CANCERVAX CORP
Form 10-Q
August 13, 2004

Table of Contents

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

TABLE OF CONTENTS

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

	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.

Table of Contents

	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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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, r