CANCERVAX CORP
Form 10-Q
November 08, 2005

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2005

OR

o **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. þ Yes o No

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes þ No

The number of outstanding shares of the registrant s common stock, par value $0.00004 per share, as of October 31, 2005 was 27,879,856.

CANCERVAX CORPORATION
FORM 10-Q QUARTERLY REPORT
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2005
TABLE OF CONTENTS

Page No

PART I FINANCIAL INFORMATION

Item 1 Financial Statements
Condensed Consolidated Balance Sheets as of September 30, 2005 (unaudited) and December 31, 2004 3
Condensed Consolidated Statements of Operations (unaudited) for the three- and nine-month periods ended September 30, 2005 and 2004 4
Condensed Consolidated Statements of Cash Flows (unaudited) for the nine-month periods ended September 30, 2005 and 2004 5
Notes to Condensed Consolidated Financial Statements (unaudited) 6
Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations 11
Item 3 Quantitative and Qualitative Disclosure about Market Risk 35
Item 4 Controls and Procedures 35
PART II OTHER INFORMATION
Item 6 Exhibits 36
SIGNATURES 37
EXHIBIT 10.1
EXHIBIT 10.2
EXHIBIT 31.1
EXHIBIT 31.2
EXHIBIT 32

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2005 (Unaudited)	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 45,566	$ 40,588
Securities available-for-sale	14,689	24,485
Receivables under collaborative agreement	4,500	26,210
Other current assets	341	1,573
Total current assets	65,096	92,856
Property and equipment, net	4,602	15,650
Goodwill	5,381	5,381
Intangibles, net	719	625
Restricted cash	1,280	1,280
Other assets	314	368
Total assets	$ 77,392	$ 116,160
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 8,852	$ 11,354
Current portion of deferred revenue		7,595
Current portion of long-term debt	3,178	525
Total current liabilities	12,030	19,474
Deferred revenue, net of current portion		17,139
Long-term debt, net of current portion	14,947	6,355
Other liabilities	1,609	1,734
Commitments		
Stockholders equity:		
Common stock, $.00004 par value; 75,000 shares authorized; 27,880 and 27,808 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	1	1
Additional paid-in capital	257,841	257,582
Accumulated other comprehensive loss	(13)	(71)
Deferred compensation	(448)	(1,276)

Accumulated deficit	(208,575)	(184,778)
Total stockholders equity	48,806	71,458
Total liabilities and stockholders equity	$ 77,392	$ 116,160

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues:				
License fee	$ 21,157	$	$ 24,684	$
Collaborative research and development	4,858		14,204	
Total revenues	26,015		38,888	
Operating expenses:				
Research and development	10,574	12,369	31,241	31,579
General and administrative	2,672	2,970	8,897	8,399
Amortization of employee stock-based compensation	331	429	882	1,531
Impairment of long-lived assets	22,838		22,838	
Total operating expenses	36,415	15,768	63,858	41,509
Interest income, net	410	112	1,173	268
Net loss	$ (9,990)	$ (15,656)	$ (23,797)	$ (41,241)
Basic and diluted net loss per share	$ (0.36)	$ (0.59)	$ (0.85)	$ (1.55)
Weighted average shares used to compute basic and diluted net loss per share	27,874	26,724	27,833	26,690
The allocation of employee stock-based compensation is as follows:				
Research and development	$ 210	$ 130	$ 555	$ 441
General and administrative	121	299	327	1,090
	$ 331	$ 429	$ 882	$ 1,531

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	Nine Months Ended September 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (23,797)	$ (41,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash stock-based compensation	941	1,729
Investment income from securities available-for-sale	256	67
Depreciation	2,089	1,541
Amortization of intangibles	48	166
Deferred rent	131	233
Impairment of long-lived assets	22,838	
Changes in operating assets and liabilities:		
Receivables under collaborative agreement	21,710	
Other assets	1,241	(129)
Accounts payable and accrued liabilities	(2,758)	3,298
Deferred revenue	(24,734)	
Net cash used in operating activities	(2,035)	(34,336)
Cash flows from investing activities:		
Purchases of property and equipment	(13,721)	(2,755)
Purchases of securities available-for-sale	(22,399)	(56,722)
Maturities of securities available-for-sale	31,997	24,324
Increase in intangibles	(300)	(175)
Decrease in restricted cash		720
Net cash used in investing activities	(4,423)	(34,608)
Cash flows from financing activities:		
Payments on long-term debt	(525)	(5,223)
Proceeds from long-term debt	11,770	
Proceeds from equity compensation plans, net	191	158
Net cash provided by (used in) financing activities	11,436	(5,065)
Increase (decrease) in cash and cash equivalents	4,978	(74,009)
Cash and cash equivalents at beginning of period	40,588	101,681
Cash and cash equivalents at end of period	$ 45,566	$ 27,672

See accompanying notes to condensed consolidated financial statements.

Table of Contents

CancerVax Corporation
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

The condensed consolidated financial statements as of September 30, 2005, and for the three and nine months ended September 30, 2005 and 2004 are unaudited. We have condensed or omitted certain information and disclosures normally included in financial statements presented in accordance with accounting principles generally accepted in the United States. We believe the disclosures made are adequate to make the information presented not misleading. However, you should read these condensed consolidated financial statements in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2004.

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

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

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

In October 2005, we announced the discontinuation of our Phase 3 clinical trial of our leading product candidate, Canvaxin, in patients with stage III melanoma, the discontinuation of all further development and manufacturing activities with respect to Canvaxin and a restructuring plan. See Notes 10 and 11 for further discussion of these events.

2. Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition in Financial Statements*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Accordingly, revenue is recognized once all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets.

Collaborative research and development revenues, representing the portion of our pre-commercialization expenses incurred under collaboration agreements that are shared with our partners, are recognized as revenue in the period in which the related expenses are incurred, assuming that collectibility is reasonably assured and the amount is reasonably estimable.

Nonrefundable up-front license fees where we have continuing involvement in research and development and/or other performance obligations are initially deferred and recognized as revenue over the estimated period until completion of our performance obligations. We regularly review our estimates of the period over which we have an ongoing performance obligation.

All revenues recognized to date relate to our collaboration with Serono Technologies, S.A. for the worldwide development and commercialization of Canvaxin.

3. Serono Collaboration

In December 2004, we entered into a collaboration and license agreement with Serono for the worldwide development and commercialization of Canvaxin. Under the agreement, we received from Serono a $12.0 million payment in December 2004 for the purchase of 1.0 million shares of our common stock and a nonrefundable up-front license fee of $25.0 million in January 2005. We initially deferred the up-front license fee from Serono and were

recognizing it as license fee revenue on a straight-line basis over our estimated performance obligation period. Under the agreement, we were also entitled to receive up to $230.0 million in potential milestone payments from Serono upon the achievement of certain development, regulatory and sales based objectives related to Canvaxin and we shared equally with Serono the costs to develop and commercialize Canvaxin in the United States. Collaborative research and development revenues recognized to date represent Serono s 50% share of our Canvaxin pre-commercialization expenses under the collaboration agreement. Serono may terminate the collaboration agreement for convenience upon 180 days prior notice. Either party may terminate the agreement for the material breach or bankruptcy of the other party. In the event of a termination of the agreement, rights to Canvaxin will revert to us.

Table of Contents

As a result of the discontinuation of all further development and manufacturing activities with respect to Canvaxin, we have no further substantive performance obligations to Serono under the collaboration agreement related to the ongoing development and commercialization of Canvaxin. Accordingly, we recognized the remaining deferred up-front license fee of $19.7 million as revenue in the third quarter of 2005. Additionally, we do not anticipate receiving any of the milestone payments under the collaboration agreement, but we will continue to share equally with Serono certain costs associated with discontinuation of the Canvaxin development program and manufacturing operations, as contemplated under the agreement.

Serono may terminate the collaboration agreement for convenience upon 180 days prior notice. Either party may terminate the agreement for the material breach or bankruptcy of the other party. In the event of a termination of the agreement, rights to Canvaxin will revert to us.

4. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(In thousands, except per share amounts)			
Numerator:				
Net loss, as reported	$ (9,990)	$ (15,656)	$ (23,797)	$ (41,241)
Denominator:				
Weighted average common shares outstanding	27,879	26,767	27,843	26,749
Weighted average unvested common shares subject to repurchase	(5)	(43)	(10)	(59)
Weighted average common shares used to calculate basic and diluted loss per share	27,874	26,724	27,833	26,690
Basic and diluted net loss per share	$ (0.36)	$ (0.59)	$ (0.85)	$ (1.55)

The following common stock equivalents were excluded from the calculation of actual diluted net loss per share as their effect would be antidilutive (in thousands):

	September 30,	
	2005	2004
Common stock subject to repurchase	4	38
Stock options	5,583	3,196
Restricted shares	213	
Stock warrants	86	86
	5,886	3,320

Table of Contents

5. Stock-Based Compensation

The following table illustrates the effect on net loss and net loss per share for the three and nine months ended September 30, 2005 and 2004 if we had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-based Compensation*, as amended, to stock-based employee compensation. For purposes of the SFAS No. 123 pro forma disclosures, the estimated fair value of stock options is amortized to expense over the vesting period of the related options using the accelerated method.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(In thousands, except per share amounts)			
Net loss, as reported	$ (9,990)	$ (15,656)	$ (23,797)	$ (41,241)
Add: Stock-based employee compensation expense included in net loss, as reported	331	429	882	1,531
Deduct: Stock-based employee compensation expense determined under the fair value based method for all awards	(1,407)	(1,793)	(5,224)	(4,635)
Pro forma net loss	$ (11,066)	$ (17,020)	$ (28,139)	$ (44,345)
Loss per share:				
Basic and diluted net loss per share, as reported	$ (0.36)	$ (0.59)	$ (0.85)	$ (1.55)
Pro forma basic and diluted net loss per share	$ (0.40)	$ (0.64)	$ (1.01)	$ (1.66)

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

	Three Months Ended September 30, 2005		Three Months Ended September 30, 2004	
	Stock Options	ESPP Purchase Rights	Stock Options	ESPP Purchase Rights
Dividend yield	0%	0%	0%	0%
Expected volatility	70%	70%	70%	70%
Risk-free interest rate	4.04%	3.28%	3.58%	2.12%
Expected life in years	4.96	0.50	5.00	0.50
Per share grant date fair value	$2.00	$ 1.09	$4.23	$ 3.71

As required under SFAS No. 123, the pro forma effects of employee stock-based compensation on net loss are estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because our employee stock-based compensation has characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, we believe that the existing models do not necessarily provide a reliable single measure of the fair value of our employee stock-based employee compensation.

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R. SFAS No. 123R requires that employee stock-based compensation is

measured based on its fair value on the grant date and is treated as an expense that is reflected in the financial statements over the related service period. SFAS No. 123R applies to all employee equity awards granted after adoption and to the unvested portion of equity awards outstanding as of adoption. In April 2005, the Securities and Exchange Commission adopted an amendment to Rule 4-01(a) of Regulation S-X that delays the implementation of SFAS No. 123R until the first interim or annual period of the registrant s first fiscal year beginning on or after June 15, 2005. As a result, we currently anticipate adopting SFAS No. 123R using the modified-prospective method effective January 1, 2006. While we are currently evaluating the impact on our consolidated financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS No. 123R will have a significant impact on our results of operations for 2006 and future periods although our overall financial position will not be effected.

Table of Contents

6. Comprehensive Loss

For the three and nine months ended September 30, 2005 and 2004, comprehensive loss consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss	$ (9,990)	$ (15,656)	$ (23,797)	$ (41,241)
Unrealized gain (loss) on securities available-for-sale	(7)	48	58	(85)
Total comprehensive loss	$ (9,997)	$ (15,608)	$ (23,739)	$ (41,326)

7. Segment Information

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

8. Related Party Transactions

We were founded by Donald L. Morton, M.D., who is currently Medical Director and Surgeon-in-Chief and a member of the board of directors of the John Wayne Cancer Institute, or JWCI, a cancer research institute located in Santa Monica, California. Dr. Morton is a member of our board of directors, a significant stockholder and provided services to us under a consulting and non-compete agreement that expired in December 2004. Under the terms of the consulting and non-compete agreement, we paid Dr. Morton $150,000 per year to provide consulting services related to the development and commercialization of Canvaxin and our other product candidates as well as consult on medical and technical matters as requested. Dr. Morton continued to provide consulting services to us during 2005. We are currently negotiating an extension of Dr. Morton s consulting and non-compete agreement with modified terms, however, we cannot be certain that the agreement will be renewed.

Included in long-term debt at September 30, 2005 and December 31, 2004 is $125,000 and $250,000, respectively, representing the remaining amount we owe to JWCI under an installment obligation. Additionally, we paid to JWCI an aggregate of approximately $18,000 and $50,000, respectively, during the three months ended September 30, 2005 and 2004 and $117,000 and $179,000, respectively, during the nine months ended September 30, 2005 and 2004 for services provided under our clinical trial services agreement with JWCI, clinical trial site payments and certain other services.

9. Guarantees

In the ordinary course of our business, we enter into agreements with third parties, including corporate partners, contractors and clinical sites, which contain standard indemnification provisions. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. Although the maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. Additionally, we have insurance policies that, in most cases, would limit our exposure and enable us to recover a portion of any amounts paid. Therefore, we believe the estimated fair value of these agreements is minimal and accordingly, we have not accrued any liabilities for these agreements as of September 30, 2005.

10. Impairment of Long-Lived Assets

On October 3, 2005, we and Serono announced the discontinuation of our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma, based on the recommendation of the independent Data and Safety Monitoring Board, or DSMB, which completed its planned, third, interim analysis of data from this study on September 30, 2005, and the discontinuation of all further development and manufacturing activities with respect to Canvaxin. As a result, we performed a recoverability test of the long-lived assets included in our Canvaxin asset group in accordance with

SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The recoverability test was based on the estimated undiscounted future cash flows expected to result from the disposition of the Canvaxin asset group, including the estimated future cash inflows from anticipated sales and returns of assets and the estimated asset disposition costs. Based on the recoverability analysis performed, management does not believe that the estimated undiscounted future cash flows expected to result from the

Table of Contents

disposition of the Canvaxin asset group are sufficient to recover the carrying value of these assets. Accordingly, we recorded a non-cash charge for the impairment of long-lived assets of $22.8 million in the third quarter of 2005 to write-down the carrying value of the Canvaxin asset group to its estimated fair value.

11. Subsequent Event Restructuring Activities

On October 3, 2005, we announced that our Board of Directors had approved a restructuring plan designed to realign resources in light of the decision to discontinue our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma, as well as all further development of Canvaxin and manufacturing activities at our Canvaxin manufacturing facilities. This restructuring plan will reduce our workforce from 183 to approximately 50 employees by December 31, 2005. In connection with this workforce reduction, we anticipate incurring approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures that will primarily be paid in the fourth quarter of 2005. We anticipate that we will incur additional costs as a result of the restructuring plan, including costs associated with the closure of our manufacturing facilities and contract terminations. We may also incur additional charges from the impairment of long-lived assets. At this time, we are unable to reasonably estimate the expected amount of additional costs that will result from the restructuring plan or the timing of the related cash expenditures, although the additional restructuring costs may have a significant impact on our results of operations.

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, 2004 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2005.

Overview

We are a biotechnology company focused on the research, development and commercialization of novel biological products for the treatment and control of cancer.

On October 3, 2005, we and Serono Technologies, S.A., our Canvaxin collaboration partner, announced the discontinuation of our Phase 3 clinical trial of our leading product candidate, Canvaxin, in patients with Stage III melanoma, based on the recommendation of the independent Data and Safety Monitoring Board, or DSMB, which completed its planned, third, interim analysis of data from this study on September 30, 2005. In April 2005, we announced the discontinuation of our Phase 3 clinical trial of Canvaxin in patients with Stage IV melanoma based upon a similar recommendation of the independent DSMB. The DSMB concluded, based on its planned, interim analysis of the data from these studies, that the data were unlikely to provide significant evidence of a survival benefit for Canvaxin-treated patients versus those receiving placebo. There were no significant safety issues identified with either of the Phase 3 clinical trials of Canvaxin, and the recommendations to close the studies were not made because of any potential safety concerns.

As a result of the discontinuation of the Canvaxin Phase 3 clinical trials, in October 2005 we and Serono announced the discontinuation of all further development and manufacturing activities with respect to Canvaxin. As a result, we recorded a non-cash charge for the impairment of long-lived assets of $22.8 million in the third quarter of 2005 to write-down the carrying value of the Canvaxin asset group to its estimated fair value. Additionally, in October 2005, we announced that our Board of Directors had approved a restructuring plan designed to realign resources in light of the decision to discontinue our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma, as well as all further development of Canvaxin and manufacturing activities at our Canvaxin manufacturing facilities. This restructuring plan will reduce our workforce from 183 to approximately 50 employees by December 31, 2005. In connection with this workforce reduction, we anticipate incurring approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures that will primarily be paid in the fourth quarter of 2005. We anticipate that we will incur additional costs as a result of the restructuring plan, including costs associated with the closure of our manufacturing facilities and contract terminations. We may also incur additional charges from the impairment of long-lived assets. At this time, we are unable to reasonably estimate the expected amount of additional costs that will result from the restructuring plan or the timing of the related cash expenditures, although the additional restructuring costs may have a significant impact on our results of operations.

We have other product candidates in research and preclinical development, including three product candidates targeting the epidermal growth factor receptor, or EGFR, signaling pathway for the treatment of cancer, and four humanized, anti-angiogenic monoclonal antibodies and several peptides that potentially target various solid tumors. Our efforts to identify, develop and commercialize these product candidates are in an early stage and, therefore, these efforts are subject to a high risk of failure.

In early 2006, we plan to file an Investigational New Drug Application, or NDA, to initiate a Phase 1 clinical trial for D93, our leading humanized, anti-angiogenic monoclonal antibody, in patients with solid tumors. Later in 2006, we plan to initiate a clinical trial with SAI-EGF, the most advanced of our three product candidates targeting the EGFR signaling pathway, in patients with advanced non-small-cell lung cancer.

We are actively considering strategic transactions and alternatives with the goal of maximizing shareholder value. These potential transactions may include a variety of difference business arrangements, including acquisitions,

strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We cannot assure you that any such transactions would be consummated on favorable terms or at all, would in fact enhance stockholder value, or would not adversely affect our business or the trading price of our stock. Any such transactions may require us to incur non-recurring or other charges and may pose significant integration challenges and/or management and business disruptions, any of which could materially and adversely affect our business and financial results.

Table of Contents

We were incorporated in Delaware in June 1998 and have incurred net losses since inception. As of September 30, 2005, our accumulated deficit was approximately $208.6 million. We expect to incur substantial and increasing losses for the next several years as we:

- advance the development of our product candidates that target the EGFR signaling pathway;
- advance our preclinical anti-angiogenesis 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. To date, we have funded our operations primarily through sales of equity securities as well as bank financing to fund certain equipment and leasehold improvement expenditures.

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, our ability to manufacture our product candidates, competition from other products, uncertainties associated with obtaining and enforcing patent rights, with maintaining our licenses related to our product candidates, obtaining the capital necessary to fund our ongoing operations and establishing and maintaining strategic collaborations to fund our product development efforts.

Research and Development

Through September 30, 2005, our research and development expenses have consisted primarily of costs associated with the clinical development of Canvaxin, including costs associated with the Phase 3 clinical trials of Canvaxin, production of Canvaxin for use in these clinical trials and manufacturing process, quality systems and analytical development for Canvaxin, including compensation and other personnel expenses, supplies and materials, costs for consultants and related contract research, facility costs, license fees and depreciation. We charge all research and development expenses to operations as they are incurred. From our inception through September 30, 2005, we incurred costs of approximately $131.2 million associated with the research and development of Canvaxin, representing over 91% of our total research and development expenses.

Under our collaboration agreement with Serono, we were entitled to receive up to $230.0 million in potential milestone payments upon the achievement of certain development, regulatory and sales based objectives related to Canvaxin. As a result of the discontinuation of all further development and manufacturing activities with respect to Canvaxin, we do not anticipate receiving any of these milestone payments, but we will continue to share equally with Serono certain costs associated with the discontinuation of the Canvaxin development program and manufacturing operations, as contemplated under the collaboration agreement. Serono may terminate the collaboration agreement for convenience upon 180 days prior notice. Either party may terminate the agreement for the material breach or bankruptcy of the other party. In the event of a termination of the agreement, rights to Canvaxin will revert to us.

Following the discontinuation of all further Canvaxin development and manufacturing activities, our research and development activities will primarily be focused on the development of product candidates based on our proprietary anti-angiogenesis technology and our three product candidates targeting the EGFR signaling pathway.

We are unable to estimate with any certainty the costs we will incur in the continued development of our other product candidates. However, we expect our research and development costs associated with these product candidates to increase as we continue to develop new indications and move these product candidates through preclinical and clinical trials.

Table of Contents

Clinical development timelines, likelihood of success and total costs vary widely. We anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an on-going basis in response to the scientific and clinical success of each product candidate.

The costs and timing for developing and obtaining regulatory approvals of our product candidates vary significantly for each product candidate and are difficult to estimate. The expenditure of substantial resources will be required for the lengthy process of clinical development and obtaining regulatory approvals as well as to comply with applicable regulations. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations.

Critical Accounting Policies and Estimates

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

Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition in Financial Statements*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Accordingly, revenue is recognized once all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Collaborative research and development revenues, representing the portion of our pre-commercialization expenses incurred under collaboration agreements that are shared with our partners, are recognized as revenue in the period in which the related expenses are incurred, assuming that collectibility is reasonably assured and the amount is reasonably estimable.

Nonrefundable up-front license fees where we have continuing involvement in research and development and/or other performance obligations are initially deferred and recognized as license fee revenue over the estimated period until completion of our performance obligations.

Our estimates of the period over which we recognize revenue are based on the contractual terms of the underlying arrangement, the level of effort required for us to fulfill our obligations and the anticipated timing of the fulfillment of our obligations. As our product candidates move through the clinical development and regulatory approval process, our estimates of the period over which we recognize revenue from nonrefundable up-front license fees and milestone payments, if any, may change. The effect of changes in our estimates of the revenue recognition period will be recognized prospectively over the remaining estimated period. We regularly review our estimates of the period over which we have ongoing performance obligations.

Goodwill

In accordance with Statement of Financial Accounting Standards, or SFAS No. 142, *Goodwill and Other Intangible Assets*, we do not amortize goodwill. Instead, we review goodwill for impairment at least annually and whenever events or changes in circumstances indicate a reduction in the fair value of the reporting unit to which the goodwill has been assigned. Conditions that would necessitate a goodwill impairment assessment include a significant adverse change in legal factors or in the business climate, an adverse action or assessment by a regulator,

unanticipated competition, a loss of key personnel, or the presence of other indicators that would indicate a reduction in the fair value of the reporting unit to which the goodwill has been assigned. SFAS No. 142 prescribes a two-step process for impairment testing of goodwill. The first step of the impairment test is used to identify potential impairment by comparing the fair value of the reporting unit

Table of Contents

to which the goodwill has been assigned to its carrying amount, including the goodwill. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete in-process projects, projecting regulatory approvals, estimating future cash inflows from product sales and other sources, and developing appropriate discount rates and probability rates by project. If the carrying value of the reporting unit exceeds the fair value, the second step of the impairment test is performed in order to measure the impairment loss.

Our goodwill had a carrying value of $5.4 million at September 30, 2005 and December 31, 2004 and resulted from our acquisition of Cell-Matrix, Inc. in January 2002. We have assigned the goodwill to our Cell-Matrix reporting unit. In the fourth quarter of 2004, we performed our annual goodwill impairment test for fiscal year 2004 in accordance with SFAS No. 142 and determined that the carrying amount of goodwill was recoverable. In determining the fair value of the Cell-Matrix reporting unit, we considered internal risk-adjusted cash flow projections which utilize several key assumptions, including estimated timing and costs to complete development of the anti-angiogenesis technology and estimated future cash inflows from anticipated future collaborations and projected product sales. Additionally, we reviewed the implied market capitalization of the Cell-Matrix reporting unit, based on the number of shares issued by us in the acquisition, and third party revenue projections for other products and product candidates utilizing similar technology. Our analysis of the fair value of the Cell-Matrix reporting unit assumes the timely and successful completion of development of the anti-angiogenesis technology. The major risks and uncertainties associated with the timely and successful completion of development of the anti-angiogenesis technology include the risk that we will not be able to confirm the safety and efficacy of the technology with data from clinical trials and the risk that we will not be able to obtain necessary regulatory approvals. No assurance can be given that the underlying assumptions used to forecast the cash flows or the timely and successful completion of development will materialize as estimated. We cannot assure you that our future reviews of goodwill impairment will not result in a material charge.

Impairment of Long-Lived Assets and Restructuring Costs

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets to be held and used, including property and equipment and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the market price of an asset or asset group, a significant adverse change in the extent or manner in which an asset or asset group is being used, a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset or asset group, or the presence of other indicators that would indicate that the carrying amount of an asset or asset group is not recoverable. Determination of recoverability is based on the undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. The determination of the undiscounted cash flows requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete in-process projects, projecting regulatory approvals and estimating future cash inflows from product sales and other sources. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated fair value.

As a result of the discontinuation of all further Canvaxin development and manufacturing activities, we performed a recoverability test of the long-lived assets included in our Canvaxin asset group in accordance with SFAS No. 144. The recoverability test was based on the estimated undiscounted future cash flows expected to result from the disposition of the Canvaxin asset group, including the estimated future cash inflows from anticipated sales and returns of assets and the estimated asset disposition costs. Based on the recoverability analysis performed, management does not believe that the estimated undiscounted future cash flows expected to result from the disposition of the Canvaxin asset group are sufficient to recover the carrying value of these assets. Accordingly, we recorded a non-cash charge for the impairment of long-lived assets of $22.8 million in the third quarter of 2005 to write-down the carrying value of the Canvaxin asset group to its estimated fair value. No assurance can be given that the underlying assumptions used to estimate the fair value of the assets will materialize as estimated. Differences between our estimate of the fair value of the assets and the actual cash flows and asset dispositions may result in an adjustment to the impairment charge.

We cannot assure you that our future reviews of the impairment of our assets will not result in additional charges.

The restructuring plan approved by our Board of Directors in October 2005 will reduce our workforce from 183 to approximately 50 employees by December 31, 2005. In connection with this workforce reduction, we anticipate incurring approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures that will primarily be paid in the fourth quarter of 2005. We anticipate that we will incur additional costs as a result of the restructuring plan, including costs associated with the closure of our manufacturing facilities and contract terminations. At this time, we are unable to reasonably estimate the expected amount of additional costs that will result from the restructuring plan or the timing of the related cash expenditures, although the additional restructuring costs may have a significant impact on our results of operations. The timing and amounts of these

Table of Contents

restructuring costs will be based on, among other things, the anticipated exit strategy for our facilities and the estimated termination dates of our employees, facility leases and other contracts. No assurance can be given that the underlying assumptions used to estimate the amounts of these restructuring costs will materialize as estimated. Differences between our estimates and the actual timing and amounts paid for employee, lease and contract terminations may result in additional restructuring costs.

Results of Operations

Revenues. Total revenues were $26.0 million and $38.9 million for the three and nine months ended September 30, 2005, respectively, compared to no revenues for the comparable periods in 2004. Revenues for the three and nine months ended September 30, 2005 consisted of $21.2 million and $24.7 million, respectively, of license fee revenues and $4.8 million and $14.2 million, respectively, of collaborative research and development revenues from our collaboration agreement with Serono. License fee revenues represent the portion of the $25.0 million up-front license fee received from Serono in January 2005 recognized as revenue. As a result of the discontinuation of Canvaxin development and manufacturing activities, we have no further substantive performance obligations to Serono under the collaboration agreement related to the ongoing development and commercialization of Canvaxin. Accordingly, we recognized the remaining deferred up-front license fee of $19.7 million as revenue in the third quarter of 2005. Collaborative research and development revenues represent Serono s 50% share of our Canvaxin pre-commercialization expenses under the agreement.

Research and Development Expenses. Research and development expenses were $10.6 million and $31.2 million for the three and nine months ended September 30, 2005, respectively, compared to $12.4 million and $31.6 million for the comparable periods in 2004. The decrease in research and development expenses for the three and nine months ended September 30, 2005 was due to decreased clinical trial expenses due to the discontinuation of the Phase 3 clinical trial of Canvaxin in patients with Stage IV melanoma in April 2005 and the completion of patient enrollment in our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma in the second half of 2004 and $2.6 million of technology access and transfer fees under our agreements with CIMAB, S.A. and YM BioSciences, Inc., which were recognized as research and development expenses in the third quarter of 2004. Also included in research and development expenses for the nine months ended September 30, 2004 were one-time payments totaling $0.8 million made under our sublicense agreement with SemaCo, Inc. The decrease in research and development expenses was offset by increased production of Canvaxin for use in our Phase 3 clinical trial, manufacturing process validation expenses associated with the expansion of the production capacity of our biologics manufacturing facility, facilities expenses associated with our warehouse and laboratory facility leased in August 2004, contract manufacturing and laboratory services expenses associated with our leading humanized, anti-angiogenic monoclonal antibody and our 50% share of Canvaxin pre-commercialization expenses incurred by Serono under the collaboration agreement.

Non-cash employee stock-based compensation of $0.2 million and $0.6 million for the three and nine months ended September 30, 2005, respectively, compared to $0.1 million and $0.4 million for the comparable periods in 2004, was excluded from research and development expenses and reported under a separate caption.

General and Administrative Expenses. General and administrative expenses were $2.7 million and $8.9 million for the three and nine months ended September 30, 2005, respectively, compared to $3.0 million and $8.4 million for comparable periods in 2004. The decrease in general and administrative expenses for the three months ended September 30, 2005 was primarily due to decreased personnel expenses and decreased expenses associated with marketing activities, offset by our 50% share of Canvaxin pre-commercialization expenses incurred by Serono under the collaboration agreement. The increase in general and administrative expenses for the nine months ended September 30, 2005 was primarily due to increased expenses associated with marketing activities, increased fees associated with financial statement, income tax and internal control compliance and our 50% share of Canvaxin pre-commercialization expenses incurred by Serono under the collaboration agreement, offset by decreased outside legal fees.

Non-cash employee stock-based compensation of $0.1 million and $0.3 million for the three and nine months ended September 30, 2005, respectively, compared to $0.3 million and $1.1 million for the comparable periods in 2004, was excluded from general and administrative expenses and reported under a separate caption.

Amortization of Employee Stock-based Compensation. Employee stock-based compensation results from stock options granted to our employees and directors prior to our initial public offering with exercise prices that were deemed to be below the estimated fair value of the underlying common stock on the option grant date as well as stock awards with performance-based vesting provisions granted to employees in 2005. We recorded the spread between the exercise price of the stock option or purchase price of the restricted stock and the fair value of the underlying common stock as deferred employee stock-based compensation. We amortize the deferred employee stock-based compensation as a non-cash charge to operations on an accelerated basis over the vesting period of the award. Amortization of deferred employee stock-based compensation was $0.3 million and $0.9 million for the three and nine months ended September 30, 2005, respectively, compared to $0.4 million and $1.5 million for the comparable periods in 2004.

Table of Contents

Impairment of Long-lived Assets. As a result of the discontinuation of all further Canvaxin development and manufacturing activities, we recorded a non-cash charge for the impairment of long-lived assets of $22.8 million in the third quarter of 2005 to write-down the carrying value of the Canvaxin asset group to its estimated fair value in accordance with SFAS No. 144.

Interest Income, Net. Interest income, net was $0.4 million and $1.2 million for the three and nine months ended September 30, 2005, respectively, compared to $0.1 million and $0.3 million for the comparable periods in 2004. The increase was primarily attributable to an increase in interest income due to higher rates of interest on invested balances in 2005.

Liquidity and Capital Resources

As of September 30, 2005, we had $60.3 million in cash, cash equivalents and securities available-for-sale as compared to $65.1 million as of December 31, 2004. This decrease was primarily due to the use of cash to fund ongoing operations and $13.7 million of purchases of property and equipment, offset by payments aggregating $35.2 million received from Serono under the collaboration agreement and $11.8 million of proceeds from long-term debt.

Net cash used in operating activities was $2.0 million during the nine months ended September 30, 2005, compared with $34.3 million during the comparable period in 2004. The increase in cash flows from operating activities was primarily due to payments aggregating $35.2 million received from Serono under the collaboration agreement, including the $25.0 million up-front license fee received from Serono in January 2005.

Net cash used in investing activities was $4.4 million during the nine months ended September 30, 2005, compared with $34.6 million during the comparable period in 2004. Significant components of cash flows from investing activities for the nine months ended September 30, 2005 included a $9.6 million net decrease in our securities available-for-sale portfolio and $13.7 million of purchases of property and equipment. Significant components of cash flows from investing activities for the nine months ended September 30, 2004 included a $32.4 million net increase in our securities available-for-sale portfolio, a $0.7 million decrease in restricted cash and $2.8 million of purchases of property and equipment.

Net cash provided by financing activities was $11.4 million during the nine months ended September 30, 2005, compared with net cash used in financing activities of $5.1 million during the comparable period in 2004. Cash flows from financing activities for the nine months ended September 30, 2005 primarily consisted of proceeds from borrowings on our $18.0 million bank credit facility. Cash flows from financing activities for the nine months ended September 30, 2004 primarily consisted of payments on long-term debt, including the full repayment in January 2004 of the notes payable that were assumed in our January 2002 acquisition of Cell-Matrix.

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

- our ability to rapidly and cost-effectively complete the closure activities associated with our clinical trials and development and manufacturing activities for Canvaxin, and to sublease the manufacturing facilities associated with Canvaxin on satisfactory terms;
- the costs involved in the research and preclinical and clinical development of D93, SAI-EGF and our other product candidates;
- the costs involved in obtaining and maintaining regulatory approvals for our product candidates;
- 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 manufacturing costs associated with our product candidates;

our ability to enter into corporate collaborations and the terms and success of these collaborations;

Table of Contents

our acquisition and development of new technologies and product candidates;

the risk of product liability claims inherent in the manufacturing, testing and marketing of therapies for treating people with cancer or other diseases; and

competing technological and market developments.

On October 3, 2005, we announced that our Board of Directors had approved a restructuring plan designed to realign resources in light of the decision to discontinue our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma, as well as all further development of Canvaxin and manufacturing activities at our Canvaxin manufacturing facilities. This restructuring plan will reduce our workforce from 183 to approximately 50 employees by December 31, 2005. In connection with this workforce reduction, we anticipate incurring approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures that will primarily be paid in the fourth quarter of 2005. We anticipate that we will incur additional costs as a result of the restructuring plan, including costs associated with the closure of our manufacturing facilities and contract terminations. We may also incur additional charges from the impairment of long-lived assets. At this time, we are unable to reasonably estimate the expected amount of additional costs that will result from the restructuring plan or the timing of the related cash expenditures, although the additional restructuring costs may have a significant impact on our results of operations.

In December 2004, we entered into an $18.0 million loan and security agreement with a financial institution. All borrowings under the credit facility must be paid in full by December 31, 2009. Borrowings under the credit facility will initially bear interest at either a fixed or variable rate at our option. The fixed interest rate is equal to the greater of the 4-year U.S. Treasury note rate plus 2.86% or 6.00%. The variable interest rate is equal to the greater of the bank s prime rate or 4.75%. However, we have the option to fix the interest rate on any variable rate borrowings at a rate equal to the greater of the bank s prime rate plus 1.25% or 6.00% prior to December 31, 2005. At our option, we may make interest-only payments on variable rate borrowings until January 31, 2006, at which time principal and interest payments are due in 48 equal monthly installments. Fixed rate borrowings are payable in 48 equal monthly installments of principal and interest from the date of the borrowing. As of September 30, 2005, we have borrowed the full $18.0 million available under this credit facility, of which $1.3 million was used to repay the remaining unpaid borrowings under a credit facility secured in 2002. The remaining $16.7 million was primarily used to finance certain capital expenditures associated with the expansion of our biologics manufacturing facility. The existing borrowings under this credit facility as of September 30, 2005 bear interest at the greater of the bank s prime rate or 4.75% (6.75% at September 30, 2005) with interest-only payments due through December 31, 2005.

We have granted the bank a first priority security interest in substantially all of our assets, excluding our intellectual property. In addition to various customary affirmative and negative covenants, the loan and security agreement requires us to maintain, as of the last day of each calendar quarter, aggregate cash, cash equivalents and securities available-for-sale in an amount at least equal to the greater of (i) our quarterly cash burn multiplied by 2 or (ii) the then outstanding principal amount of the obligations under such agreement multiplied by 1.5. In the event that we breach this financial covenant, we are obligated to pledge and deliver to the bank a certificate of deposit in an amount equal to the then-outstanding borrowings under the credit facility. We were in compliance with our debt covenants as of September 30, 2005.

The loan and security agreement contains certain customary events of default, including, among other things, non-payment of principal and interest, violation of covenants, the occurrence of a material adverse change in our ability to satisfy our obligations under the loan agreement or with respect to the lender s security interest in our assets and in the event we are involved in certain insolvency proceedings. Upon the occurrence of an event of default, the lender may be entitled to, among other things, accelerate all of our obligations and sell our assets to satisfy our obligations under the loan agreement. In addition, in an event of default, our outstanding obligations may be subject to increased rates of interest. We do not believe that the restructuring announced in October 2005 constitutes an event of default under the loan agreement, nor has the lender indicated that it views the restructuring as such. We can provide no assurance, however, that the lender will not at some time in the future seek to declare us in default of the loan as a

result of the restructuring. The loan agreement also requires that the proceeds we receive from the sale or return of assets that are collateralized under the loan agreement, if any, must be used to repay our obligations under the credit facility. There can be no assurance that such proceeds, if any, will be sufficient to satisfy our obligations under the credit facility.

To date, we have funded our operations primarily through the sale of equity securities as well as through equipment and leasehold improvement financing. Through September 30, 2005, we have received aggregate net proceeds of approximately $208.6 million from the sale of equity securities. In addition, through September 30, 2005, we have borrowed an aggregate of approximately $27.3 million under certain credit facilities primarily to finance the purchase of equipment and leasehold improvements. Our remaining obligation under these credit facilities as of September 30, 2005 consists solely of borrowings under our $18.0 million bank credit facility.

Table of Contents

We expect that operating losses and negative cash flows from operations will continue for at least the next several years. We believe that our existing cash, cash equivalents and securities available-for-sale as of September 30, 2005 and the remaining cost-sharing payments from Serono associated with the costs of the discontinuation of the Canvaxin development program and manufacturing operations will be sufficient to meet our projected operating requirements until December 31, 2006.

We will need to raise additional funds to meet future working capital and capital expenditure needs. We have filed an S-3 shelf registration statement, declared effective by the Securities and Exchange Commission on December 9, 2004, under which we may raise up to $80 million through the sale of our common stock. We may also raise additional funds through additional debt financing or through additional strategic collaboration agreements. We do not know whether additional financing will be available when needed, or whether it will be available on favorable terms, or at all. If we were to raise additional funds through the issuance of common stock under our S-3 shelf registration statement or otherwise, substantial dilution to our existing stockholders would likely result. If we were to raise additional funds through additional 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. 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 may adversely affect our ability to operate as a going concern.

Table of Contents

Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue, anticipate, seek, plan, expect, should, or would. Among the factors that could cause actual results to differ materially from t indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, statements about the progress and timing of our clinical trials; difficulties or delays in development, testing, obtaining regulatory approval, producing and marketing our products; unexpected adverse side effects or inadequate therapeutic efficacy of our products that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; the scope and validity of patent protection for our products; competition from other pharmaceutical or biotechnology companies; our ability to obtain additional financing to support our operations; and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2005 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 additional factors that could cause actual results to differ, see the Risk Factors section in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 15, 2005.

Risks Related to Our Business and Industry

Our business to date has been largely dependent on the success of Canvaxin, which was the subject of Phase 3 clinical trials that we recently terminated. Although we have ceased the development of Canvaxin and undertaken a workforce reduction, we may be unable to successfully manage our remaining resources, including available cash, while we seek to implement other restructuring and strategic alternatives.

Both of our Phase 3 clinical trials for Canvaxin in patients with advanced-stage melanoma were discontinued earlier this year based upon the recommendations of the independent Data and Safety Monitoring Board, or DSMB, with oversight responsibility for these clinical trials, that the data were unlikely to provide significant evidence of a survival benefit for Canvaxin-treated patients versus patients who received placebo. We had previously devoted substantially all of our research, development and clinical efforts and financial resources toward the development Canvaxin. In connection with the termination of our clinical trials for Canvaxin, we announced restructuring activities, including workforce reductions, and estimate that we will incur approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures. We have also ceased the manufacture of Canvaxin at our facility in Los Angeles, California, and are exploring alternatives to sublease the facility and divest related equipment and tenant improvements. However, we may be unable to adequately reduce expenses associated with our existing clinical trial agreements, manufacturing facilities and other commitments related to Canvaxin.

As a result of the discontinuation of our clinical trials of Canvaxin, we are actively considering strategic transactions and alternatives with the goal of maximizing stockholder value. In addition to our workforce reductions and the termination of our Canvaxin development activities, we are considering a number of restructuring alternatives, including the conservation of remaining financial resources and a variety of different business arrangements such as spin-offs, acquisitions, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not successfully implement any of these restructuring alternatives, and even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable financial terms. Our restructuring measures implemented to date and any of these potential future transactions may disappoint investors and further depress the price of our common stock and the value of an investment in our common stock. Any such transactions may require us to incur non-recurring or other charges and may pose significant integration challenges and/or

management and business disruptions, any of which could materially and adversely affect our business and financial results.

Table of Contents

Our remaining product candidates are in early stages of development and our efforts to develop and commercialize these pipeline product candidates are subject to a high risk of failure. If we fail to successfully develop our product candidates, our ability to generate revenues will be substantially impaired.

The process of successfully developing product candidates is very time-consuming, expensive and unpredictable. and there is a high rate of attrition for product candidates in preclinical and clinical trials. Until recently, our business strategy depended upon the successful clinical development of Canvaxin and the subsequent development of additional pipeline product candidates to complement our initial focus on Canvaxin. Our remaining product candidates are in earlier stages of development than Canvaxin, so we will require substantial additional financial resources, as well as research, development and clinical capabilities, to pursue the development of these product candidates, and we may never develop an approvable product.

Our remaining principal product candidates are D93, a humanized, anti-angiogenic monoclonal antibody, and SAI-EGF, a product candidate that targets the epidermal growth factor receptor, or EGFR, signaling pathway. SAI-EGF has been evaluated in Phase 1/2 clinical trials in Cuba, the United Kingdom and Canada, but has not been evaluated in any clinical trials in the U.S. to date. We are planning to file an Investigational New Drug, or IND, application to initiate a Phase 1 clinical trial for D93 in patients with solid tumors in early 2006, but we have not yet completed the required preclinical testing of this product candidate, and there can be no assurance that such testing will be successfully completed so that we may commence clinical trials with D93.

Subject to our diligence obligations to our licensors for these product candidates, we are considering strategic alternatives with respect to our product candidates given the substantial reduction in our research and development and clinical resources in connection with the termination of our Canvaxin development activities. We may be unable to successfully develop these product candidates ourselves, and we also may be unable to enter into strategic collaborations with third parties to pursue the development of these product candidates. Even if we are able to identify potential strategic collaborators our licensees for these product candidates, we may be unable to obtain required consents from our licensors and the financial terms available to us may not be acceptable. In any event, we do not anticipate that any of our product candidates will reach the market for at least several years.

We do not know whether our planned preclinical development or clinical trials for our 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. We cannot assure you that any of our product candidates will:

be successfully developed;

prove to be safe and effective in clinical trials;

be approved for marketing by United States or foreign regulatory authorities;

be adequately protected by our intellectual property rights or the rights of our licensors;

be capable of being produced in commercial quantities at acceptable costs;

achieve market acceptance and be commercially viable; or

be eligible for third party reimbursement from governmental or private insurers.

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

Preclinical development, clinical trials, manufacturing and commercialization of our product candidates are all subject to extensive regulation by United States and foreign governmental authorities. It takes many years and significant expenditures 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 substantial resources. As demonstrated by the recent discontinuation of our Phase 3 clinical trials of Canvaxin in patients with advanced-stage melanoma, 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.

Table of Contents

We have no manufacturing capabilities or manufacturing personnel and expect to depend on third parties to manufacture the product candidates that we are currently developing. We will be dependent on sole-source suppliers to provide our product candidates for early-stage clinical trials.

We recently ceased our manufacturing efforts for Canvaxin as part of our restructuring activities related to our decision to discontinue the Phase 3 clinical trials of this product candidate. We do not operate any facilities for manufacturing D93, SAI-EGF or any of the other product candidates that we are currently developing. As a result, we will rely on third parties to manufacture these product candidates for our early-stage clinical trials. Our dependence upon third parties for the manufacture of these product candidates may result in unforeseen delays or other problems beyond our control.

In January 2005, we entered into an agreement with AppTec Laboratory Services, Inc., to manufacture D93 for early-stage clinical trials. There can be no assurance that we, AppTec or any other third party manufacturing organization will be able to develop adequate manufacturing capabilities to supply the quantities of D93 needed for our clinical trials or commercial-scale quantities.

Under our licensing agreement, CIMAB, S.A., a Cuban company, has the right and obligation, subject to specified terms and conditions, to supply SAI-EGF for Phase 1 and Phase 2 clinical trials, and for Phase 3 clinical trials and commercialization in countries in our territory other than the United States, Canada and Mexico. Production of these product candidates may require raw materials for which the sources and amounts are limited. Any inability to obtain adequate supplies of such raw materials could significantly delay the development, regulatory approval and marketing of these product candidates. In addition, prior to the initiation of Phase 3 clinical trials in the U.S., we will need to transfer the manufacturing and quality assurance processes for these product candidates to a facility outside of Cuba. Our ability to transfer information to CIMAB that might be beneficial in scaling-up such manufacturing processes is significantly limited due to U.S. government restrictions. Difficulties or delays in the transfer of the manufacturing and quality processes related to these product candidates could cause significant delays in the initiation of the Phase 3 clinical trials and in the establishment of our own commercial-scale manufacturing capabilities for these products. There can be no assurance that we or CIMAB will be able to develop adequate manufacturing capabilities to supply the quantities of SAI-EGF needed for our clinical trials or commercial-scale quantities.

There are a limited number of manufacturers that are capable of manufacturing biological product candidates. We may not be able to obtain services from such manufacturers in a timely manner, if at all, to meet our requirements for clinical trials and, subject to the receipt of regulatory approvals, commercial sale. We also depend on third party contract laboratories to perform quality control testing of our product candidates.

If our third party manufacturers facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.

Our third party manufacturers must comply with the FDA s current good manufacturing practice, or CGMP, regulations, and similar regulations of foreign regulatory authorities in jurisdictions where we may seek to market our products. These regulations include quality control, quality assurance and the maintenance of records and documentation. Manufacturing facilities for our product candidates may be subject to the licensing requirements of state regulatory authorities and may be inspected by the FDA, foreign and state regulatory authorities at any time. We and our present or future suppliers may be unable to comply with the applicable CGMP regulations and with other FDA, state and foreign regulatory requirements. Failure to maintain any required licenses from regulatory authorities or to meet the applicable inspection criteria of the FDA, state and foreign regulatory authorities would disrupt our manufacturing processes and would delay our clinical trials and the eventual commercialization of our product candidates.

If an inspection by the FDA, state or a foreign regulatory authority, as applicable, indicates that there are deficiencies, we or our suppliers could be required to take remedial actions or be prohibited from supplying product for our ongoing clinical trials, and our facilities or those of our suppliers could be closed.

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. Patients who participated in our clinical trials

for Canvaxin or patients who participate in our future clinical trials may bring product liability claims. A product liability claim may damage our reputation by raising questions about a product s safety and efficacy and could limit our ability to continue to conduct clinical trials and develop or product candidates. If our claims experience results in higher rates, or if product liability insurance otherwise becomes costlier because of general economic, market or industry conditions, then we may not be able to maintain product liability coverage on acceptable terms.

Table of Contents

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.

If third-party clinical investigators and medical institutions and other third parties that perform data collection and analysis for our clinical trials do not perform in an acceptable and timely manner, our clinical trials could be delayed and we may be unable to obtain required regulatory approvals.

We will rely on clinical investigators and medical institutions to perform clinical trials on our product candidates, and on other third parties to perform related data collection and analysis for our clinical trials. If we cannot locate acceptable clinical investigators to conduct our clinical trials, if the investigators do not timely enroll and perform the required follow-up on patients and comply with all applicable FDA and international requirements for the conduct of clinical trials, or if we cannot locate and maintain relationships with third-parties to perform data collection and analysis for our clinical trials, we will be unable to obtain required approvals and will be unable to commercialize our products on a timely basis, if at all.

Changes in the laws or regulations of the United States or Cuba related to the conduct of our business with CIMAB may adversely affect our ability to develop and commercialize SAI-EGF and the two other product candidates that we have licensed from that company.

The United States government has maintained an embargo against Cuba for more than 40 years. The embargo is administered by the Office of Foreign Assets Control, or OFAC, of the U.S. Department of Treasury. Without a license from OFAC, U.S. individuals and companies may not engage in any transaction in which Cuba or Cubans have an interest. In order to enter into and carry out the licensing agreements with CIMAB, we have obtained from OFAC a license authorizing us to carry out all transactions set forth in the license agreements that we have entered into with CIMAB for the development, testing, licensing and commercialization of SAI-EGF, and with CIMAB and YM Biosciences for the two other product candidates that target the EGF receptor signaling pathway. In the absence of such a license from OFAC, the execution of and our performance under these agreements could have exposed us to legal and criminal liability. At any time, there may occur for reasons beyond our control a change in United States or Cuban law, or in the regulatory environment in the U.S. or Cuba, or a shift in the political attitudes of either the U.S. or Cuban governments, that could result in the suspension or revocation of our OFAC license or in our inability to carry out part or all of the licensing agreements with CIMAB. There can be no assurance that the U.S. or Cuban governments will not modify existing law or establish new laws or regulations that may adversely affect our ability to develop, test, license and commercialize these product candidates. Our OFAC license may be revoked or amended at anytime in the future, or the U.S. or Cuban governments may restrict our ability to carry out all or part of our respective duties under the licensing agreements between us, CIMAB and YM BioSciences. Similarly, any such actions may restrict CIMAB s ability to carry out all or part of its licensing agreements with us. In addition, we cannot be sure that the FDA or other regulatory authorities will accept data from the clinical trials of these products that were conducted in Cuba as the basis for our applications to conduct additional clinical trials, or as part of our application to seek marketing authorizations for such products.

In 1996, a significant change to the United States embargo against Cuba resulted from congressional passage of the Cuban Liberty and Democratic Solidarity Act, also known as the Helms-Burton Bill. That law authorizes private lawsuits for damages against anyone who traffics in property confiscated, without compensation, by the government of Cuba from persons who at the time were, or have since become, nationals of the United States. We do not own any property in Cuba and do not believe that any of CIMAB s properties or any of the scientific centers that are or have been involved in the development of the technology that we have licensed from CIMAB were confiscated by the government of Cuba from persons who at the time were, or who have since become, nationals of the U.S. However, there can be no assurance that our understanding in this regard is correct. We do not intend to traffic in confiscated property, and have included provisions in our licensing agreements to preclude the use of such property in association with the performance of CIMAB s obligations under those agreements.

As part of our interactions with CIMAB, we will be subject to the U.S. Commerce Department s export administration regulations that govern the transfer of technology to foreign nationals. Specifically, we will require a license from the Commerce Department s Bureau of Industry and Security, or BIS, in order to export or otherwise

transfer to CIMAB any information that constitutes technology under the definitions of the Export Administration Regulations, or EAR, administered by BIS. The export licensing process may take months to be completed, and the technology transfer in question may not take place unless and until a license is

Table of Contents

granted by the Commerce Department. Due to the unique status of the Republic of Cuba, technology that might otherwise be transferable to a foreign national without a Commerce Department license requires a license for export or transfer to a Cuban national. If we fail to comply with the export administration regulations, we may be subject to both civil and criminal penalties. There can be no guarantee that any license application will be approved by BIS or that a license, once issued, will not be revoked, modified, suspended or otherwise restricted for reasons beyond our control due to a change in U.S.-Cuba policy or for other reasons.

As a result of the reduction in our workforce that we announced in October 2005, we may not be successful in retaining key employees and in attracting qualified new employees as required in the future. 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.

In October 2005, we announced the discontinuation of any further development and manufacturing activities with respect to Canvaxin, and a corporate restructuring plan that included a reduction in our workforce from 183 to approximately 50 employees. Competition among biotechnology companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to our success. We may experience further reductions in force due to additional restructuring activities, voluntary employee resignations and a diminished ability to recruit new employees to further the development of our product candidates. We may be unable to attract or retain key personnel on acceptable terms, if at all.

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, could significantly delay or prevent the achievement of our scientific and business objectives. In October 2005, Mr. Hale s employment agreement was extended through October 2008; however, this employment relationship is terminable at will subject to certain notice periods. As a result of the discontinuation of our Phase 3 clinical trials of Canvaxin, and the subsequent reduction in our workforce, our employment agreement with John Petricciani, M.D., our Senior Vice President, Medical and Regulatory Affairs, will terminate by the end of 2005.

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.

Our consulting agreement with our founder, Donald L. Morton, M.D., expired in December 2004, and Dr. Morton is now able to develop products that compete with 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.

We do not maintain key person life insurance on any of our officers, employees or consultants, including Mr. Hale and Dr. Morton.

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.

We may become involved in securities class action litigation that could divert management s attention and harm our business.

The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical and biotechnology companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, following periods of volatility in the market price of a particular company s securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

Table of Contents

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

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

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

Specifically, we face competition from a number of companies working in the fields of specific active immunotherapy for the treatment of solid tumors, anti-angiogenesis, and signal transduction through the EGFR pathway. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position. Some of these products use therapeutic approaches that may compete directly with our product candidates, and the companies developing these competing technologies may have significantly greater resources that we do, and 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. For example, several products that target the EGFR signaling pathway in the treatment of cancer have recently been approved by the FDA or are in the late phases of clinical development. The approved products are AstraZeneca Pharmaceutical LP s Iressa (gefitinib), an EGFR-targeted tyrosine kinase inhibitor for refractory Stage IV NSCLC, ImClone Systems, Inc. s Erbitux (cetuximab), an EGFR monoclonal antibody for Stage IV refractory colorectal cancer, and Genentech, Inc. and OSI Pharmaceuticals, Inc. s EGFR-targeted tyrosine kinase inhibitor, Tarceva (erlotinib HCl), for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Subsequent to its approval for the treatment of NSCLC in the U.S., a phase IV clinical study of Iressa failed to demonstrate a survival benefit. As a result, AstraZeneca withdrew its request for approval of this product in the European Union, and suspended its promotion of Iressa in the U.S. Two other products that are currently being evaluated in Phase 3 clinical trials are GlaxoSmithKline s lapatinib (GW572016), a tyrosine kinase dual inhibitor of EGFR and HER-2, which is being studied in patients with advanced metastatic breast cancer whose disease progressed on Herceptin® (trastuzumab) therapy, and Abgenix, Inc. and Amgen, Inc. s panitumumab (ABX-EGF), a fully human monoclonal antibody targeting the EGFR, which is being studied in patients with advanced colorectal and renal cell cancer. Several other monoclonal antibodies and tyrosine kinase inhibitors targeting the EGFR signaling pathway are in the early stages of development. If we receive approval to market and sell any of our product candidates that target the EGFR signaling pathway, we may compete with certain of these companies and their products as well as other product candidates in varying stages of development. In addition, researchers are continually learning more about the treatment of NSCLC and other forms of cancer, and new discoveries may lead to new technologies for treatment.

We also face competition from a number of companies working in the fields of anti-angiogenesis and specific active immunotherapy for the treatment of other solid tumors. We expect that competition among such products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position. As a result, any product candidates that we may develop may be rendered obsolete and noncompetitive.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. Because part of our strategy is to target markets outside of the United States through collaborations with third parties, we will compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused.

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.

The 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.

Table of Contents

In addition, our decision to discontinue our Phase 3 clinical trials for Canvaxin in patients with advanced-stage melanoma based upon the recommendations of the independent DSMB could create negative publicity that, although not directly related to our remaining product candidates, could nevertheless affect their market acceptance. Even if we receive regulatory approval and satisfy the above criteria for our product candidates, physicians may be reluctant to recommend, or patients may be reluctant to use, our products.

Risks Related to Our Financial Results and Need for Financing

We have a history of losses and expect to incur substantial losses and negative operating cash flows for the foreseeable future, and we may never achieve sustained profitability.

The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never generate revenue. We recently announced restructuring activities, including workforce reductions, and estimate that we will incur approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures. We will incur additional substantial expenses in connection with the early termination of clinical trial agreements and other commitments related to Canvaxin. We do not expect to generate any revenue for several years because our remaining pipeline product candidates are in the early stages of development. Our ability to generate revenue depends on a number of factors, including our ability to successfully develop and obtain regulatory approvals to commercialize D93, SAI-EGF and our other product candidates. We have not yet completed the development, including obtaining regulatory approvals, of any products and, consequently, have not generated revenues from the sale of products. Even if these early-stage product candidates receive regulatory approval, we will need to establish and maintain sales, marketing and distribution capabilities, and even if we are able to commercialize our product candidates, we may not achieve profitability for at least several years after generating material revenue. If we are unable to become profitable, we may be unable to continue our operations.

If we fail to obtain the capital necessary to fund our operations, we will be unable to develop or commercialize our product candidates and our ability to operate as a going concern may be adversely affected.

We believe that our existing cash, cash equivalents, and securities available-for-sale as of September 30, 2005 and any remaining pre-commercialization cost-sharing payments from our collaboration for Canvaxin with Serono Technologies, S.A., will be sufficient to meet our projected operating requirements until December 31, 2006. In addition to our workforce reductions and the termination of our Canvaxin development activities, we are considering a number of additional restructuring alternatives, including the conservation of remaining financial resources and a variety of different business arrangements such as spin-offs, acquisitions, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not successfully implement any of these restructuring alternatives, and even if we determine to pursue one or more of these alternatives, we may be unable to do so on acceptable financial terms. Our restructuring measures implemented to date and any of these potential future activities may disappoint investors and further depress the price of our common stock and the value of an investment in our common stock.

We will require substantial funds to conduct development, including preclinical testing and clinical trials of our product candidates, including D93 and SAI-EGF. Our ability to conduct the required development activities related to these product candidates will be significantly limited if we are unable to obtain the necessary capital. We may seek to raise additional funds to meet our working capital and capital expenditure needs. We have filed an S-3 shelf registration statement, declared effective by the Securities and Exchange Commission on December 9, 2004, under which we may raise up to $80 million through the sale of our common stock. We may also raise additional funds through additional debt financing or through additional strategic collaboration agreements. However, we do not know whether additional financing will be available when needed, or whether it will be available on favorable terms or at all. 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.

Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- our ability to rapidly terminate the clinical trials and development and manufacturing activities for Canvaxin in patients with advanced-stage melanoma, and to sublease on satisfactory terms the manufacturing facilities

associated with the production of Canvaxin;

the costs involved in the research and preclinical and clinical development of D93, SAI-EGF and our other product candidates;

Table of Contents

the costs involved in obtaining and maintaining regulatory approvals for our product candidates;

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;

potential product liability claims associated with Canvaxin or our other product candidates;

the manufacturing costs associated with our product candidates;

our ability to enter into corporate collaborations and the terms and success of these collaborations;

our acquisition and development of new technologies and product candidates; and

competing technological and market developments.

If we do not establish and maintain strategic collaborations to fund our product development activities, we may have to reduce or delay our rate of product development and increase our expenditures.

We intend to rely on strategic collaborations for research, development, marketing and commercialization of our product candidates. We have not yet obtained regulatory approval for, marketed or sold any of our product candidates in the United States or elsewhere and we will need 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. Any collaborations we may develop in the future 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 will require:

significant time and effort from our management team;

coordination of our research and development programs with the research and development priorities of our collaborators; and

effective allocation of our resources to multiple projects.

If we enter into research and development collaborations at an early phase of product development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our product candidates. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our product candidates. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to the collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, our collaborators may terminate our relationships, and we may be unable to establish additional corporate collaborations in the future on acceptable terms, if at all. If clinical trials of our product candidates are not successful, or 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. For example, Serono may terminate our collaboration agreement for Canvaxin for convenience upon 180 days prior notice.

27

Table of Contents

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 $174.2 million in net losses from our inception through September 30, 2005. We expect to increase our operating expenses over the next several years as we conduct clinical trials with D93 and SAI-EGF, expand our research and development activities, acquire or license new technologies and product candidates and contract for manufacturing and quality services for our product candidates that are in clinical trials. In addition, we recently announced restructuring activities, including workforce reductions, and estimate that we will incur approximately $3.8 million of severance and related costs, the substantial majority of which will be cash expenditures. Because of the numerous risks and uncertainties associated with our restructuring activities and our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our operating and financial flexibility, including our ability to borrow money, is limited by certain debt arrangements.

In December 2004, we entered into a loan and security agreement with a financing institution under which we have borrowed the full $18.0 million available under this credit facility. In general, our loan agreement requires us to use the proceeds from the loan for office equipment, laboratory equipment, furnishings, leasehold improvements, freight, taxes, intangible property and limited use property. We used the proceeds from the loan agreement primarily to construct and equip an additional production suite in our existing manufacturing facility, and to create additional warehouse and laboratory space to support the manufacture of Canvaxin. As a result of the discontinuation of our clinical trials, development program and manufacturing operations for Canvaxin, we are planning to sublease both our manufacturing facility, which includes the additional production suite, and our warehouse facility. We cannot predict whether any such subleasing arrangements would be consummated on favorable terms or at all, and anticipate that such transactions may require us to incur significant additional costs and obtain third-party consents beyond our control. We have granted the bank a first priority security interest in substantially all of our assets, excluding our intellectual property, to secure our obligations under the loan agreement.

The loan agreement contains various customary affirmative and negative covenants, including, without limitation:

financial reporting;

limitation on liens;

limitations on the occurrence of future indebtedness;

maintenance of a minimum amount of cash in deposit accounts of our lenders or in the accounts of affiliates of our lenders;

limitations on mergers and other consolidations;

limitations on dividends;

limitations on investments; and

limitations on transactions with affiliates.

In addition, under this loan agreement, we are generally obligated to maintain, as of the last day of each quarter, cash, cash equivalents and securities available-for-sale in an amount at least equal to the greater of (i) our quarterly cash burn multiplied by 2 or (ii) the then outstanding principal amount of the obligations under such agreement multiplied by 1.5. In the event that we breach this financial covenant, we are obligated to pledge and deliver to the bank a certificate of deposit in an amount equal to the aggregate outstanding principal amount of the obligations under such agreement.

Our loan agreements contain certain customary events of default, which generally include, among others, non-payment of principal and interest, violation of covenants, cross defaults, the occurrence of a material adverse change in our ability to satisfy our obligations under our loan agreements or with respect to one of our lender s security interest in our assets and in the event we are involved in certain insolvency proceedings. Upon the occurrence of an event of default, our lenders may be entitled to, among other things, accelerate all of our obligations and sell our assets to satisfy our obligations under our loan agreements. In addition, in an event of default, our outstanding obligations may be subject to increased rates of interest.

Table of Contents

In addition, we may incur additional indebtedness from time to time to finance acquisitions, investments or strategic alliances or capital expenditures or for other purposes. Our level of indebtedness could have negative consequences for us, including the following:

- our ability to obtain additional financing, if necessary, for working capital, capital expenditures, acquisitions or other purposes may be impaired or such financing may not be available on favorable terms;
- payments on our indebtedness will reduce the funds that would otherwise be available for our operations and future business opportunities;
- we may be more highly leveraged than our competitors, which may place us at a competitive disadvantage;
- our debt level reduces our flexibility in responding to changing business and economic conditions; and
- there would be an adverse effect on our business and financial condition if we are unable to service our indebtedness or obtain additional financing, as needed.

We may engage in strategic transactions, which could adversely affect our business.

As a result of the discontinuation of our clinical trials of Canvaxin, we are actively considering strategic transactions and alternatives with the goal of maximizing stockholder value. These potential transactions may include a variety of different business arrangements, including spin-offs, acquisitions, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We cannot assure you that any such transactions would be consummated on favorable terms or at all, would in fact enhance stockholder value, or would not adversely affect our business or the trading price of our stock. Any such transactions may require us to incur non-recurring or other charges and may pose significant integration challenges and/or management and business disruptions, any of which could materially and adversely affect our business and financial results.

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 progress of our restructuring activities, including with respect to our discontinuation of our Phase 3 clinical trials for Canvaxin and the closure of our manufacturing facilities;
- the status of development of our product candidates;
- the time at which we enter into research and license agreements with strategic collaborators that provide for payments to us, and the timing and accounting treatment of payments to us, if any, under those agreements;
- whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by commercial collaborators of any amounts payable to us;
- the addition or termination of research programs or funding support;
- the timing of milestone and other payments that we may be required to make to others; and
- variations in the level of expenses related to our product candidates or potential product candidates during any given period.

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

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, on December 16, 2004, the Financial Accounting Standards Board issued

Table of Contents

Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R. SFAS No. 123R requires that employee stock-based compensation be measured based on its fair-value on the grant date and treated as an expense that is reflected in the financial statements over the related service period. In April 2005, the U.S. Securities and Exchange Commission adopted an amendment to Rule 4-01(a) of Regulation S-X that delays the implementation of SFAS No. 123R until the first interim or annual period of the registrant s first fiscal year beginning on or after June 15, 2005. As a result, we currently anticipate adopting SFAS No. 123R using the modified-prospective method effective January 1, 2006. While we are currently evaluating the impact on our consolidated financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS 123R will have a significant impact on our results of operations for 2006 and subsequent periods.

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. Because of the substantial length of time and expense associated with development of new products, we, along with the rest of the biotechnology industry, place considerable importance on obtaining and maintaining patent protection for new technologies, products and processes. The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including us, are generally uncertain and involve complex legal and factual questions. We will continue to attempt to protect our intellectual property position by filing United States patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. 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 and the related underlying technology;

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

maintain our patents, and, along with our collaborators and licensors, those of our collaborators and our licensors, that we use in our business;

protect our trade secrets and know-how; and

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

Our success depends on whether we are able to maintain and enforce our licensing arrangements with various third party licensors.

We hold exclusive rights through two agreements with CIMAB to develop and commercialize within a specific territory, which includes the U.S., Canada, Japan, Australia, New Zealand, Mexico, the countries comprising the European Union and certain other countries in Europe, SAI-EGF, a product candidate being evaluated in Phase 2 clinical trials that targets the EGFR signaling pathway for the treatment of cancer. In addition, we obtained from CIMAB and YM BioSciences the exclusive rights to develop and commercialize, within the same territory, SAI-TGF-a, which targets transforming growth factor-alpha, and SAI-EGFR-ECD, which targets the extracellular domain of the EGF receptor, both of which are in preclinical development. In exchange for these rights, we will pay to CIMAB and YM BioSciences technology access fees and transfer fees totaling $5.7 million, to be paid over the first three years of the agreement. We will also make future milestone payments to CIMAB and YM BioSciences up to a maximum of $34.7 million upon meeting certain regulatory, clinical and commercialization objectives, as well as royalties on future sales of commercial products, if any. Each agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under each respective agreement or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreements. CIMAB may terminate one or both of the agreements if we have not used reasonable commercial efforts to file an IND submission to the FDA for the leading product candidate by July 12, 2006, or if the first regulatory approval for marketing this

product candidate within our territory is not obtained by July 12, 2016, provided that CIMAB has timely complied with all of its obligations under the agreements, or if CIMAB does not receive timely payment of the initial access fees and technology transfer fees under the agreements. In addition, if CIMAB does not receive payments under the agreements due to changes in U.S. law, actions by the U.S. government or by order of any U.S. court for a period of more than one year, CIMAB may terminate our rights to the licensed product candidates in countries within our territory other than the U.S. and Canada. We may terminate the agreements for any reason following 180 days written notice to CIMAB.

Table of Contents

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

In addition, we hold rights to commercialize our anti-angiogenesis product candidates and our rights to additional cell lines for the development of other product candidates under agreements that require, among other things, royalty payments on future sales, if any, and our achievement of certain development milestones. We hold rights to a human monoclonal antibody 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.

On October 15, 2004, we amended and restated our collaboration agreement with Applied Molecular Evolution, Inc., or AME, which is now a wholly-owned subsidiary of Eli Lilly and Company, under which AME utilized its technology to humanize D93 and another of our anti-angiogenic monoclonal antibodies. Under the amended and restated collaboration agreement, AME may terminate the agreement if we fail to make milestone or royalty payments to AME, if we fail to file an IND application for one or more products that incorporate or are derived from one or more of the humanized monoclonal antibodies that are the subject of the agreement by February 28, 2006, 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 humanized monoclonal antibodies that are the subject of this agreement and the products that incorporate or are derived from one or more of the humanized monoclonal antibodies that are the subject of the agreement. AME also received a right of first negotiation to obtain from us an exclusive license under our intellectual property rights related to the making, using and selling of any products that incorporate or are derived from one or more of the humanized monoclonal antibodies that are the subject of the agreement should we decide to negotiate with or seek a collaborator for the commercialization of such product. The amended and restated collaboration agreement also obligates us to pay for the preparation, filing, prosecution, maintenance and enforcement of all patent applications directed at the humanized monoclonal antibodies that are the subject of the amended agreement. We made a $0.2 million payment to AME in the fourth quarter of 2004 in connection with the execution of the amended and restated collaboration agreement.

If we were to materially breach any of our license or 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 we will be able to obtain additional patent protection to protect our product candidates and technology.

We cannot be certain that additional patents will be issued on our product candidates that target the EGFR signaling pathways, or that any patents will be issued on our anti-angiogenesis product candidates, as a result of pending applications filed to date. If a third party has also filed a patent application relating to an invention claimed by us or our licensors, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us. The degree of future protection for our proprietary rights is uncertain. For example:

- we might not have been the first to make the inventions covered by each of our patents and 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;

Table of Contents

any of the issued patents under which we hold rights may not be valid or enforceable; or

we may develop additional proprietary technologies that are not patentable and which may not be adequately protected through trade secrets, for example if a competitor independently develops duplicative, similar, or alternative technologies.

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

If we are not able to protect and control our unpatented trade secrets, know-how and other technological innovation, we may suffer competitive harm.

We also rely on proprietary trade secrets and unpatented know-how to protect our research, development and manufacturing activities, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We attempt to protect our trade secrets and unpatented know-how by requiring our employees, consultants and advisors to execute a confidentiality and non-use agreement. We cannot guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our trade secrets, and those of our present or future collaborators that we utilize by agreement, may become known or may be independently discovered by others, which could adversely affect the competitive position of our product candidates.

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.

Our commercial success will depend in part on not infringing the patents or violating the proprietary rights of third parties. We are aware of competing intellectual property relating to our areas of practice. Competitors or third parties may obtain patents that may cover subject matter we use in developing the technology required to bring our products to market, that we use in producing our products, or that we use in treating patients with our products.

In addition, from time to time we receive correspondence inviting us to license patents from third parties. There has been, and we believe that there will continue to be, significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights. While we believe that our pre-commercialization activities fall within the scope of an available exemption against patent infringement provided by 35 U.S.C. §271(e), and that our subsequent manufacture of our commercial products will also not require the license of any of these patents, claims may be brought against us in the future based on these or other patents held by others.

Third parties could bring legal actions against us claiming we infringe their patents or proprietary rights, and seek monetary damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or products. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. However, there can be no assurance that any such license will be available on acceptable terms or at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of claims of patent infringement or violation of other intellectual property rights, which could harm our business.

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 published in the United States or foreign countries, and in certain circumstances applications are not published until a patent issues, it may not be possible to be fully informed of all relevant third party patents. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. All issued patents are entitled to a rebuttable presumption of validity under the laws of the United States and certain other countries. Issued patents held by others 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.

32

Table of Contents

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

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

We face possible delisting from the Nasdaq National Market, which would result in a limited public market for our common stock.

Our common stock trades on the Nasdaq National Market, which specifies certain requirements for the continued listing of common stock. There are several requirements for the continued listing of our common stock on the Nasdaq National Market including, but not limited to, a minimum stockholders equity value of $10.0 million and a minimum stock bid price of $1.00 per share. As of September 30, 2005, we had a stockholders deficit of $208.6 million, and our closing stock price as of November 4, 2005 was $1.42 per share. While we expect that our stock would continue to trade on the Over The Counter Bulletin Board following any delisting from the Nasdaq National Market, any such delisting of our common stock could have a material adverse effect on the market price of, and the efficiency of the trading market for, our common stock. Also, if in the future we were to determine that we need to seek additional equity capital, it could have an adverse effect on our ability to raise such equity capital

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

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

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

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

- developments in our restructuring activities, including with respect to our discontinuation of our Phase 3 clinical trials for Canvaxin and the closure of our manufacturing facilities;

changes in the regulatory status of our product candidates, including results of our clinical trials for SAI-EGF, our product candidates targeting the EGFR signaling pathway, and for D93, our lead humanized, anti-angiogenic monoclonal antibody;

Table of Contents

changes in significant contracts, new technologies, acquisitions, commercial relationships, joint ventures or capital commitments;

announcements of the results of clinical trials by companies with product candidates in the same therapeutic category as our product candidates;

events affecting Serono or our collaboration agreement with Serono;

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

announcements of new products or technologies, commercial relationships or other events by us or our competitors;

our ability to successfully complete one or more restructuring alternatives designed to conserve our remaining financial resources, such as spin-offs, acquisitions, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments;

variations in our quarterly operating results;

changes in securities analysts estimates of our financial performance;

changes in accounting principles;

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

additions or departures of key personnel; and

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

If our officers and directors choose to act together, they can significantly influence our management and operations in a manner that may be in their best interests and not in the best interests of other stockholders.

As of April 1, 2005, our officers and directors beneficially owned approximately 37.6% 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.

Our stockholder rights plan, 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 stockholder rights plan and provisions contained in 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. The provisions in our certificate of incorporation and bylaws 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Borrowings under our $18.0 million bank credit facility will initially bear interest at either a fixed or variable rate at our election. The fixed interest rate is equal to the greater of the 4-year U.S. Treasury note rate plus 2.86% or 6.00%. The variable interest rate is equal to the greater of the bank s prime rate or 4.75%. However, we have the option to fix the interest rate on any variable rate borrowings at a rate equal to the greater of the bank s prime rate plus 1.25% or 6.00% prior to December 31, 2005. Our remaining debt bears interest at fixed rates. Therefore, we do not have significant market risk exposure with respect to our debt obligations.

Item 4. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure 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. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2005.

Changes in Internal Control Over Financial Reporting

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 6. Exhibits

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
3.3(2)	Certificate of Designations for Series A Junior Participating Preferred Stock
10.1#	First Amendment to Amended and Restated Employment Agreement between CancerVax Corporation and David F. Hale
10.2#	First Amendment to Second Amended and Restated Employment Agreement between CancerVax Corporation and Dennis Van Epps, Ph.D.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

(2) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on November 8, 2004.

# Indicates management contract or compensatory plan.

* 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.

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: November 7, 2005

CancerVax Corporation

By: /s/ William R. LaRue

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

37