were, or who have since become, nationals of the U.S. However, there can be no assurance that our understanding in this regard is correct. We do not intend to traffic in confiscated property, and have included provisions in our licensing agreements to preclude the use of such property in association with the performance of CIMAB s obligations under those agreements.

As part of our interactions with CIMAB, we will be subject to the U.S. Commerce Department s export administration regulations that govern the transfer of technology to foreign nationals. Specifically, we will require a license from the Commerce Department s Bureau of Industry and Security, or BIS, in order to export or otherwise transfer to CIMAB any information that constitutes technology under the definitions of the Export Administration Regulations, or EAR, administered by BIS. The export licensing process may take months to be completed, and the technology transfer in question may not take place unless and until a license is granted by the Commerce Department. Due to the unique status of the Republic of Cuba, technology that might otherwise be transferable to a foreign national without a Commerce Department license requires a license for export or transfer to a Cuban national. If we fail to comply with the export administration regulations, we may be subject to both civil and criminal penalties. There can be no guarantee that any license application will be approved by BIS or that a license, once issued, will not be revoked, modified, suspended or otherwise restricted for reasons beyond our control due to a change in U.S.-Cuba

policy or for other reasons.

If we are unable to retain our management, scientific staff and scientific advisors or to attract additional qualified personnel, our product development efforts will be seriously jeopardized.

We have a consulting agreement with our founder, Donald L. Morton, M.D. This agreement expires in December 2004, and Dr. Morton will thereafter be able to develop products that compete with Canvaxin and our other product candidates. In addition, Dr. Morton has retained the right to use the cell lines in Canvaxin for the diagnosis or detection of cancer.

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The loss of the services of any principal member of our management and scientific staff, including David F. Hale, our President and Chief Executive Officer, and John Petricciani, M.D., our Senior Vice President, Medical and Regulatory Affairs, could significantly delay or prevent the achievement of our scientific and business objectives. Mr. Hale s employment agreement expires in October 2005, and Dr. Petricciani s employment agreement expires in January 2005. Competition among biotechnology companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to our success. We may be unable to attract and retain key personnel on acceptable terms, if at all. We do not maintain key person life insurance on any of our officers, employees or consultants, including Mr. Hale or Drs. Morton and Petricciani.

We have relationships with scientific advisors at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research, development or clinical strategy. These scientific advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these scientific advisors and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our programs could harm our business. In addition, these advisors may have arrangements with other companies to assist those companies in developing technologies that may compete with our products.

Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time-consuming and costly.

Our research and development involves the controlled use of biological, hazardous and radioactive materials and waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for damages or penalized with fines, and this liability could exceed our resources. We may have to incur significant costs to comply with future environmental laws and regulations.

Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the manufacturing, testing and marketing of therapies for treating people with cancer or other diseases. A product liability claim may damage our reputation by raising questions about a product s safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with product commercialization.

Product liability claims may stem from side effects that are associated with Canvaxin, including blistering, stinging, itching and redness at the site of injection and a decrease in energy. Some patients have experienced flu-like symptoms, including headache, muscle aches, joint aches, fever, nausea, diarrhea, vomiting, cough, chills and loss of appetite, as well as irritation and ulceration at the injection sites. A small number of patients who received Canvaxin have had a drop in the number of white blood cells in their blood or developed white patches on their skin. Two patients out of approximately 3,000 who have received Canvaxin experienced degeneration of part of their retinas. In addition, although Canvaxin is treated with radiation to prevent the melanoma cells in Canvaxin from replicating when administered to patients, there is a theoretical possibility that these cells may develop into a tumor after injection. There is also a small possibility that Canvaxin may contain unidentified agents, such as bacteria or viruses, which could cause infections or other diseases, or that patients could have a localized skin reaction to Canvaxin. Side effects may also be associated with BCG, which we administer to patients with the first two doses of Canvaxin. BCG is also used to prevent tuberculosis and some patients treated with BCG have developed serious complications such as

an infection with BCG or a severe muscle and nerve weakness known as Guillain Barre syndrome. To date, neither of these complications has been reported in patients who received BCG with Canvaxin. However, both Canvaxin and BCG are investigational for treating metastatic melanoma and may, along with our other product candidates, have other side effects that have not been seen or predicted. While we would expect to provide adequate disclosure to patients of the potential for adverse side effects, we cannot be sure that we will be able to do so or that we will be able to avoid the cost and expense of defending product liability claims.

Although we have product liability and clinical trial liability insurance with coverage limits of $5 million, this coverage may be inadequate, or may be unavailable in the future on acceptable terms, if at all. Defending a suit, regardless of its merit, could be costly and could divert management attention.

Risks Related to Our Financial Results and Need for Financing

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We have a history of net losses, which we expect to continue for at least several years and, as a result, we are unable to predict the extent of any future losses or when we will become profitable.

We have incurred $120.4 million in net losses from our inception through June 30, 2004. To date, we have recognized no revenues and we do not anticipate generating significant revenues for at least several years. We expect to increase our operating expenses over the next several years as we expand the clinical trials for Canvaxin, advance other product candidates into clinical trials, expand our research and development activities, acquire or license new technologies and product candidates and scale-up our manufacturing and quality operations. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

If we fail to obtain the capital necessary to fund our operations, we will be unable to develop or commercialize Canvaxin or other product candidates.

We will need to raise additional capital in order to expand the clinical trials for Canvaxin, initiate clinical trials with our specific active immunotherapeutic product candidates that target the EGFR signaling pathway, advance other product candidates into clinical trials and expand our research and development activities. Our ability to scale-up our manufacturing and quality operations and respond to competitive pressures could be significantly limited if we are unable to obtain the necessary capital. We do not know whether additional financing will be available when needed, or whether it will be available on favorable terms or at all. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the expansion of clinical testing for Canvaxin and the initiation of clinical trials for our specific active immunotherapeutic product candidates that target the EGFR signaling pathway;
- progress in preclinical development and clinical trials for our other product candidates;
- the time and costs involved in obtaining and maintaining regulatory approvals for Canvaxin and our other product candidates;
- progress in, and the costs of, our research and development programs;
- the scope, prioritization and number of programs we pursue;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- the costs of expanding our manufacturing capabilities;
- our ability to enter into corporate collaborations and the terms and success of these collaborations;
- our acquisition and development of technologies and product candidates; and
- competing technological and market developments.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.

We currently have no source of revenue and may never become profitable.

Our ability to generate revenue depends on a number of factors, including our ability to successfully complete our ongoing Phase 3 clinical trials for Canvaxin and obtain regulatory approvals to commercialize this product candidate as well as others. To date, Canvaxin has not generated any revenue, and we do not know when or if any of our product candidates will generate revenue. Even if Canvaxin receives regulatory approvals, we will need to establish and maintain sales, marketing and distribution capabilities. We plan to rely on strategic collaborators to help generate revenues in markets outside of the United States, and, potentially, to co-promote our products in the United States, and we cannot be sure that our collaborations, if any, will be successful. Even if we are able to commercialize Canvaxin, we may not achieve profitability for at least several years after generating material revenue. If we are unable to generate

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revenue, we may not become profitable, and we may be unable to continue our operations.

Our quarterly operating results and stock price may fluctuate significantly.

We expect our results of operations to be subject to quarterly fluctuations. The level of our revenues, if any, and results of operations at any given time, will be based primarily on the following factors:

- the status of development of Canvaxin, our EGFR-targeted specific active immunotherapeutic product candidates and our other product candidates;
- the time at which we enter into research and license agreements with strategic collaborators that provide for payments to us, and the timing and accounting treatment of payments to us, if any, under those agreements;
- whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by commercial collaborators of any amounts payable to us;
- the addition or termination of research programs or funding support;
- the timing of milestone and other payments that we may be required to make to others; and
- variations in the level of expenses related to our product candidates or potential product candidates during any given period.

These factors may cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected financial reporting fluctuations and affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, any changes requiring that we record compensation expense in the statement of operations for employee stock options using the fair value method or changes in existing taxation rules related to stock options could have a significant negative effect on our reported results. Several agencies and entities are considering, and the Financial Accounting Standards Board has announced, proposals to change generally accepted accounting principles in the United States, that, if implemented, would require us to record charges to earnings for employee stock option grants measured using the fair value method. This pending requirement would negatively impact our earnings. For example, if we accounted for employee stock options under the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation, our net loss would have increased by $1.2 million and $1.8 million for the three and six months ended June 30, 2004, respectively, compared to $0.2 million and $0.3 million for the comparable periods of 2003.

Risks Related to Our Intellectual Property and Litigation

Our success depends upon our ability to protect our intellectual property and our proprietary technology and to maintain and enforce our licensing arrangements with various third party licensors.

The patent protection of our product candidates and technology is generally very uncertain and involves complex legal and factual questions. We cannot be certain that any of the patents or patent applications related to our products and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we can:

obtain and maintain patents to protect our product candidates;

obtain and maintain licenses to use certain technologies of third parties, which may be protected by patents or subject to U.S. regulation;

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protect our trade secrets and know-how; and

operate without infringing the intellectual property and proprietary rights of others.

We hold exclusive rights to commercialize the technology under the patents related to Canvaxin for the treatment or prevention of cancer in humans under a contribution and exchange agreement between us and Donald L. Morton, M.D. and a license agreement, and amendments to that agreement, between us and Cancer Diagnostic Laboratories, Inc., a company wholly-owned by Dr. Morton. Cancer Diagnostic Laboratories has retained the rights to this patented technology for diagnostic applications, and has retained the right to control the prosecution of these diagnostic patent applications. However, we have obtained rights to the diagnostic applications under Cancer Diagnostic Laboratories patents and patent applications where necessary for us to treat or prevent cancer in humans.

We hold exclusive rights from CIMAB, S.A., a Cuban corporation, and YM BioSciences, Inc., a Canadian corporation, to develop and commercialize within a specific territory, which includes the U.S., Canada, Japan, Australia, New Zealand, Mexico and certain countries in Europe, three specific active immunotherapeutic product candidates that target the EGFR signaling pathway for the treatment of cancer. In exchange, we will pay to CIMAB and YM BioSciences technology access fees and transfer fees totaling $5.7 million, to be paid over the next three years. We will also make future milestone payments to CIMAB and YM BioSciences up to a maximum of $34.7 million upon meeting certain regulatory, clinical and commercialization objectives, and royalties on future sales of commercial products, if any. These agreements terminate upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreements or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreements. CIMAB may terminate the agreements if we have not used reasonable commercial efforts to file an investigational new drug, or IND, submission to the FDA for the leading product candidate by July 12, 2006, or if the first regulatory approval for marketing this product candidate within our territory is not obtained by July 12, 2016, provided that CIMAB has timely complied with all of its obligations under the agreements, or if CIMAB does not receive timely payment of the initial access fees and technology transfer fees under the Agreement. In addition, if CIMAB does not receive payments under the agreements due to changes in U.S. law, actions by the U.S. government or by order of any U.S. court for a period of more than one year, CIMAB may terminate our rights to the licensed product candidates in countries within our territory other than the U.S. and Canada. We may terminate the agreement for any reason following 180 days written notice to CIMAB.

Although our license agreements with CIMAB are governed by the laws of England, their enforcement may necessitate pursuing legal proceedings and obtaining orders in other jurisdictions, including the U.S. and the Republic of Cuba. There can be no assurance that a court judgment or order obtained in one jurisdiction will be enforceable in another. In addition, as is the case in many developing countries, the commercial legal environment in Cuba may be subject to political risk. It is possible that we may not be able to enforce our legal rights in Cuba or against Cuban entities to the same extent as we would in a country with a more developed commercial and legal system. Termination of our license arrangements or difficulties in the enforcement of such arrangements may have a material adverse effect on our business, operations and financial condition.

In addition, we hold rights to commercialize our anti-angiogenesis product candidates and our rights to additional cell lines for the development of cancer vaccines under agreements that require, among other things, royalty payments on future sales, if any, and our achievement of certain development milestones. We hold rights to three human monoclonal antibodies under a license from M-Tech Therapeutics, which can be terminated if we determine not to file and obtain approval of an IND application for a licensed product by a specified date and conduct clinical trials for such product, or if we determine not to file and obtain approval of an IND application for a licensed product by a specified date because of negative pre-clinical results. We hold rights to certain T-oligonucelotide technology under a sublicense agreement from SemaCo, which can be terminated if we fail to perform any of the obligations that we are required to perform under that agreement, including using commercially reasonable efforts to develop commercially

viable products based on the licensed technology.

We are party to a collaboration agreement with Applied Molecular Evolution, Inc., or AME, under which AME utilized their technology to humanize two of our antibodies. AME, which recently completed a merger with Eli Lilly and Company, may terminate the agreement if we fail to make milestone or royalty payments to AME or if we fail to file an IND application for one or more products that incorporate or are derived from one or more of the antibodies that are the subject of the agreement by November 29, 2004 or fail to meet certain other specified commercial development obligations. In the event of such termination, we will be required to grant to AME an exclusive license under all of our patent rights relating to the antibodies that are the subject of this agreement and the products that incorporate or are derived from one or more of the antibodies that are the subject of the agreement. If we were to materially breach any of the agreements discussed above or any of our other license and collaboration agreements, we could lose our ability to commercialize the related technologies, and our business could be materially and adversely affected.

We cannot be certain that additional patents will be issued on our specific active immunotherapeutic product candidates that target

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the EGFR signaling pathways or on our T-oligonucleotide technology, or that any patents will be issued on our anti-angiogenesis product candidates, as a result of pending applications filed to date. If a third party has also filed a patent application relating to an invention claimed by us or our licensors, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us. The degree of future protection for our proprietary rights is uncertain. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for commercially-viable products, may not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or unenforceable under United States or foreign laws;
- any of the issued patents under which we hold rights may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

Additionally, there may be risks related to the licensing of the proprietary rights for the specific active immunotherapeutic product candidates that target the EGFR signaling pathway that were developed in Cuba. Under current Cuban patent law, ownership of the inventions of the Cuban inventors for which patent applications have been filed rests with the state.

Proprietary trade secrets and unpatented know-how are also very important to our research, development and manufacturing activities. However, we cannot be certain that others will not develop the same or similar technologies on their own. Although we have taken steps, including entering into confidentiality and intellectual property disclosure agreements with all of our employees to protect our trade secrets and unpatented know-how and keep them secret, third parties may still obtain this information. In particular, before we obtained commercial development rights to Canvaxin and related technology, development of some of the related technology was carried out at UCLA Medical Center and JWCI over a period of 15 years. While we have agreements with these parties designed to protect our trade secrets and know-how, these agreements may not be sufficient to prevent all parties who have had access to this proprietary information over the years from using this information to compete with us.

If our products violate third party patents or were derived from a patient s cell lines without the patient s consent, we could be forced to pay royalties or cease selling our products.

We know that others have filed patent applications in various countries that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. The pending patent applications may also result in patents being issued. In addition, since patent applications are secret until patents are issued in the United States, or corresponding applications are published in foreign countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that Dr. Morton, from whom we have acquired the patent rights for Canvaxin, was the first to make his inventions or to file patent applications for those inventions. Issued patents are entitled to a rebuttable presumption of validity under the laws of the United States and certain other countries. These issued patents may therefore limit our ability to develop commercial products. If we need licenses to such patents to permit us to develop or market our

product candidates, we may be required to pay significant fees or royalties and we cannot be certain that we would be able to obtain such licenses at all.

It is the standard policy of the UCLA Medical Center and JWCI to obtain each patient s consent to use their tumor cell lines. However, we cannot be certain that all of these consents were obtained. If any of the cell lines that comprise Canvaxin or the other cell lines derived from human tumors that we have acquired were derived from a patient without his or her consent, that patient or his or her estate could assert a claim for royalties on the use of the cell line or prevent us from selling our products.

We may be involved in lawsuits or proceedings to protect or enforce our patent rights, trade secrets or know-how, which could be expensive and time consuming.

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There has been significant litigation in the biotechnology industry over patents and other proprietary rights. One of our issued European patents covering Canvaxin was challenged in Europe by Boehringer Ingelheim GmbH.

While we prevailed in the opposition proceeding and the appeal by Boehringer Ingelheim was rejected on procedural grounds, our patents and patents that we have licensed the rights to may be the subject of other challenges by our competitors in Europe, the United States and elsewhere. Furthermore, our patents and the patents that we have licensed the rights to may be circumvented or challenged and declared narrow in scope, invalid or unenforceable.

Legal standards relating to the scope of claims and the validity of patents in the biotechnology field are still evolving, and no assurance can be given as to the degree of protection any patents issued to or licensed to us would provide. The defense and prosecution of intellectual property suits and related legal and administrative proceedings can be both costly and time consuming. Litigation and interference proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. Further, the outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. An adverse determination in an interference proceeding or litigation, particularly with respect to Canvaxin, to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. If required, the necessary licenses may not be available on acceptable terms or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from commercializing our product candidates, which could have a material and adverse effect on our business, financial condition and results of operations.

Risks Related to the Securities Markets and Ownership of Our Common Stock

Future sales of our common stock may cause our stock price to decline.

Our current stockholders hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. A significant portion of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, the holders of approximately 14,481,602 shares of common stock, including shares issued upon the exercise of warrants, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered all common stock that we may issue under our stock incentive plans and employee stock purchase plan. These shares generally can be freely sold in the public market upon issuance. If any of these holders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

Our stock price may be volatile, and you may lose all or a substantial part of your investment.

The market price for our common stock is volatile and may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

changes in the regulatory status of our product candidates, including results of our clinical trials for Canvaxin and our specific active immunotherapeutic product candidates targeting the EGFR signaling pathway, significant contracts, new technologies, acquisitions, commercial relationships, joint ventures or capital commitments;

fluctuations in stock market prices and trading volumes of similar companies;

variations in our quarterly operating results;

changes in securities analysts estimates of our financial performance;

changes in accounting principles;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

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additions or departures of key personnel; and

discussion of CancerVax or our stock price by the financial and scientific press and online investor communities such as chat rooms.

We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules proposed by the Securities and Exchange Commission and by the Nasdaq Stock Market, could result in increased costs to us. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

If our officers and directors choose to act together, they may be able to control our management and operations, acting in their best interests and not in the best interests of other stockholders.

As of March 31, 2004, our officers and directors beneficially owned approximately 38.2% of our common stock. As a result, these stockholders, acting together, can significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent 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.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that 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 and other rights of the holders of our common stock. These provisions include:

dividing our board of directors into three classes serving staggered three-year terms;

prohibiting our stockholders from calling a special meeting of stockholders;

permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;

prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and

requiring advance notice for raising matters of business or making nominations at stockholders meetings.

We are also subject to 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.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist principally of cash, cash equivalents and securities available-for-sale. These financial instruments, principally comprised of corporate obligations and U.S. government obligations, are subject to interest rate risk and will decline in value if interest rates increase. Because of the relatively short maturities of our investments, we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

Our long-term debt bears interest at fixed rates and therefore we do not have significant market risk exposure with respect to our debt obligations.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

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PART II - OTHER INFORMATION

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-107993) that was declared effective by the Securities and Exchange Commission on October 29, 2003. On November 4, 2003, 6,000,000 shares of common stock were sold on our behalf at an initial public offering price of $12.00 per share, for an aggregate offering price of approximately $72.0 million, through a syndicate of underwriters managed by Lehman Brothers Inc., Citigroup Global Markets Inc., Thomas Weisel Partners LLC and U.S. Bancorp Piper Jaffray Inc.

We paid underwriting discounts and commissions to the underwriters totaling approximately $5.0 million in connection with the offering. In addition, we incurred additional expenses of approximately $1.9 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $6.9 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $65.1 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of June 30, 2004, we have used approximately $28.2 million of the net proceeds from the public offering to continue the development of our specific active immunotherapeutic product candidate, Canvaxin, and to fund other working capital and general corporate purposes. We expect to use the majority of the balance of the net proceeds of the offering to continue the development and to prepare for the commercialization of our specific active immunotherapy product candidate, Canvaxin, and to scale-up our manufacturing operations and quality systems. To a lesser extent, we anticipate using the net proceeds from the offering to:

- complete the development of and commercialize specific active immunotherapeutic candidates that target the EGFR signaling pathway;
- expand our research and development programs;
- advance our preclinical anti-angiogenesis and human monoclonal antibody product candidates into clinical development;
- in-license technology and acquire or invest in businesses, products or technologies that are complementary to our own; and
- fund other working capital and general corporate purposes.

Although we periodically engage in preliminary discussions with respect to acquisitions, we are not currently a party to any agreements or commitments and we have no understandings with respect to any acquisitions.

The amounts and timing of our actual expenditures depend on several factors, including the progress of our research and development efforts and the amount of cash used by our operations. We have not determined the amount or timing of the expenditures in the areas listed above. Pending their use, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

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Item 4. Submission of Matters to a Vote of Security Holders.

On June 10, 2004, we held our Annual Meeting of Stockholders at which the stockholders approved all of the proposals listed below:

(1) The election of James Clayburn LaForce, Jr., Ph.D., Barclay A. Phillips, and Gail S. Schoettler, Ph.D. to the Board of Directors to serve for a three-year term to expire at the 2007 Annual Meeting of Stockholders.

(2) The approval of the Amended and Restated 2003 Equity Incentive Award Plan, which amends the existing plan to provide that (a) the number of shares of stock which may be issued pursuant to awards under the plan will be increased as described in our proxy statement and (b) in the event of a participant s termination of employment on account of disability or death, a portion of such participant s unvested awards will immediately become vested on the date of termination.

(3) The selection of Ernst & Young LLP as our independent public accountants for the fiscal year ending December 31, 2004.

The following directors received the number of votes set opposite their respective names:

	For Election	Votes Against or Withheld
James Clayburn LaForce, Jr., Ph.D.	18,322,734	4,110
Barclay A. Phillips	18,323,034	3,810
Gail S. Schoettler, Ph.D.	18,322,934	3,910

The proposal to approve the Amended and Restated 2003 Equity Incentive Award Plan received 12,162,942 affirmative votes (for the proposal), 3,352,525 negative votes (against the proposal) and 47,525 votes abstained. The proposal received 2,763,852 broker non-votes.

The proposal to select Ernst & Young LLP as our independent public accountants received 17,809,628 affirmative votes (for the selection), 3,866 negative votes (against the selection), and 513,350 votes abstained. This proposal did not receive any broker non-votes.

Ivor Royston, M.D., Robert E. Kiss, CFA and Phillip M. Schneider continued in office as members of the Board of Directors, with their terms expiring at the 2005 Annual Meeting of Stockholders. David F. Hale, Donald L. Morton, M.D., Cam L. Garner and Michael G. Carter, M.B., Ch.B., F.R.C.P., also continued in office as members of the Board of Directors, with their terms expiring at the 2006 Annual Meeting of Stockholders.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
10.1	TGF-α HER-1 Vaccine License, Development, Manufacturing and Supply Agreement, dated July 13, 2004, by and among Tarcanta, Inc., Tarcanta, Ltd., CIMAB, S.A., YM BioSciences, Inc. and CIMYM, Inc.
10.2	EGF Vaccine License, Development, Manufacturing and Supply Agreement, dated July 13, 2004, by and among Tarcanta, Inc., Tarcanta, Ltd. and CIMAB, S.A.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to CancerVax Corporation s Form 10-Q filed with the Securities and Exchange Commission on December 11, 2003.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the Securities and Exchange Commission.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of CancerVax Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

(b) Reports on Form 8-K

None.

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SIGNATURES

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

Dated: August 13, 2004

CancerVax Corporation

By: /s/ William R. LaRue

William R. LaRue
Senior Vice President and
Chief Financial Officer
(Duly authorized Officer and Principal Financial Officer)