CANCERVAX CORP
Form 10-Q
December 11, 2003

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 September 30, 2003

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. [ ] Yes [X] 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 December 1, 2003 was 26,735,687.

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION
Item 1. Financial Statements
Condensed Consolidated Balance Sheets
Condensed Consolidated Statements of Operations
Condensed Consolidated Statements of Cash Flows
Notes to the Condensed Consolidated Financial Statements
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations
Item 3. Quantitative and Qualitative Disclosures About Market Risk
Item 4. Controls and Procedures
PART II OTHER INFORMATION
Item 2. Changes in Securities and Use of Proceeds
Item 4. Submission of Matters to a Vote of Security Holders
Item 6. Exhibits and Reports on Form 8-K
SIGNATURES
EXHIBIT 3.01
EXHIBIT 3.02
EXHIBIT 31.1
EXHIBIT 31.2
EXHIBIT 32

Table of Contents

CANCERVAX CORPORATION

FORM 10-Q QUARTERLY REPORT
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003

TABLE OF CONTENTS

		Page No
PART I	**FINANCIAL INFORMATION**	
Item 1	Financial Statements	
	Condensed Consolidated Balance Sheets as of September 30, 2003 (unaudited) and December 31, 2002	3
	Condensed Consolidated Statements of Operations (unaudited) for the three and nine month periods ended September 30, 2003 and 2002	4
	Condensed Consolidated Statements of Cash Flows (unaudited) for the nine month periods ended September 30, 2003 and 2002	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2	Management s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3	Quantitative and Qualitative Disclosure about Market Risk	32
Item 4	Controls and Procedures	32
PART II	**OTHER INFORMATION**	
Item 2	Changes in Securities and Use of Proceeds	34
Item 4	Submission of Matters to a Vote of Security Holders	35
Item 6	Exhibits and Reports on Form 8-K	35
SIGNATURES		37

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

CancerVax Corporation
Condensed Consolidated Balance Sheets

	September 30, 2003	December 31, 2002	Pro Forma Redeemable Convertible Preferred Stock and Stockholders Equity at September 30, 2003
	(Unaudited)		(Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 45,950,062	$ 26,082,735	
Securities available-for-sale	6,419,689	10,117,513	
Other current assets	97,627	133,303	
Total current assets	52,467,378	36,333,551	
Property and equipment, net	10,310,332	10,844,774	
Goodwill	5,381,147	5,381,147	
Intangibles, net	558,173	587,940	
Other assets	1,518,181	489,215	
Restricted cash, long-term	1,550,000	1,550,000	
Total assets	$ 71,785,211	$ 55,186,627	
Liabilities and stockholders equity (deficit)			
Current liabilities:			
Accounts payable and accrued liabilities	$ 5,084,331	$ 3,907,811	
Current portion of long-term debt	6,023,092	2,960,182	
Total current liabilities	11,107,423	6,867,993	
Long-term debt, net of current portion	2,593,437	7,379,249	
Deferred rent	273,506	236,079	
Redeemable convertible preferred stock, $.00004 par value; 56,364,254 and 35,791,465 shares authorized at September 30, 2003 and December 31, 2002, respectively; 55,727,829 and 35,155,040 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively; no shares outstanding pro forma (unaudited)	144,638,280	96,581,528	$
Stockholders equity (deficit):			
Convertible preferred stock, $.00004 par value; 31,579,187 shares authorized at September 30, 2003 and December 31, 2002, respectively; 27,188,877 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively; no shares outstanding pro forma (unaudited)	1,087	1,087	
Common stock, $.00004 par value; 105,000,000 and 80,000,000 shares authorized at September 30, 2003 and	24	20	828

December 31, 2002, respectively; 601,266 and 495,684 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively; 20,708,143 shares outstanding pro forma (unaudited)			
Additional paid-in capital	34,455,214	14,408,517	179,093,777
Unrealized gain (loss) on securities available-for-sale	13,395	(42,796)	13,395
Deferred compensation	(4,247,087)	(1,267,586)	(4,247,087)
Accumulated deficit	(117,050,068)	(68,977,464)	(117,050,068)
Total stockholders equity (deficit)	(86,827,435)	(55,878,222)	$ 57,810,845
Total liabilities and stockholders equity (deficit)	$ 71,785,211	$ 55,186,627	

See accompanying notes.

Table of Contents

CancerVax Corporation
Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
Operating expenses:				
Research and development	$ 7,165,723	$ 6,151,321	$ 19,374,329	$ 17,764,076
General and administrative	1,756,783	1,674,602	4,901,065	5,256,475
Amortization of employee stock-based compensation	984,632	355,687	1,779,148	1,125,709
Purchased in-process research and development				2,840,000
Total operating expenses	9,907,138	8,181,610	26,054,542	26,986,260
Other income (expense):				
Interest income	112,193	210,975	332,157	533,857
Interest expense	(218,011)	(142,049)	(707,165)	(388,439)
Total other income (expense)	(105,818)	68,926	(375,008)	145,418
Net loss	(10,012,956)	(8,112,684)	(26,429,550)	(26,840,842)
Accretion to redemption value of redeemable convertible preferred stock	(2,568,764)	(2,149,645)	(6,868,053)	(5,485,763)
Deemed dividend-beneficial conversion feature for Series C preferred stock	(14,775,003)		(14,775,003)	
Net loss applicable to common stockholders	$(27,356,723)	$(10,262,329)	$(48,072,606)	$(32,326,605)
Basic and diluted net loss per share	$ (57.14)	$ (32.46)	$ (113.33)	$ (124.87)
Shares used to compute basic and diluted net loss per share	478,797	316,138	424,184	258,881
Pro forma basic and diluted net loss per share	$ (1.35)	$ (0.52)	$ (2.47)	$ (1.90)
Pro forma shares used in computing basic and diluted net loss per share	18,349,501	15,722,183	16,677,516	14,098,517
The allocation of employee stock-based compensation is as follows:				
Research and development	$ 332,369	$ 87,768	$ 568,108	$ 306,335
General and administrative	652,263	267,919	1,211,040	819,374

$ 984,632	$ 355,687	$ 1,779,148	$ 1,125,709

See accompanying notes.

Table of Contents

CancerVax Corporation
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,	
	2003	**2002**
Operating activities		
Net loss	$(26,429,550)	$(26,840,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of employee stock-based compensation	1,779,148	1,125,709
Interest expense for the warrants issued in conjunction with debt	69,712	23,050
Amortization of premium/discount on securities available-for-sale	128,449	4,751
Interest receivable on securities available-for-sale	89,301	(31,674)
Compensation expense for stock options and warrants to consultants	116,557	27,378
Depreciation	1,391,518	1,008,955
Amortization of intangibles	186,116	152,932
Purchased in-process research and development		2,840,000
Deferred rent	37,427	60,264
Changes in operating assets and liabilities:		
Other current assets	(851,490)	(130,771)
Accounts payable and accrued liabilities	1,176,520	226,933
Net cash used in operating activities	(22,306,292)	(21,533,315)
Investing activities		
Cash paid for Cell-Matrix acquisition		(221,756)
Purchases of property and equipment	(857,076)	(4,096,738)
Purchases of securities available-for-sale	(2,942,481)	(5,131,466)
Proceeds from sale of securities available-for-sale	6,478,745	
Purchases of intangibles	(156,349)	(159,093)
Restricted cash		578,000
Net cash provided by (used in) investing activities	2,522,839	(9,031,053)
Financing activities		
Proceeds from notes payable	462,339	
Principal payments on notes and capital leases	(2,060,241)	(686,987)
Proceeds from exercise of stock options	184,981	180,015
Payment of installment obligation	(125,000)	(125,000)
Proceeds from sale of preferred stock, net of issuance costs	41,188,701	55,594,814
Net cash provided by financing activities	39,650,780	54,962,842
Increase (decrease) in cash and cash equivalents	19,867,327	24,398,474
Cash and cash equivalents at beginning of period	26,082,735	10,102,993
Cash and cash equivalents at end of period	$ 45,950,062	$ 34,501,467
Supplemental schedule of non-cash investing and financing activities:		
Series A redeemable convertible preferred stock issuable	$	$ 644,999
Acquisitions (cancellations) of equipment purchased through capital leases	$	$ (59,695)
Stock issued in conjunction with Cell-Matrix acquisition	$	$ 5,721,418

Issuance of warrants in connection with lease facility, equipment loans and consulting agreement	$ 245,364	$ 295,983
Unrealized gain (loss) on securities available-for-sale	$ 56,191	$ (7,664)
Accretion to redemption value of redeemable convertible preferred stock	$ 6,868,053	$ 5,485,763
Deemed dividend-beneficial conversion feature for Series C preferred stock	$ 14,775,003	$

See accompanying notes.

Table of Contents

CancerVax Corporation
Notes to the Condensed Consolidated Financial Statements
(Unaudited)

1. The Company

CancerVax Corporation (the Company) is focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. The Company s lead product candidate, Canvaxin , is in two international Phase 3 clinical trials for the treatment of advanced-stage melanoma. In addition, the Company is developing a pipeline of products based upon its proprietary specific active immunotherapy and anti-angiogenesis technology platforms, as well as human monoclonal antibodies. The Company has a biologics manufacturing facility that produces Canvaxin for use in clinical trials and will be used to produce commercial quantities of Canvaxin, if any. The Company also has collaborations with both private and academic institutions.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company s wholly owned subsidiary, Cell-Matrix, Inc. (Cell-Matrix). These statements have been prepared in accordance with accounting principles generally accepted in the United States of America and with the rules and regulation of the Securities and Exchange Commission related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. All intercompany accounts and transactions have been eliminated in consolidation. The interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature.

Operating results for the three and nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2003. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2002 included in the Prospectus filed by the Company pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), relating to the Registration Statement on Form S-1, as amended (File No. 333-107993), with the Securities and Exchange Commission on October 30, 2003.

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

3. Pro Forma Stockholders Equity

Upon completion of the Company s initial public offering on November 4, 2003, all shares of Redeemable Convertible Preferred Stock and Convertible Preferred Stock (collectively, the Preferred Stock) outstanding at September 30, 2003 automatically converted into 20,106,877 shares of common stock. The unaudited pro forma Redeemable Convertible Preferred Stock and stockholders equity at September 30, 2003 reflects the effect of the Preferred Stock conversion.

4. Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in stockholders equity that are excluded from net income (loss), specifically unrealized gains and losses on securities available-for-sale. For the three months ended September 30, 2003 and 2002, the comprehensive loss was $10.0 million and $8.1 million, respectively. For the nine months ended September 30, 2003 and 2002, the comprehensive loss was $26.4 million and $26.8 million, respectively.

5. Stock-Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations in accounting for its employee stock options. Under APB 25, if the exercise price of the Company s employee and director stock options is less than the estimated fair value of the underlying stock on the date of grant, the Company records deferred compensation for the difference. In conjunction with the Company s initial public offering, which was completed on November 4, 2003, the Company reviewed its historical exercise prices through September 30, 2003 and, as a result, revised the estimate of fair value for all stock options granted in March 2002 and between April 30, 2003 and September 30, 2003.

Table of Contents

With respect to these options granted, deferred stock-based compensation of $5.0 million and $2.7 million was recorded as a component of stockholders equity for the nine months ended September 30, 2003 and 2002, respectively, for the difference between the original exercise price per share and the revised estimate of fair value per share at the respective grant dates. The deferred stock-based compensation is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation (FIN) No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options, generally four years. The Company recorded stock-based compensation expense related to employees of $985,000 and $356,000 for the three months ended September 2003 and 2002, respectively, and $1.8 million and $1.1 million for the nine months ended September 2003 and 2002, respectively.

Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation,* and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services,* and are periodically revalued as the options vest and are recognized as expense over the related service period. The Company granted stock options to non-employees as follows: 55,682 in 2000, 12,386 in 2001, 1,136 in 2002 and 2,272 for the nine months ended September 30, 2003. Compensation expense related to the non-employee stock option grants was $83,000 and $27,000 for the nine months ended September 30, 2003 and 2002, respectively. The options were valued using the following weighted-average assumptions for the nine months ended September 30, 2003 and 2002: risk-free interest rates of 3.54% and 4.79%, respectively; dividend yield of 0% for both periods; expected volatility of 70% for both periods; and contractual term of 7.78 and 8.78 years, respectively.

As required under SFAS No. 123 and newly issued SFAS No. 148, *Accounting for Stock-based Compensation-Transition and Disclosure*, the pro forma effects of stock-based compensation on net loss and net loss per common share are estimated at the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because the Company s employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The fair value of these options was estimated at the date of grant using the Black-Scholes option valuation model based on the following weighted average assumptions for the three months ended September 30, 2003 and 2002 and the nine months ended September 30, 2003 and 2002: risk free interest rates of 2.74%, 3.91%, 2.35% and 3.80%, respectively; a dividend yield of 0% for all periods; expected volatility of 70% for all periods; and a weighted average expected life of the options of 4.27, 5.00, 4.80 and 4.98 years, respectively. The estimated weighted average fair value of stock options granted for the three months ended September 30, 2003 and 2002 and the nine months ended September 30, 2003 and 2002 was $9.19, $1.99, $6.98 and $1.93, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period of the related options. The Company s pro forma information follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss applicable to common stockholders as reported	$(27,356,723)	$(10,262,329)	$(48,072,606)	$(32,326,605)
Pro forma net loss applicable to common stockholders	$(27,743,994)	$(10,536,077)	$(48,755,631)	$(32,873,282)
Basic and diluted net loss per share as reported	$ (57.14)	$ (32.46)	$ (113.33)	$ (124.87)
Pro forma basic and diluted net loss per share	$ (57.95)	$ (33.33)	$ (114.94)	$ (126.98)

6. Net Loss Per Share

The Company calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share (EPS) is calculated by dividing the net income or loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income or loss by the weighted average number of

common shares equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, Preferred Stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive. Potentially dilutive securities totaled 22,445,602 and 21,614,389 for the nine-months ended September 30, 2003 and 2002,

Table of Contents

respectively. The Company incurred net losses for the three and nine months ended September 30, 2003, and accordingly did not assume exercise or conversion of any of the common stock equivalents because to do so would be anti-dilutive.

The unaudited pro forma shares used to compute basic and diluted net loss per share represent the weighted average common shares outstanding, reduced by the weighted average unvested common shares subject to repurchase, and including the assumed conversion of all outstanding shares of Preferred Stock into shares of common stock using the as-if converted method as of the date of issuance.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Historical:				
Numerator:				
Net loss	$(10,012,956)	$ (8,112,684)	$(26,429,550)	$(26,840,842)
Accretion to redemption value of redeemable convertible preferred stock	(2,568,764)	(2,149,645)	(6,868,053)	(5,485,763)
Deemed dividend - beneficial conversion feature for Series C preferred stock	(14,775,003)		(14,775,003)	
Net loss applicable to common stockholders	$(27,356,723)	$(10,262,329)	$(48,072,606)	$(32,326,605)
Denominator:				
Weighted average common shares	590,339	496,287	545,997	460,371
Weighted average unvested common shares subject to repurchase	(111,542)	(180,149)	(121,813)	(201,490)
Denominator for basic and diluted earnings per share	478,797	316,138	424,184	258,881
Basic and diluted net loss per share	$ (57.14)	$ (32.46)	$ (113.33)	$ (124.87)
Pro forma:				
Numerator:				
Net loss used above	$(10,012,956)	$ (8,112,684)	$(26,429,550)	$(26,840,842)
Deemed dividend - beneficial conversion feature for Series C preferred stock	(14,775,003)		(14,775,003)	
Pro forma net loss applicable to common stockholders	$(24,787,959)	$ (8,112,684)	$(41,204,553)	$(26,840,842)
Denominator:				
Shares used above	478,797	316,138	424,184	258,881
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock	17,870,704	15,406,045	16,253,332	13,839,636

Pro forma shares used to compute basic and diluted net loss per share	18,349,501	15,722,183	16,677,516	14,098,517
Pro forma basic and diluted net loss per share	$ (1.35)	$ (0.52)	$ (2.47)	$ (1.90)

7. Related Party Transactions

The Company was founded in 1998 by Donald L. Morton, M.D. (Dr. Morton), who is currently Medical Director and Surgeon-in-Chief of the John Wayne Cancer Institute (JWCI), a cancer research institute located in Santa Monica, California. In 1998, OncoVac, Inc. (OncoVac), which is wholly owned by Dr. Morton and was previously named CancerVax, Inc., cross-licensed from JWCI the rights to patents and patent applications, cell banks and manufacturing know-how. In July 2000, OncoVac assigned all of its rights and obligations under the cross-license agreement to the Company. Under the cross-license agreement, the Company committed to issue to JWCI a specified ownership interest in the Company and pay upfront and periodic payments aggregating $1,250,000. In August 2000, the Company satisfied its ownership commitment to JWCI by issuing JWCI 284,090 shares of common stock. In accordance with SAB No. 48, *Transfer of Nonmonetary Assets by Promoters or Shareholders*, JWCI, Dr. Morton and companies owned by Dr. Morton are considered to be founders or promoters. Accordingly, no value has been ascribed to the

Table of Contents

technology acquired upon the formation of the Company in 1998 or upon the assignment of the cross-license agreement to the Company during 2000, as the carrying value of the assets acquired was zero.

Under the cross-license agreement, the Company made a $500,000 payment to JWCI and committed to make six annual installments of $125,000 beginning in 2001 through 2006 and such installment amount (aggregating $750,000) was recorded as an installment payable at December 31, 2000. In June 2001, June 2002 and June 2003 the Company paid the first three installments reducing the aggregate balance to $375,000 at September 30, 2003 (Note 8). There are no further milestone payments that could be due under the agreement, but the Company is obligated to pay JWCI a specified percentage of the initial net royalties, if any, up to a maximum amount, which the Company receives on sales by its sublicensees of Canvaxin. In the event that the specified amount of net royalties are paid to JWCI, the Company would then be obligated to pay to JWCI a specified royalty on net sales, if any, of Canvaxin to third parties by the Company, its sublicensees and affiliates. The $1,250,000 cash and installment payable were expensed in 2000 pursuant to SFAS No. 2, *Accounting for Research and Development Costs*, as ultimate commercialization of the Company s lead product candidate, Canvaxin, was uncertain and the technology had no alternative uses.

In July 2000, the Company entered into three agreements with OncoVac, whereby the Company issued 408,163 shares of Series A Preferred Stock in December 2000, for the assignment of the cross license agreement with JWCI, the assignment of a supply agreement with Organon Teknika Corporation and a trademark assignment. In accordance with SAB No. 48, no value was assigned to the assets acquired or the shares of Series A Preferred Stock because Dr. Morton s carrying value of the assets acquired was zero.

In July 2000, the Company entered into an agreement with Cancer Diagnostics Laboratories, Inc., which is also controlled by Dr. Morton, under which the Company obtained 20 cell lines and licenses to patent rights and related technology in exchange for an obligation to pay $750,000. The $750,000 payment was made in December 2000 and was recorded as an intangible asset because the Company plans to use this acquired technology in research and development related to new biological product candidates for the treatment of cancer. The acquired technology is being amortized over a period of four years. The Company also assumed Cancer Diagnostics Laboratories obligation to pay to the party from whom Cancer Diagnostic Laboratories originally acquired the 20 cell lines a royalty of up to 2% of net sales of any vaccines that include those cell lines.

In preparation for the sale of the Series A Preferred Stock, on December 5, 2000, the Company effected a reorganization and its outstanding common stock was exchanged for Junior Preferred Stock. As a result of this reorganization, 5,973,066 shares of common stock were exchanged for 26,281,500 shares of Junior Preferred Stock, including the shares of common stock held by Dr. Morton and JWCI.

In December 2000, the Company entered into a contribution of technology and exchange agreement with Dr. Morton, under which the Company acquired three cell lines that comprise the Company s lead product candidate, Canvaxin, for a cash payment of $550,000. In 2000, the $550,000 payment was included in research and development expense because the acquired assets are being used in the Company s principal research activities associated with Canvaxin and the acquired assets have no alternative uses. In addition, the Company acquired patent rights and other property, for which 3,673,469 shares of Junior Preferred Stock held by Dr. Morton were converted into 3,673,469 shares of Series A Preferred Stock. No value was assigned to the conversion of shares because the transaction involved the Company s majority stockholder and did not result in a change in his relative control of the Company.

In December 2000, the Company entered into a consulting agreement with Dr. Morton. This agreement, and Dr. Morton s obligation not to compete with the Company, expires in December 2004. Under the terms of the agreement, the Company is obligated to pay Dr. Morton $150,000 per year. Dr. Morton is required to provide consulting services for the Company to develop and commercialize Canvaxin and other product candidates, as well as to consult on medical and technical matters as requested. Dr. Morton is not required to devote more than 33 business days to the Company in any 12-month period.

In July 2001, the Company entered into a clinical trial services agreement with JWCI, under which the Company agreed to reimburse JWCI for all approved payments to clinical trial study sites that are not covered by National Cancer Institute (NCI) grants. In addition, the Company agreed to reimburse JWCI for expenses and disbursements actually incurred up to $5,000 per month, plus a 25% administrative fee on specified expenses. The Company also agreed to pay JWCI $25,000 per year during the time period when payments to the clinical trial study sites are covered by the National Cancer Institute grants and $50,000 per year thereafter, or such greater amounts incurred by JWCI in connection with the Phase 3 clinical trials. In July 2002, the services agreement was amended, pursuant to which the Company became obligated to directly reimburse the clinical trial study sites for all approved payments that are not covered by NCI grants. JWCI remains obligated to reimburse the clinical trial study sites for all approved payments for which NCI grants are available. The Company is responsible for compliance with the payment terms of the agreements with the various clinical trial study sites regardless of the amount of NCI grant funds available. Reimbursements to JWCI by the Company under the services agreement amounted to $57,200 and $119,400 for the nine months ended September 30, 2003 and 2002, respectively. Reimbursements to the clinical trial study sites by JWCI under the services agreement terms amounted to $145,400 and $395,400 for the nine months ended September 30, 2003 and 2002, respectively. As of September 30, 2003 a liability of $199,000 was

9

Table of Contents

included in accounts payable for current approved payments owed to the clinical trial study sites, of which $13,700 will be reimbursed by JWCI.

For the nine months ended September 30, 2003 and 2002, the Company also reimbursed JWCI $353,900 and $293,000, respectively, primarily for assays and the installment obligation. The Company has included such costs in operating expenses or the reduction of installment payables and as of September 30, 2003 and 2002, a liability of $48,200 and $103,400, respectively, to JWCI was included in accounts payable and accrued liabilities.

8. Debt

Debt consisted of the following (which is representative of fair value):

	September 30, 2003	December 31, 2002
Notes payable	$ 5,543,410	$ 7,216,167
Note payable to related parties	2,698,119	2,615,791
Installment obligations	375,000	500,000
Capital lease obligations		7,473
	8,616,529	10,339,431
Current portion of debt	(6,023,092)	(2,960,182)
Long-term debt, less current portion	$ 2,593,437	$ 7,379,249

Note Payable

During 2001, the Company entered into a $4,000,000 loan and security agreement with a financial institution to fund the purchase of certain capital expenditures. As the credit facility was fully utilized, separate promissory notes were executed. Each promissory note has monthly payments ranging from 36 to 42 months with the interest rate being fixed at the funding date of each promissory note (9.34% to 10.41%). Each promissory note is collateralized by the related equipment acquired with the loan. In conjunction with these promissory notes, the Company issued warrants to purchase 65,306 shares of Vendor Preferred Stock, Series 1, with an exercise price of $2.45 per share.

During 2002, the Company entered into a $6,000,000 loan and security agreement with a financial institution to fund the purchase of eligible equipment and tenant improvements. As the credit facility was utilized, separate promissory notes were executed. As of December 31, 2002 and September 30, 2003, a total of $4,901,000 and $5,363,000 respectively, was borrowed by the Company under the credit facility. Each promissory note has payments ranging from 30 to 38 months with the interest rate being fixed at the funding date of each promissory note (8.58% to 14.04%). Each promissory note is collateralized by the related equipment or tenant improvements. In conjunction with these promissory notes, the Company issued warrants to purchase 151,685 shares of Vendor Preferred Stock, Series 2, with an exercise price of $2.67 per share. The credit facility terminated on September 30, 2003.

Annual principal payments due on the equipment and tenant improvements notes payable are as follows at December 31, 2002:

2003	$2,827,710
2004	3,157,252
2005	1,205,918
2006	25,287
Total	$7,216,167

Notes Payable to Related Parties

In connection with the acquisition of Cell-Matrix in January 2002, the Company assumed a $2,000,000 and a $500,000 note payable between Cell-Matrix and certain parties who became stockholders of the Company. The notes and accrued interest become due and payable upon the earlier of one year after the closing of a firm commitment underwritten public offering, or January 2004. As of September 30, 2003, the outstanding loan balance has been classified as a current liability. The notes bear interest at prime and the $2,000,000 note is secured by Cell-Matrix s assets.

Table of Contents

9. Series C Preferred Stock Financing

In August 2003, the Company sold 20,572,789 shares of Series C Redeemable Convertible Preferred Stock at a purchase price of $2.01 per share for total proceeds of $41.2 million, net of $164,000 of offering costs.

The Series C preferred stock, adjusted for the 1-4.4 reverse stock split, would have equated to a common stock price of $8.84 per share. This price per share was below the initial public offering price (Note 12). Accordingly, pursuant to EITF 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, the Company recorded a non-cash deemed dividend on the Series C preferred stock of $14.8 million, which is equal to the number of shares of Series C preferred stock sold times the difference between the initial public offering price and the Series C preferred stock price per share. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share but did not have any effect on total stockholders equity.

10. Reverse Stock Split

On September 10, 2003, the Company s Board of Directors approved a 1-for-4.4 reverse stock split of the then-outstanding common stock. The 1-for-4.4 reverse stock split was approved by the Company s stockholders on October 9, 2003. The accompanying financial statements give retroactive effect to the reverse stock split for all periods presented.

11. Effect of New Accounting Standards

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.* SFAS No. 148 is an amendment to SFAS No. 123 providing alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and also provides additional disclosures about the method of accounting for stock-based employee compensation. Amendments are effective for financial statements for the Company beginning January 1, 2003. The Company has currently chosen not to adopt the voluntary change to the fair value based method of accounting for stock-based employee compensation. If the Company chooses to adopt such a method, its implementation pursuant to SFAS No. 148 would have a material effect on the Company s consolidated results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity.* SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective the beginning of the first interim period after June 15, 2003. The adoption of SFAS 150 did not have a material impact on the Company s consolidated financial statements.

12. Subsequent Event Initial Public Offering

On November 4, 2003, the Company completed an initial public offering of 6,000,000 shares of common stock at $12.00 per share raising estimated net proceeds of $65.3 million, net of underwriting discounts and offering expenses. Upon completion of the initial public offering, all outstanding shares of the Company s Redeemable Convertible Preferred Stock and Convertible Preferred Stock automatically converted into an aggregate of 20,106,877 shares of common stock.

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, 2002 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission on October 30, 2003.

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 more than 65 sites internationally 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, and we are finalizing the design of a Phase 2 clinical trial for patients with Stage III colorectal cancer.

In addition to Canvaxin, we have a number of product candidates in research and preclinical development, including a specific active immunotherapy product candidate for lung cancer and three humanized monoclonal antibodies, three human antibodies and six peptides that target various solid tumor cancers. We also plan to identify and develop new product candidates based on our proprietary specific active immunotherapy platform, our anti-angiogenesis technology platform and other technologies.

We were incorporated in Delaware in June 1998 and have incurred net losses since inception. As of September 30, 2003, our accumulated deficit was approximately $117.1 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 specific active immunotherapy product candidate, Canvaxin;
- scale up our manufacturing operations and quality systems;
- advance our preclinical anti-angiogenesis and human monoclonal antibody product candidates into clinical development;
- 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. As of September 30, 2003, we have funded our operations primarily through the private placement of equity securities as well as through equipment and leasehold improvement financing. In addition, on November 4, 2003, we completed an initial public offering which raised estimated net proceeds of $65.3 million, net of underwriting discounts and offering expenses.

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 abroad. Our agreements with collaborators may include joint marketing or promotion arrangements. Alternatively, we may grant exclusive marketing rights to our collaborators in exchange for up-front fees, milestones and royalties on future sales, if any. We manufacture Canvaxin at our biologics manufacturing facility, which we believe has the capacity to satisfy commercial demand for several years after the initial launch of Canvaxin, if any.

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 and uncertainties associated with obtaining and enforcing patent rights.

In January 2002, we completed the acquisition of Cell-Matrix, Inc., a private company focused on developing products and technologies in the field of angiogenesis, in a transaction accounted for as a purchase. In connection with the acquisition of Cell-Matrix, we paid cash of $118,402, assumed $2.5 million of notes payable and issued shares of our acquisition preferred stock valued

Table of Contents

at approximately $5.7 million, which converted into 487,012 shares of our common stock upon completion of our initial public offering on November 4, 2003. The operating results of Cell-Matrix are included in our results of operations commencing as of the date of acquisition. Upon completing the acquisition, the Company recorded goodwill of $5.4 million and a charge for purchased in-process research and development of $2.8 million.

Research and Development

Our research and development expenses consist primarily of costs associated with the clinical trials of our product candidate, Canvaxin, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, 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 preclinical development of product candidates based on our proprietary specific active immunotherapy and anti-angiogenesis technology platforms. We are also developing several human monoclonal antibodies that target various solid tumor cancers.

From our inception through September 30, 2003, we incurred costs of approximately $59.6 million associated with the research and development of Canvaxin, representing over 97% of our research and development expenses for all program areas. While difficult to predict, we estimate that the completion of the Phase 3 clinical trials for advanced-stage melanoma will cost at least an additional $85.0 million. We are unable to estimate with any certainty the costs we will incur in the continued development of our other product candidates for commercialization. However, we expect our research and development costs to increase as we continue to develop new applications for our proprietary specific active immunotherapy technology, 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.

Product candidate completion dates and completion costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of clinical development and seeking regulatory approvals, and the requirement that we comply with applicable regulations during this process and subsequently, require the expenditure of substantial resources. 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. If we obtain the requisite regulatory approvals of Canvaxin, we anticipate launching the product candidate in the United States and Europe in 2006. Our projected launch date for Canvaxin in 2006 is dependent upon the FDA s acceptance of a positive result in one of our two ongoing Phase 3 clinical trials as sufficient for marketing approval. Although the FDA typically requires successful results in two Phase 3 clinical trials to support marketing approval, the FDA has, on a number of occasions, approved products based on a single Phase 3 clinical trial that demonstrates a high level of statistical significance where there is an unmet need for a life-threatening condition. In the event that the FDA requires the results of a second Phase 3 clinical trial before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin would be delayed. We cannot be certain when any net cash inflow from Canvaxin or any of our other development projects will commence.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States and with the rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis. 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 basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policy to be critical to the judgments and estimates used in the preparation of our consolidated financial statements:

Valuation of Goodwill, Intangibles and Other Long-Lived Assets. We are required to periodically assess the impairment of goodwill, intangibles and other long-lived assets which requires us to make assumptions and judgments regarding the carrying value

13

Table of Contents

of these assets. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

a determination that the carrying value of such assets can not be recovered through undiscounted cash flows;

loss of legal ownership or title to the assets;

significant changes in our strategic business objectives and utilization of the assets; or

the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the useful life of the assets. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

Results Of Operations

Comparison of the Three Months Ended September 30, 2003 and 2002

Research and Development Expenses. We generally classify our research and development expenses into three project areas: our specific active immunotherapy platform, including Canvaxin, our anti-angiogenesis platform and our human monoclonal antibody program. The costs related to the continuing development of Canvaxin constitute the majority of our research and development expenses for the three months ended September 30, 2003 and 2002.

Research and development expenses were $7.2 million for the third quarter 2003 compared with $6.2 million for the respective period in 2002. The $1.0 million increase reflects several factors, including new hires in the clinical affairs, quality and research departments, and increased operating costs associated with our Phase 3 clinical trials of Canvaxin due to increased patient enrollment. Excluded from research and development expenses for the three months ended September 30, 2003 and 2002 was $333,000 and $88,000, respectively, of non-cash employee stock-based compensation, which is reported under a separate caption.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and benefits for administrative, finance, business development, human resources, legal and internal systems support personnel. In addition, general and administrative expenses include insurance costs, professional services and facilities costs. General and administrative expenses were $1.8 million for the three months ended September 30, 2003 compared with $1.7 million for the respective period in 2002. The $0.1 million increase is primarily due to a general increase in compensation costs. Excluded from general and administrative expenses for the three months ended September 30, 2003 and 2002 was $652,000 and $268,000, respectively, of non-cash employee stock-based compensation, which is reported under a separate caption.

Amortization of Employee Stock-Based Compensation. In connection with the grant of stock options to employees and directors, we recorded deferred stock-based compensation of $560,000 for the three months ended September 30, 2003. The $560,000 represents the difference between the exercise price and the estimated fair value of the underlying common stock on the date the options were granted. We recorded the $560,000 as a component of stockholders equity and will amortize the amount, on an accelerated basis, as a non-cash charge to operations over the vesting period of the options. There was no deferred stock-based compensation for the three months ended September 30, 2002. We recorded amortization of deferred stock-based compensation of $985,000 and $356,000 for the three months ended September 30, 2003 and 2002, respectively. The $629,000 increase is due to the additional grant of stock options to employees and directors in May through September of 2003 that contained exercise prices that were below our revised estimated fair value of our common stock. As of September 30, 2003, we had $4.2 million of deferred stock-based compensation. We anticipate recording amortization of deferred compensation expense of approximately $886,000, $2.0 million, $956,000, $346,000 and $35,000 for the three months ended December 31, 2003 and the years ended December 31, 2004, 2005, 2006 and 2007, respectively.

Interest Income. Interest income was $112,000 for the three months ended September 30, 2003 compared with $211,000 for the respective period in 2002, a decrease of $99,000. The decrease was primarily due to lower average cash and investment balances and lower prevailing interest rates during 2003.

Interest Expense. Interest expense was $218,000 for the three months ended September 30, 2003 compared with $142,000 for the respective period in 2002, an increase of $76,000. The increase was primarily due to our increased debt balances that were incurred during the second half of 2002 related to the purchase of equipment and leasehold improvements.

Table of Contents

Net Loss Applicable to Common Stockholders. Net loss applicable to common stockholders for the three months ended September 30, 2003 was $27.4 million, or $57.14 per share, compared to $10.3 million, or $32.46 per share, for the respective period in 2002. The increase in the net loss applicable to common stockholders is primarily a result of a deemed dividend on the beneficial conversion of our Series C preferred stock of approximately $14.8 million. The deemed dividend was a result of the Series C preferred stock being sold at a price per share below the initial public offering price. The sale of the Series C preferred stock occurred in August 2003.

Comparison of the Nine Months Ended September 30, 2003 and 2002

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2003 were $19.4 million compared with $17.8 million for the respective period in 2002. The expenses are associated with our three main research and development programs, our specific active immunotherapy platform, including Canvaxin, our anti-angiogenesis platform and our human monoclonal antibody program. The costs related to the continuing development of Canvaxin constitute the majority of our research and development expenses for the nine months ended September 30, 2003 and 2002.

The $1.6 million increase in our research and development expenses for the nine months ended September 30, 2003 as compared to nine months ended September 30, 2002 reflects several factors, including new hires in the clinical affairs, quality and research departments, higher manufacturing expenses for our lead product candidate, Canvaxin, due to the resumption of patient enrollment in our Phase 3 clinical trials, and an increase in facility costs due to our relocation into a new corporate headquarters and research and development facility, which has higher monthly operating expenses than the previous locations. Excluded from research and development expenses for the nine months ended September 30, 2003 and 2002, was $568,000 and $306,000, respectively, of non-cash employee stock-based compensation which is reported under a separate caption.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2003 were $4.9 million compared with $5.3 million for the respective period in 2002. The $0.4 million decrease in expenses was primarily due to legal and accounting fees associated with a discontinued financing in 2002. Excluded from general and administrative expenses for the nine months ended September 30, 2003 and 2002 was $1.2 million and $819,000, respectively, of non-cash employee stock-based compensation which is reported under a separate caption.

Amortization of Employee Stock-Based Compensation. In connection with the grant of stock options to employees and directors, we recorded deferred stock-based compensation of $5.0 million and $2.7 million for the nine months ended September 30, 2003 and 2002, respectively. The $5.0 million and the $2.7 million represents the difference between the exercise price and the estimated fair value of the underlying common stock on the date the options were granted. We recorded the $5.0 million and the $2.7 million as a component of stockholders equity and will amortize the amounts, on an accelerated basis, as a non-cash charge to operations over the vesting period of the options. We recorded amortization of deferred stock-based compensation of $1.8 million and $1.1 million for the nine months ended September 30, 2003 and 2002, respectively. The $0.7 million increase is due to the additional grant of stock options to employees and directors in May through September of 2003 that contained exercise prices that were below our revised estimated fair value of our common stock.

Purchased In-Process Research and Development. In connection with the Cell-Matrix acquisition in January 2002, and the related purchase price allocation, we recorded an expense of $2.8 million in the first quarter of 2002, representing the write-off of the fair value of acquired in-process research and development that had not reached technological feasibility and had no alternative future use. The principal technology acquired related to anti-angiogenic monoclonal antibodies and peptides that were in the process of being developed. The fair value of each of the in-process research and development projects was based on a cost approach that attempts to estimate the cost of replicating the technology, including outside contracted services, the level of full-time employees and lab supplies that would be required in the development effort, net of tax.

Interest Income. Interest income for the nine months ended September 30, 2003 was $332,000 compared with $534,000 for the respective period in 2002, a decrease of $202,000. The decease was due to lower average cash and investment balances and lower prevailing interest rates during 2003.

Interest Expense. Interest expense for the nine months ended September 30, 2003 was $707,000 compared with $388,000 for the respective period in 2002, an increase of $319,000. The increase was primarily due to our increased debt balances that were incurred during the second half of 2002 related to the purchase of equipment and leasehold improvements.

Net Loss Applicable to Common Stockholders. Net loss applicable to common stockholders for the nine months ended September 30, 2003 was $48.1 million, or $113.33 per share, compared to $32.3 million, or $124.87 per share, for the same period in 2002. The increase in the net loss applicable to common stockholders is primarily a result of a deemed dividend on the beneficial conversion of our Series C preferred stock of approximately $14.8 million. The deemed dividend was a result of the Series C

15

Table of Contents

preferred stock being sold at a price per share below the initial public offering price. The sale of the Series C preferred stock occurred in August 2003. The decrease in the net loss per share, $113.33, for the nine months ended September 30, 2003, compared to $124.87 net loss per share for the same period in 2002, results from the $15.8 million increase in net loss applicable to common stockholders, which was offset by the dilutive effect of an increased number of common shares outstanding in 2003 versus 2002.

Liquidity and Capital Resources

To date, we have funded our operations primarily through the sale of equity securities as well as through equipment and leasehold improvement financing. As of September 30, 2003, we had received approximately $131.5 million from the sale of equity securities. In addition, as of September 30, 2003, we had financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately $9.4 million, of which $5.5 million was outstanding at that date. These obligations are secured by the purchased equipment and leasehold improvements, bear interest at rates ranging from approximately 8.6% to 14.0% and are due in monthly installments through June 2006.

As of September 30, 2003, we had $52.4 million in cash and cash equivalents and securities available-for-sale as compared to $36.2 million as of December 31, 2002, an increase of $16.2 million. This increase resulted primarily from the proceeds of our Series C preferred stock issuance, with the offsetting decrease related to our operating loss and principal payments on notes and capital leases. In November 2003, we completed an initial public offering and raised an additional $65.3 million of cash proceeds, net of underwriting discounts and offering expenses.

Net cash used in operating activities was $22.3 million during the nine months ended September 30, 2003, compared to $21.5 million during the same period last year. The increase in net cash used in operating activities in 2003 compared to 2002 was primarily due to the increase in our operating expenses as we grew our research and development activities.

Net cash provided by investing activities was $2.5 million during the nine months ended September 30, 2003, compared to net cash used of $9.0 million for the same period last year. The increase in net cash provided by investing activities in 2003 compared to 2002 was primarily due to the spending in 2002 for leasehold improvements associated with our new corporate headquarters and research and development facility and purchases of securities available-for-sale.

Net cash provided by financing activities was $39.7 million during the nine months ended September 30, 2003, compared to $55.0 million for the same period last year. The decrease in net cash provided by financing activities in 2003 as compared to 2002 was primarily due to higher proceeds received from the sale of Series B preferred stock in March 2002, $55.6 million net of issuance costs versus proceeds from the sale of Series C preferred stock in August 2003, $41.2 million net of issuance costs.

We anticipate that we will have invested approximately $2.0 million through December 31, 2003 for leasehold improvements and capital equipment necessary to support our future growth.

The following summarizes our long-term contractual obligations as of December 31, 2002:

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1 to 3 Years**	**4 to 5 Years**	**After 5 Years**
			(In thousands)		
Operating leases	$21,655	$2,260	$4,752	$5,010	$ 9,633
Capital leases	8	8			
Mandatory license payments	1,208	154	389	120	545
Equipment financing	7,216	2,828	4,363	25	
Other contractual obligations	3,116	2,741	375		
Total	$33,203	$7,991	$9,879	$5,155	$10,178

We also enter into agreements with clinical trial sites for the conduct of our clinical trials. We make payments to clinical trial sites based upon the number of patients enrolled and the length of their participation in the trials. For the 12 months ended December 31, 2002 and the nine

months ended September 30, 2003, we had made aggregate payments of $1.8 million and $1.7 million, respectively, to clinical trial sites in connection with our Phase 3 clinical trials for our product candidate, Canvaxin. At this time, due to the variability associated with these agreements, we are unable to estimate with certainty the future patient enrollment costs we will incur.

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

Table of Contents

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 our product candidate, Canvaxin; and

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

We believe that our existing cash and cash equivalents, as well as proceeds from our initial public offering, will be sufficient to meet our projected operating requirements for up to 24 months.

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 other equity securities, as well as through strategic collaboration agreements and debt financing. However, we may not be successful in establishing 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.

As of September 30, 2003 and 2002, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties other than what is disclosed in Note 7 to the unaudited condensed consolidated financial statements included elsewhere in this filing.

Related Party Transactions

For a description of our related party transactions see Note 7 to the unaudited condensed consolidated financial statements included elsewhere in this filing.

Recent Accounting Pronouncements

In December 2002, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.* SFAS No. 148 is an amendment to SFAS No. 123 providing alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and also provides additional disclosures about the method of accounting for stock-based employee compensation. Amendments are effective for our consolidated financial statements beginning January 1, 2003. We have currently chosen not to adopt the voluntary change to the fair value based method of accounting for stock-based employee

Table of Contents

compensation. If we are required to adopt such a method, its implementation pursuant to SFAS No. 148 would have a material effect on our consolidated results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatorily redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on our consolidated financial statements.

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, intend, seek, plan, expect, should, or would. Among the factors that cou differ materially from those 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 approvals, 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 product 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 Prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission on October 30, 2003 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 Prospectus filed pursuant to Rule 424(b) under the Securities Act with the Securities and Exchange Commission on October 30, 2003.

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 stinging, itching and redness at the site of injection, flu-like symptoms and a decrease in energy. Side effects, such as allergic reactions, 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 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.

Table of Contents

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 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.

Our projected launch date for Canvaxin in 2006 is dependent upon the FDA s acceptance of a positive result in a single Phase 3 clinical trial as sufficient for marketing approval. Although the FDA typically requires successful results in two Phase 3 clinical trials to support marketing approval, the FDA has, on a number of occasions, approved products based on a single Phase 3 clinical trial that demonstrates a high level of statistical significance where there is an unmet need for a life-threatening condition. In the event that the FDA requires the results of a second Phase 3 clinical trial before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin would be delayed.

In addition, manufacturers of biological products, including specific active immunotherapies, must comply with the FDA s current good manufacturing practice regulations. These regulations apply to our biologics manufacturing facility, located in Los Angeles, California, 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 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. Failure to maintain a license from the California Department of Health Services or to meet the inspection criteria of the FDA and the California Department of Health Services would disrupt our manufacturing processes and would delay our clinical trials. If an inspection by the FDA, California Department of Health Services or a foreign regulatory authority indicates that there are deficiencies, we could be required to take remedial actions, or our facility 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, we estimate that it will cost at least an additional $85.0 million to complete our two Phase 3 clinical trials for advanced-stage melanoma. Failure can occur at any phase of the 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 planned completion of the clinical trials. At each interim analysis, an independent data and safety monitoring board 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 monitoring board 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.

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 our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. 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 clinical trial patients. 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 similar requests for additional information sent to all 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

19

Table of Contents

were allowed to continue treating patients who were already enrolled in the 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. We 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. 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. 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 December 2002, the FDA notified the two clinical trial sites that received the warning letters that no further response was 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 reinspect 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.

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. Dr. Morton and JWCI are both stockholders and, as of November 1, 2003, beneficially owned approximately 19.4% and 1.1%, respectively, of our common stock. 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.

Table of Contents

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 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;

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.

We plan to enroll 1,118 patients in our Phase 3 clinical trial in Stage III melanoma, and 670 patients in our Phase 3 clinical trial in Stage IV melanoma, and we rely on clinical investigators and medical institutions to enroll these patients. As of December 1, 2003, 800 patients had been enrolled in our Phase 3 clinical trial in Stage III melanoma and 326 patients had been enrolled in our Phase 3 clinical trial for Stage IV melanoma. Since June 1, 2003, the rate of patient enrollment in these trials has been between 20 and 31 patients per month for the clinical trial in Stage III melanoma, and between 4 and 11 patients per month for the clinical trial in Stage IV melanoma. We anticipate that the rate of enrollment will increase as we add additional clinical trial sites to our program, 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. 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 expired before we can perform the final analyses on these clinical trials. We currently rely on more than 65 clinical trial sites to enroll patients into our two Phase 3 clinical trials, and we plan to increase the number of clinical trial sites participating in these clinical trials to approximately 75. 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.

Table of Contents

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 other third parties 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 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 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 and manufacturing processes. However, we have no experience producing commercial quantities of Canvaxin. During the last year, we 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 these new processes 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. If we are unable to manufacture sufficient quantities of Canvaxin using our commercial-scale process in accordance with FDA and foreign regulatory authority regulations, the lack of supply could delay our clinical trials, thereby delaying submission of Canvaxin for regulatory approval and its 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, including Canvaxin, our ability to manufacture and deliver products in a timely manner could be impaired or precluded.

If we are unable to renew our leases for our sole manufacturing facility in Los Angeles, California 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 Los Angeles, California, to manufacture Canvaxin. Our leases are 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 new leases 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 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;

Table of Contents

we may be required to reformulate our products, conduct additional clinical trials, make changes in labeling of our products or implement changes to or obtain re-approvals of our manufacturing facilities;

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 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 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 technology platform, our anti-angiogenesis technology platform or other technologies. Our ability to develop successfully 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 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 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.

Management of our relationships with our collaborators requires:

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 related to the collaboration

Table of Contents

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, 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, colorectal 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, they have already achieved market acceptance. In addition, Corixa Corporation s Melacine® has been approved in Canada for the treatment of melanoma, however, Corixa recently announced that it is discontinuing the U.S. development of Melacine for melanoma. A number of other competitors are developing immunotherapeutics and other approaches for the treatment of melanoma, including Progenics Pharmaceuticals, Inc. s GMK , Antigenics Oncophage®, Maxim Pharmaceutical s Ceplene , Celgene s Revimid 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, and in December 2003, Genta announced that it had completed the submission of a new drug application for Genasense, for use in combination with dacarbazine for the treatment of patients with advanced malignant melanoma. Oncophage, Ceplene, Revimid and Genasense are all being studied in patients with metastatic melanoma, but none of these clinical trials require that patients be considered free of residual disease at the time of treatment. This is contrasted with patients who are being studied in Canvaxin s Phase 3 clinical trials, who have their 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.

Various companies are currently marketing or developing biopharmaceutical products that may compete with our product candidates that target colorectal cancer. Canvaxin and other product candidates we may develop are subject to competition in the treatment of colorectal cancer from a number of products already approved and on the market, including the following chemotherapy products: AstraZeneca PLC s Tomudex®, Hoffmann-LaRoche s Xeloda® (capecitabine), Immunex Corporation s Leucovorin® calcium, Pfizer Inc. s Camptosar® (irinotecan) and Aduracil® (5-FU) and Sanofi-Synthelabo Groupe s Eloxatin (oxaliplatin). Genentech and Imclone Systems have filed Biologics License Applications of Avastin , for use in combination with the IFL chemotherapy regimen (5-FU/Leucovorin/CPT-11), and Erbitux , for use in combination with irinotecan, respectively, for the treatment of colorectal cancer. In addition, in November 2003, Merck KgAa announced that the Swiss Agency for Therapeutic Products approved the use of Erbitux in Switzerland for patients with colorectal cancer. Other product candidates currently in late stages of development for the treatment of colorectal cancer include Antigenics, Inc. s Oncophage , Aphton Corporation s G-17 , AVI BioPharma s Avicine , GlaxoSmithKline s Eniluracil , Intracel Corporation s Oncovax and Titan Pharmaceuticals CeaV 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 tumor cancers. We expect that competition among specific active immunotherapy and anti-angiogenesis products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

Table of Contents

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 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 stinging, itching and redness at the site of injection, flu-like symptoms and a decrease in energy. Side effects, such as allergic reactions, may also be associated with BCG, which we administer to patients with the first two doses of Canvaxin. The treatment protocols for Canvaxin, which include a total of 33 doses over five years,

Table of Contents

may limit physician and patient acceptance of the product. Additionally, patients may be unwilling to forego chemotherapy treatment and their physicians may be unwilling to recommend foregoing such treatment. 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.

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 colorectal 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 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 any distribution service we retain to comply with exacting standards and precise specifications in order to preserve 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 our product, 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, we have purchased BCG recently, which should preserve our agreement with Oganon Teknika for the foreseeable future. FDA regulations require that if the manufacturing source of BCG is changed, comparability must be demonstrated before patients may be administered BCG from the alternative source with Canvaxin. 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 failed to comply with applicable regulatory requirements or if the FDA or another regulatory agency instituted a hold on the manufacture of BCG. 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 140 as of September 30, 2003, and we expect to continue to grow to meet our strategic objectives. If we continue to grow, it is possible that our management and scientific personnel, systems

Table of Contents

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;

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.

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.

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. For example, it took more than six months to fill executive positions in our research, quality and manufacturing areas. 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.

Table of Contents

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 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, 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 an allergic 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 and may 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.

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 November 1, 2003, our officers and directors beneficially owned approximately 37.8% 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.

Table of Contents

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.

Risks Related to Our Financial Results and Need for Financing

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 $83.7 million in net losses from our inception through September 30, 2003. To date, we have recognized no significant 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, 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;
- 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;

Table of Contents

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. 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 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 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.

Risks Related to Our Intellectual Property and Litigation

Our success depends upon our ability to protect our intellectual property and our proprietary technology.

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;

protect our trade secrets and know-how; and

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

Table of Contents

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.

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 also 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 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 has announced its intention to merge 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 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 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.

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.

Table of Contents

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.

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 may be the subject of other challenges by our competitors in Europe, the United States and elsewhere. Furthermore, this and other issued patents 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United States interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

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 quarter covered by this report. Based on the

Table of Contents

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.

Table of Contents

PART II - OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

During the quarter ended September 30, 2003, we issued and sold the following unregistered securities:

In August 2003, we issued and sold an aggregate of 20,572,789 shares of Series C preferred stock to institutional and accredited investors at a per share price of $2.01 for aggregate consideration of $41.4 million. Upon completion of our initial public offering on November 4, 2003, these shares of Series C preferred stock were converted into 4,675,588 shares of common stock at a conversion price of $8.84 per share. The offer, sale, and issuance of the Series C preferred stock were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The purchasers of securities in such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates issued in such transaction. Each of the recipients of securities in the sale of Series C preferred stock were accredited investors under Rule 501 of Regulation D; and

Between July 1, 2003 and September 30, 2003, we granted options to purchase 100,843 shares of common stock to employees, directors and consultants under our stock incentive plan at exercise prices ranging from $3.30 to $6.60 per share. During such time, 32,683 shares of common stock were purchased pursuant to exercises of stock options and no shares were repurchased and returned to the stock incentive plan option pool. The offers, sales, and issuances of the options and common stock were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under such rule. The recipients of such options and common stock were our employees, directors or bona fide consultants and received the securities under our stock incentive plan. Appropriate legends were affixed to the share certificates issued in such transactions. Each of these recipients had adequate access, through employment or other relationships, to information about us.

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. The Registration Statement registered up to $115,000,000 of common stock to be sold by us. 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. Following the sale of the 6,000,000 shares and the expiration of the underwriters over-allotment option, the offering terminated.

We paid to the underwriters underwriting discounts and commissions totaling approximately $5.0 million in connection with the offering. In addition, we estimate that we incurred additional expenses of approximately $1.7 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total estimated expenses of approximately $6.7 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately $65.3 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.

We expect to use the majority of the proceeds of this offering to continue the development and 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 of this offering to:

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.

Table of Contents

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.

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

On August 13, 2003, our stockholders acted by written consent to approve the following:

the agreements entered into in connection with the sale of our Series C preferred stock, which resulted in aggregate proceeds of $41.4 million; and

a restated certificate of incorporation which, among other things, authorized the Series C preferred stock.

Stockholders holding an aggregate of 11,444,381 shares approved each of the above matters and stockholders holding approximately 4,555,405 shares did not vote with respect to such matters.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit Number	Description
2.01(1)	Agreement and Plan of Merger, dated January 8, 2002, by and among CancerVax Corporation, CMI Acquisition Corp. and Cell-Matrix, Inc.
3.01	Amended and Restated Certificate of Incorporation
3.02	Amended and Restated Bylaws
4.01(1)	Form of Specimen Common Stock Certificate
4.02(1)	Second Amended and Restated Investors Rights Agreement, made as of August 13, 2003, among CancerVax Corporation and the investors listed on Schedule A thereto
4.03(1)	Form of Warrant to Purchase Vendor Preferred Stock, Series 1
4.04(1)	Warrant to Purchase Vendor Preferred Stock, Series 2, dated September 6, 2002, issued to Venture Lending & Leasing III, LLC
4.05(1)	Form of Incidental Registration Rights Agreement
10.36(1)	License Agreement, effective as of June 2, 2003, between New York University and Cell-Matrix, Inc.
10.41(1)	Third Amended and Restated Stockholders Agreement, dated as of August 13, 2003, by and among CancerVax Corporation, The Donald L. Morton Family Trust created under trust dated June 2, 1989, the Donald L. Morton, M.D., Grantor Retained Annuity Trust dated September 6, 2002, OncoVac, Inc., the investors listed on Exhibit A thereto and John Wayne Cancer Institute
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 Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 24, 2003.

Table of Contents

CancerVax Corporation has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have 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

There were no current reports on Form 8-K filed by CancerVax Corporation this quarter.

Table of Contents

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: December 11, 2003

/s/ William R. LaRue

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