EASTMAN KODAK CO
Form SC 13G/A
February 13, 2014
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

SCHEDULE 13G

(Rule 13d-102)

INFORMATION TO BE INCLUDED IN STATEMENTS FILED PURSUANT TO § 240.13d-1(b), (c) AND (d) AND AMENDMENTS THERETO FILED PURSUANT TO § 240.13d-2

UNDER THE SECURITIES EXCHANGE ACT OF 1934

(Amendment No. 2)

Eastman Kodak Company
(Name of Issuer)

Common Stock, par value $0.01 per share
(Title of Class of Securities)

277461406
(CUSIP Number)

December 31, 2013
(Date of Event Which Requires Filing of this Statement)

Check the appropriate box to designate the rule pursuant to which this Schedule is filed:

¨ Rule 13d-1(b)
ý Rule 13d-1(c)
¨ Rule 13d-1(d)

13G

CUSIP No. 277461406 Page 2 of 8 Pages

1) NAME OF REPORTING PERSON
Contrarian Capital Management, L.L.C.

2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (a) [_]
(b) [x]

3) SEC USE ONLY

4) CITIZENSHIP OR PLACE OF ORGANIZATION
Delaware

| | | |
|---|---|---|
| NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH | 5) | SOLE VOTING POWER<br>0 |
| | 6) | SHARED VOTING POWER<br>4,741,909 |
| | 7) | SOLE DISPOSITIVE POWER<br>0 |
| | 8) | SHARED DISPOSITIVE POWER<br>4,741,909 |

9) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
4,741,909

10) CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES
¨

11) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)
11.3%

12) TYPE OF REPORTING PERSON
IA

CUSIP No. 277461406 Page 3 of 8 Pages

1) NAME OF REPORTING PERSON
Contrarian Capital Fund I, L.P.

2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (a) [_]
(b) [x]

3) SEC USE ONLY

4) CITIZENSHIP OR PLACE OF ORGANIZATION
Delaware

| | | |
|---|---|---|
| NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH | 5) | SOLE VOTING POWER<br>0 |
| | 6) | SHARED VOTING POWER<br>2,823,817 |
| | 7) | SOLE DISPOSITIVE POWER<br>0 |
| | 8) | SHARED DISPOSITIVE POWER<br>2,823,817 |

9) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
2,823,817

10) CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES
¨

11) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (9)
6.8%

12) TYPE OF REPORTING PERSON
PN

Item 1(a). Name of Issuer:

Eastman Kodak Company

Item 1(b). Address of Issuer's Principal Executive Offices:

343 State Street
Rochester, New York 14650

Item 2(a). Name of Persons Filing:

Contrarian Capital Management, L.L.C.
Contrarian Capital Fund I, L.P.

Item 2(b). Address of Principal Business Office or, if None, Residence:

Contrarian Capital Management, L.L.C.
411 West Putnam Avenue, Suite 425
Greenwich, CT 06830

Contrarian Capital Fund I, L.P.
c/o Contrarian Capital Advisors, L.L.C.
411 West Putnam Avenue, Suite 425
Greenwich, CT 06830

Item 2(c). Citizenship or Place of Organization:

Contrarian Capital Management, L.L.C. - Delaware

Contrarian Capital Fund I, L.P. - Delaware

Item 2(d). Title of Class of Securities:

Common Stock, $0.01 par value per share

Item 2(e). CUSIP Number:

277461406

CUSIP No. 277461406

Item 3. If this statement is filed pursuant to §§ 240.13d-1(b), or 240.13d-2(b) or (c), check whether the person filing is a:

(a) [_] Broker or Dealer registered under Section 15 of the Act (15 U.S.C. 78o);

(b) [_] Bank as defined in Section 3(a)(6) of the Act (15 U.S.C. 78c);

(c) [_] Insurance company as defined in Section 3(a)(19) of the Act (15 U.S.C. 78c);

(d) [_] Investment company registered under Section 8 of the Investment Company Act of 1940 (15 U.S.C. 80a-8);

(e) [_] An investment adviser in accordance with § 240.13d-1(b)(1)(ii)(E);

(f) [_] An employee benefit plan or endowment fund in accordance with § 240.13d-1(b)(1)(ii)(F);

(g) [_] A parent holding company or control person in accordance with § 240.13d-1(b)(1)(ii)(G);

(h) [_] A savings association as defined in Section 3(b) of the Federal Deposit Insurance Act (12 U.S.C. 1813);

(i) [_] A church plan that is excluded from the definition of an investment company under Section 3(c)(14) of the Investment Company Act (15 U.S.C. 80a-3);

(j) [_] A non-U.S. institution in accordance with § 240.13d-1(b)(1)(ii)(J);

(k) [_] Group, in accordance with § 240.13d-1(b)(1)(ii)(K).

Item 4. Ownership.

(a) Amount beneficially owned:

Contrarian Capital Management, L.L.C.: 4,741,909
Contrarian Capital Fund I, L.P.: 2,823,817

(b) Percent of class:

Contrarian Capital Management, L.L.C.: 11.3%
Contrarian Capital Fund I, L.P.: 6.8%

(c) Number of shares as to which Contrarian Capital Management, L.L.C. has:

(i) Sole power to vote or to direct the vote: 0

(ii) Shared power to vote or to direct the vote: 4,741,909

(iii) Sole power to dispose or to direct the disposition of: 0

(iv) Shared power to dispose or to direct the disposition of: 4,741,909

(d) Number of shares as to which Contrarian Capital Fund I, L.P. has:

(i) Sole power to vote or to direct the vote: 0

(ii) Shared power to vote or to direct the vote: 2,823,817

(iii) Sole power to dispose or to direct the disposition of: 0

(iv) Shared power to dispose or to direct the disposition of: 2,823,817

Item 5. Ownership of Five Percent or Less of a Class.

Not applicable

Item 6. Ownership of More than Five Percent on Behalf of Another Person.

The securities reported in this Schedule 13G, which are beneficially owned by Contrarian Capital Management, L.L.C., are owned by advisory clients of Contrarian Capital Management, L.L.C., none of whom, with the exception of Contrarian Capital Fund I, L.P., owns more than 5% of the class.

Item 7. Identification and Classification of the Subsidiary Which Acquired the Security Being Reported on by the Parent Holding Company or Control Person.

Not applicable

Item 8. Identification and Classification of Members of the Group.

Not applicable

Item 9. Notice of Dissolution of Group.

Not applicable

Item 10. Certification.

By signing below the undersigned certifies that, to the best of its knowledge and belief, the securities referred to above were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the issuer of the securities and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect, other than activities solely in connection with a nomination under § 240.14a-11.

SIGNATURE

After reasonable inquiry and to the best knowledge and belief of the undersigned, the undersigned certifies that the information set forth in this statement with respect to the Reporting Person on whose behalf the undersigned is executing this statement is true, complete and correct.

Date: February 14, 2014

CONTRARIAN CAPITAL MANAGEMENT LLC

By: /s/ Jon R. Bauer
Name: Jon R. Bauer
Title: Managing Member

CONTRARIAN CAPITAL FUND I, L.P.

By: Contrarian Capital Advisors, L.L.C.

By: /s/ Jon R. Bauer
Name: Jon R. Bauer
Title: Managing Member

Exhibit A

Agreement of Joint Filing

Pursuant to 13d-1(k) promulgated under the Securities Exchange Act of 1934, as amended, the undersigned hereby confirm the agreement by and among them to join in the filing on behalf of each of them of a Statement on Schedule 13G and any and all amendments thereto, and that this Agreement be included as an Exhibit to such filing.

This Agreement may be executed in any number of counterparts each of which shall be deemed to be an original and all of which together shall be deemed to constitute one and the same agreement.

IN WITNESS WHEREOF, the undersigned have executed this Agreement.

DATED: February 14, 2014

CONTRARIAN CAPITAL MANAGEMENT LLC

By: /s/ Jon R. Bauer
Name: Jon R. Bauer
Title: Managing Member

CONTRARIAN CAPITAL FUND I, L.P.

By: Contrarian Capital Advisors, L.L.C.

By: /s/ Jon R. Bauer
Name: Jon R. Bauer
Title: Managing Member

SK 01385 0001 1453429
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.

In February 2005, we received notification from Eyetech Pharmaceuticals, Inc. regarding its decision to terminate its sublicense agreement with us, effective May 2005. As a result, we performed a recoverability test of the long-lived assets included in our Cell-Matrix 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 use of the Cell-Matrix asset group, including the estimated timing and costs to complete the development of the anti-angiogenesis technology and the estimated future cash inflows from an anticipated future collaboration with a third party and product sales. Management believes

such undiscounted future cash flows are sufficient to recover the carrying amount of the Cell-Matrix asset group and therefore the Cell-Matrix asset group is not considered to be impaired as of March 31, 2005. 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 the recoverability of the Cell-Matrix asset group will not result in a material charge.

*Goodwill*

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

Our goodwill had a carrying value of $5.4 million at March 31, 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

Table of Contents

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.

**Results of Operations**

*Revenues.* Total revenues were $6.6 million for the three months ended March 31, 2005, compared to no revenues for the three months ended March 31, 2004. Revenues for the three months ended March 31, 2005 consist of $1.9 million of license fee revenues and $4.7 million of collaborative agreement revenues from our 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. Collaborative agreement revenues represent Serono s share of our Canvaxin pre-commercialization expenses under the agreement.

*Research and Development Expenses.* Research and development expenses were $10.0 million for the three months ended March 31, 2005, compared to $9.6 million for the comparable period in 2004. The increase in research and development expenses for the three months ended March 31, 2005 primarily reflects additional investment in personnel in the quality, research and development and manufacturing departments, increased costs associated with the production of Canvaxin for use in our Phase 3 clinical trials resulting from higher patient enrollment in these clinical trials, manufacturing process validation expenses associated with the expansion of the production capacity of our biologics manufacturing facility and facilities expenses associated with our warehouse, laboratory and office facility leased in August 2004, offset by payments totaling $0.8 million made under our sublicense agreement with SemaCo, Inc. in March 2004, which were recognized as research and development expenses.

Non-cash employee stock-based compensation of $0.1 million and $0.2 million for the three months ended March 31, 2005 and 2004, respectively, was excluded from research and development expenses and reported under a separate caption.

*General and Administrative Expenses.* General and administrative expenses were $3.3 million for the three months ended March 31, 2005, compared to $2.7 million for comparable period in 2004. The increase in general and administrative expenses for the three months ended March 31, 2005 was primarily due to additional investment in personnel in the finance and marketing and business development departments and increased expenses associated with marketing activities.

Non-cash employee stock-based compensation of $0.2 million and $0.4 million for the three months ended March 31, 2005 and 2004, respectively, 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 shares of restricted stock granted to management in the first quarter of 2005. We recorded the spread between the exercise price of the stock option or purchase price of the restricted share 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 related options or restricted stock. Amortization of deferred employee stock-based compensation was $0.3 million and $0.6 million for the three months ended March 31, 2005 and 2004, respectively.

*Interest Income, Net.* Interest income, net for the three months ended March 31, 2005 was $0.4 million, compared to $0.1 million for the comparable period in 2004. The increase was primarily attributable to an increase in interest income due to higher rates of interest on invested balances in the first quarter of 2005.

**Liquidity and Capital Resources**

As of March 31, 2005, we had $76.4 million in cash, cash equivalents and securities available-for-sale as compared to $65.1 million as of December 31, 2004. This increase was primarily due to the $25.0 million up-front license fee received from Serono in January 2005 and proceeds from long-term debt, offset by the use of cash to fund ongoing operations.

**Table of Contents**

Net cash provided by operating activities was $14.5 million during the three months ended March 31, 2005, compared with net cash used in operating activities of $11.7 million during the three months ended March 31, 2004. The increase in cash flows from operating activities was primarily due to the $25.0 million up-front license fee received from Serono in January 2005.

Net cash provided by investing activities was $1.6 million during the three months ended March 31, 2005, compared with net cash used in investing activities of $51.2 million during the three months ended March 31, 2004. Significant components of cash flows from investing activities for the three months ended March 31, 2005 included a $8.0 million net decrease in our securities available-for-sale portfolio and $6.4 million of purchases of property and equipment. Significant components of cash flows from investing activities for the three months ended March 31, 2004 included a $51.7 million net increase in our securities available-for-sale portfolio, a $1.0 million decrease in restricted cash and $0.5 million of purchases of property and equipment.

Net cash provided by financing activities was $3.4 million during the three months ended March 31, 2005, compared with net cash used in financing activities of $3.5 million during the three months ended March 31, 2004. Cash flows from financing activities for the three months ended March 31, 2005 primarily consisted of proceeds from borrowings on our $18.0 million bank credit facility. Cash flows from financing activities for the three months ended March 31, 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:

the progress of our clinical trials;

the progress of our research and preclinical activities;

the number and scope of our research programs;

our ability to establish and maintain strategic collaborations;

the costs involved in enforcing or defending patent claims and other intellectual property rights;

the costs and timing of regulatory approvals;

the costs of establishing or expanding manufacturing, sales and distribution capabilities;

the success of the commercialization of Canvaxin;

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

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

In December 2004, we entered into an $18.0 million loan and security agreement with a financial institution. We may draw on the credit facility at any time prior to December 31, 2005 and 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. 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 a certain cash position at the end of each calendar quarter. 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 March 31, 2005.

Table of Contents

As of March 31, 2005, we have borrowed $9.8 million 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 $8.5 million, as well as future borrowings under the credit facility, will primarily be used to finance certain capital expenditures associated with the expansion of our biologics manufacturing facility. The existing borrowings under this credit facility as of March 31, 2005 bear interest at the greater of the bank s prime rate or 4.75% (5.75% at March 31, 2005) with interest-only payments due through December 31, 2005.

In 2004, we initiated an expansion of the production capacity of our biologics manufacturing facility located in the Los Angeles, California area, which we anticipate completing in 2005. Total capital expenditures associated with this expansion are estimated to be approximately $18 million, of which $12.0 million has been invested through March 31, 2005. We will fund a significant portion of these capital expenditures through our $18.0 million bank credit facility. Of the capital expenditures invested in the expansion through March 31, 2005, $8.0 million have been funded through this 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 March 31, 2005, we have received aggregate net proceeds of approximately $208.6 million from the sale of equity securities. In addition, through March 31, 2005, we have borrowed an aggregate of approximately $19.1 million under certain credit facilities primarily to finance the purchase of equipment and leasehold improvements, of which $10.0 million is our current obligation under our existing credit facilities as of March 31, 2005. Of our existing borrowings as of March 31, 2005, $9.8 million represent borrowings under our $18.0 million bank credit facility and the remainder represent borrowings under an existing credit facility which will be repaid in full in 2005.

We expect that operating losses and negative cash flows from operations will continue at least until the commercialization of Canvaxin which is anticipated to occur in 2007. We believe that our existing cash, cash equivalents and securities available-for-sale as of March 31, 2005, pre-commercialization cost-sharing payments received from Serono and additional borrowings under our $18.0 million bank credit facility will be sufficient to meet our projected operating requirements until June 30, 2006.

We may need to raise additional funds to meet future working capital and capital expenditure needs, potentially through the sale of up to $80 million of common stock under our S-3 shelf registration statement, declared effective by the Securities and Exchange Commission on December 9, 2004, 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 the factors that could cause actual results to differ, see the Risk Factors section in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 15, 2005.*

*Risks Related to Our Business and Industry*

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

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

In April 2005, we discontinued our Phase 3 clinical trial of Canvaxin in Stage IV melanoma based upon the recommendation of the independent DSMB responsible for oversight of this clinical trial. The DSMB concluded, based on its planned, second, interim analysis of the data from this study, that the data were unlikely to provide significant evidence of a survival benefit for Canvaxin-treated patients with Stage IV melanoma versus those receiving placebo. At the same time, based on a limited review of data from the Phase 3 clinical trial of Canvaxin in Stage III melanoma, the DSMB recommended that this clinical trial continue as planned. There were no safety issues identified with either of the Phase 3 clinical trials of Canvaxin, and the recommendation to close the Stage IV study was not made because of any potential safety concern. If the data from the Phase 3 clinical trial in Stage III melanoma are positive, we anticipate submitting a request for marketing approval in the United States and Europe in early 2007. If the FDA and European regulatory authorities accept a positive result in a single Phase 3 clinical trial as sufficient for marketing approval, and if our manufacturing processes and facility are approved by the FDA and European regulatory authorities in connection with our marketing applications, we expect to launch Canvaxin in the United

States and in Europe in 2007. Although the FDA and European regulatory authorities typically require successful results in two Phase 3 clinical trials to support marketing approval, both agencies have approved products based on a single Phase 3 clinical trial that demonstrates statistical significance and where there is an unmet medical need for a life-threatening condition. In the event that the FDA or the European regulatory authorities require the results of an additional clinical trial of Canvaxin before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin in the United States or Europe would be delayed.

Even if we were to ultimately receive regulatory approval for Canvaxin in Stage III melanoma, we may be unable to gain market acceptance of Canvaxin for a variety of reasons, including the treatment regimen. Under this treatment regimen, patients will require 33 doses of Canvaxin over a five-year period and will be advised against the use of other approved treatments during this period that suppress their immune systems, such as chemotherapy. In addition, the success of Canvaxin may be affected by the prevalence and

Table of Contents

severity of adverse side effects, which include blistering, stinging, itching and redness at the site of injection, flu-like symptoms and a decrease in energy. Side effects, such as a localized skin reaction, may also be associated with BCG, which is the immunologic adjuvant we administer to patients with the first two doses of Canvaxin. Furthermore, the availability of alternative treatments, the cost effectiveness of Canvaxin and our collaboration agreement with Serono, discussed below, will affect our ability to commercialize Canvaxin. If we fail to commercialize this lead product candidate, our business, financial condition and results of operations will be materially and adversely affected.

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

The preclinical development, clinical trials, manufacturing and marketing of our product candidates are all subject to extensive regulation by United States and foreign governmental authorities. It takes many years and significant expense to obtain the required regulatory approvals for biological products. Satisfaction of regulatory requirements depends upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. In particular, the specific active immunotherapy technology on which Canvaxin is based is a relatively new form of cancer therapy that presents novel issues for regulatory authorities to consider and, therefore, may be subject to heightened scrutiny in the regulatory process. For example, in 2002, the FDA sent a letter requesting additional information from all holders of Investigational New Drug, or IND, applications for products involving somatic cell or gene therapies, including Canvaxin. As demonstrated by our recent discontinuation of the Phase 3 clinical trial of Canvaxin in patients with Stage IV 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.

In addition to the ongoing Phase 3 clinical trial in patients with Stage III melanoma, in 2005, we expect to begin enrollment of patients in a Phase 2 clinical trial to evaluate the clinical response to Canvaxin of patients with *in-transit* melanoma. *In-transit* melanoma is an uncommon form of Stage III melanoma in which multiple metastases are visible on the surface of the skin. We currently anticipate that we will complete the target enrollment of 100 patients in the Phase 2 clinical trial in patients with *in-transit* melanoma in late 2006.

In addition, manufacturers of biological products, including specific active immunotherapies, 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, which apply to our biologics manufacturing and warehouse facilities, include quality control, quality assurance and the maintenance of records and documentation. Our manufacturing facility also is subject to the licensing requirements of the California Department of Health Services and may be inspected by the FDA, foreign regulatory authorities and the California Department of Health Services at any time. We and our present or future suppliers may be unable to comply with the applicable CGMP regulations and with other FDA, state and foreign regulatory requirements. Failure to maintain a license from the California Department of Health Services or to meet the inspection criteria of the FDA and foreign regulatory authorities would disrupt our manufacturing processes and would delay our clinical trials and the eventual commercialization of our product candidates. Our suppliers include CIMAB, which will supply our newly licensed specific active immunotherapeutic product candidates that target the EGFR signaling pathway for Phase 2 clinical trials, and for Phase 3 clinical trials and commercialization in countries in our territory other than the United States, Canada and Mexico.

If an inspection by the FDA, California Department of Health Services 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 for commercial sale, or our facilities or those of our suppliers could be closed.

*If clinical trials of Canvaxin do not produce successful results, we will be unable to commercialize this product candidate.*

Our collaboration agreement with Serono allows us to share equally the ongoing development costs related to Canvaxin with Serono. However, in order to receive regulatory approval for this product candidate, we must conduct extensive clinical trials to demonstrate safety and efficacy. Clinical testing is expensive, can take many years and has an uncertain outcome. While difficult to predict, we estimate that we and our collaboration partner, Serono, will incur at least an additional $115 million in development costs through 2007, when we anticipate commercializing Canvaxin. Failure can occur at any phase of clinical testing.

**Table of Contents**

While Canvaxin is currently being evaluated in a Phase 3 clinical trial in patients with Stage III melanoma, and we plan to commence a Phase 2 clinical trial of Canvaxin in patients with *in-transit* melanoma, these trials may not produce positive results and may, under some circumstances, be terminated early.

Both of our Phase 3 clinical trials of Canvaxin in patients with Stage III and Stage IV melanoma were designed with three interim analyses prior to the final analysis at the planned completion of the clinical trials. At each interim analysis, the independent DSMB reviews unblinded data from the clinical trials primarily to evaluate the safety of Canvaxin. Our Phase 3 clinical trial of Canvaxin in Stage IV melanoma was discontinued in April 2005 based upon the recommendation of the DSMB, which concluded, based on its second interim analysis, that the data were unlikely to provide significant evidence of a survival benefit for Canvaxin-treated patients with Stage IV melanoma versus those receiving placebo. At the same time, based on a limited review of data from the Phase 3 clinical trial of Canvaxin in Stage III melanoma, the DSMB recommended that this clinical trial continue as planned. There were no safety issues identified with either of the Phase 3 clinical trials of Canvaxin, and the recommendation to close the Stage IV study was not made because of any potential safety concern.

We anticipate that the independent DSMB will complete its review of the planned, third interim analysis of data from our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma late in the third quarter of 2005, and that the final analysis of this data will occur in mid-2006. The interim analyses of data from our Phase 3 clinical trial in patients with Stage III melanoma may only be performed after 392 patients have expired. Thus, these dates are only estimates based on our periodic analyses of the rate of patient deaths in the clinical trial, and may be delayed or accelerated if these rates change.

It is possible that in connection with the interim analyses, the independent DSMB may determine that there are safety risks associated with Canvaxin, that the data from the trials has been shown to meet the pre-established efficacy endpoint and continuing the trial would not be in the best interests of the patients who are receiving the placebo as opposed to the active agent or, as occurred with our Phase 3 clinical trial in patients with Stage IV melanoma, that treatment with the active agent is not likely to provide evidence of a survival benefit. The DSMB may also recommend the discontinuation of the trials for safety reasons at any other time.

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

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

We may also encounter difficulties related to the clinical trials of the specific active immunotherapeutic product candidates that target the EGFR signaling pathway that we have licensed from CIMAB. 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 the three specific active immunotherapeutic product candidates that target the EGFR signaling pathway. In the absence of such a license from OFAC, the execution of and our performance under the agreement with CIMAB would expose us to legal and criminal liability. At any time, there may occur for reasons beyond our control a change in U.S. or Cuban law, or in the regulatory environment in the U.S. or Cuba, or a shift in the political attitudes of either the U.S. or Cuban governments, that could result in the suspension or revocation of our OFAC license or in our inability to carry out part or all of the licensing agreements with CIMAB. There can be no assurance that the U.S. government will not modify existing law or establish new laws or regulations that may adversely affect our ability to develop, test, license and commercialize these product

Table of Contents

candidates. There can be no guarantee that our OFAC license may not be revoked or amended in the future, or that either the U.S. or Cuban governments may not restrict our ability to carry out all or part of our licensing agreements with CIMAB. 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 Phase 2 clinical trials of these products that were conducted in Cuba as the basis for our applications to conduct additional Phase 2 or Phase 3 clinical trials, or as part of our application to seek marketing authorizations for such products.

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

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting the ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. In April 2002, the FDA inspected our clinical trial operations and three of our clinical trial sites. As a result of the FDA s inspections, we received a report of observations from the FDA. The deficiencies noted in this report included inadequate documentation of the review and approval of clinical site investigators and a contract clinical trial monitoring firm; delays in obtaining formal internal approvals of some of our standard operating procedures; and lack of timeliness in preparing and filing certain reports associated with the clinical trials and in obtaining compliance with corrective action plans by several clinical trial sites. We responded to the FDA s report of observations with a corrective action plan and, in December 2002, we received an untitled letter from the FDA, requesting additional follow-up information related to the April 2002 inspection. We provided the requested information and have received no further requests from the FDA in that regard.

In addition, JWCI and the Medical College of Virginia received reports of observations and formal warning letters from the FDA in connection with the 2002 inspections. The deficiencies noted in these warning letters included the use of an incorrect version of patient informed consent forms, delayed reporting of serious adverse events to the sponsor and to relevant institutional review boards, and failures to rigorously follow the investigational plan. Both sites responded to the FDA s report of observations and, in December 2002, the FDA notified the two clinical trial sites that received the warning letters that it had reviewed their responses and that no further responses were necessary at that time. There were no delays to the clinical trials attributable to these inspections, reports of observations or warning letters. We cannot be sure that the FDA or other regulatory authorities will not request further data or information regarding our clinical trial operations in the future. The FDA may elect to re-inspect our clinical operations for a variety of reasons, including to confirm that we and our clinical trial sites continue to observe the corrective actions taken in response to the initial FDA inquiry. Moreover, if the FDA determines that the deficiencies noted at any of the sites are of sufficient concern, it could require that data from such sites be excluded from our clinical trial results and additional patients be enrolled as part of the protocol, that the Phase 3 studies be redone, or that additional Phase 3 clinical trials be conducted. In August 2004, JWCI received a warning letter from the FDA with respect to a Phase 2 clinical study of Canvaxin in patients with advanced-stage colorectal cancer that was initiated in 1997, prior to the formation of our company. The warning letter resulted from an inspection conducted at JWCI in May 2004, and noted several deficiencies, including failure to follow the investigational plan, conducting tests prior to obtaining patient informed consent, failure to provide information to the responsible institutional review board, and failure to maintain accurate case histories and other data pertinent to the investigation. This advanced-stage

colorectal cancer study was closed by us in May 2003.

*Based on the positive results of the Phase 1 and Phase 2 clinical trials of Canvaxin conducted by our founder, Dr. Morton, who has a substantial ownership interest in our common stock and other economic incentives, two Phase 3 clinical trials of Canvaxin for the treatment of patients with Stage III and Stage IV melanoma were undertaken. If the results from the Phase 1 and Phase 2 clinical trials were affected by a bias or conflict of interest and we fail to obtain satisfactory Phase 3 clinical trial results, our development of Canvaxin would be significantly delayed or may be terminated.*

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

Table of Contents

Of the approximately 2,600 patients who have been administered Canvaxin in Phase 1 and Phase 2 clinical trials, fewer than 50 of those patients received Canvaxin at locations other than JWCI and UCLA. As of April 1, 2005, Dr. Morton beneficially owned approximately 18.6% of our common stock. In addition, pursuant to a cross-license agreement with JWCI, in August 2000 we issued JWCI 284,090 shares of common stock, which represented approximately 4.8% of our common stock at the time of issuance. Moreover, Dr. Morton and JWCI received significant funding from the National Institutes of Health to support the early clinical trials of Canvaxin and this funding was a significant source of revenue for JWCI. We are obligated to pay JWCI 50% of the initial net royalties we receive from any sublicensees from sales of Canvaxin, if any, up to $3.5 million. Subsequently, we are obligated to pay JWCI a 1% royalty on net sales, if any, of Canvaxin to third parties by us, our sublicensees and affiliates. Based on the positive results of the Phase 1 and Phase 2 clinical trials conducted by Dr. Morton and other investigators at JWCI and UCLA, two international Phase 3 clinical trials of Canvaxin for the treatment of patients with Stage III and Stage IV melanoma were undertaken. In April 2005, we discontinued our Phase 3 clinical trial of Canvaxin in Stage IV melanoma based upon the recommendation of the independent DSMB, which concluded that the data were unlikely to provide significant evidence of a survival benefit for Canvaxin-treated patients with Stage IV melanoma versus those receiving placebo. At the same time, based on a limited review of data from the Phase 3 clinical trial of Canvaxin in Stage III melanoma, the DSMB recommended that this clinical trial continue as planned. There were no safety issues identified with either of the Phase 3 clinical trials of Canvaxin, and the recommendation to close the Stage IV study was not made because of any potential safety concern. If it is determined that the results of these Phase 1 and Phase 2 clinical trials are affected by a bias or conflict of interest and we fail to obtain satisfactory results from our Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma, our development of Canvaxin would be significantly delayed or may be terminated.

*The analyses of data collected during Phase 1 and Phase 2 clinical trials may not be predictive of the future results of our ongoing Phase 3 clinical trial of Canvaxin in patients with Stage III melanoma. Data from these Phase 1 and Phase 2 clinical trials were evaluated using retrospective survival analyses that may be subject to potential selection biases.*

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

In addition to analyses of survival data from all patients with Stage III melanoma in the JWCI database who met certain criteria, matched-pair analyses were performed. These matched-pair analyses were conducted by using prognostic factors that may be predictive of survival to match patients with Stage III melanoma who received Canvaxin with similar, historical control patients in the database who did not receive Canvaxin. Median overall survival and five-year survival rates were compared between patients with Stage III melanoma who were treated with Canvaxin and the matched-pair patient historical control groups who were not treated with Canvaxin. All clinical data reported regarding the patients in the Phase 1 and Phase 2 clinical trials were obtained from JWCI s database and we have not independently performed any audit or other reconciliation against actual patient medical records. In addition, retrospective analyses of matched-pair data are not generally deemed sufficient by the FDA and most foreign regulatory authorities as a basis for approval to market an oncology product because such approval generally requires prospective, randomized clinical trials.

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

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

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

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

severity of disease, such as size of the patient s initial tumors and the number of lymph nodes affected.

In particular, specialty cancer centers such as JWCI tend to treat patients with more advanced disease than other types of healthcare facilities. As a result of these factors and the uncertainties affecting the clinical trial process generally, the results of the

Table of Contents

Phase 1 and Phase 2 clinical trials may not be predictive of the future results of our Phase 3 clinical trial in patients with Stage III melanoma.

*We are dependent on our collaboration with Serono to commercialize Canvaxin, our lead product candidate. Events or circumstances may occur that delay or prevent the commercialization of Canvaxin or cause Serono to terminate our collaboration agreement.*

Under the terms of our collaboration agreement with Serono, we granted Serono a worldwide license under some of our trademarks, patents and know-how to develop, manufacture, commercialize and use for the prevention and treatment of any human disease our investigational specific active immunotherapy product, Canvaxin. The license is co-exclusive with us in the United States, and exclusive to Serono in the rest of the world.

While our agreement with Serono requires them to use commercially reasonable efforts to jointly develop Canvaxin worldwide, to jointly commercialize and co-promote Canvaxin in the United States, and to commercialize Canvaxin outside the United States, we will have limited control over the amount and timing of resources Serono may devote to our collaboration following FDA approval in the United States nor can we control when Serono will seek regulatory approvals outside of the United States. In addition, if Serono s sales and marketing activities for Canvaxin are otherwise not effective, Canvaxin sales and our business may be harmed.

We are subject to a number of additional risks associated with our dependence on our collaboration with Serono, including:

- we and Serono could disagree as to development plans, including the number and timing of clinical trials;
- Serono could independently develop, develop with third parties or acquire products that could compete with Canvaxin, including drugs approved for other indications that are used by physicians off-label for the treatment of melanoma; and
- disputes regarding the collaboration agreement that delay or terminate the development, receipt of regulatory approvals, or commercialization of Canvaxin, delay or prevent the achievement of clinical or regulatory objectives that would result in the payment of milestone payments or result in significant litigation or arbitration.

Serono may terminate the collaboration agreement for convenience upon 180 days prior notice. If Serono elects to terminate the agreement after receipt of FDA approval, we would be forced to fund the entire sales force for Canvaxin and/or seek new marketing partners for Canvaxin. This could lead to loss of sales and negatively impact our business. In the event Serono elects to terminate the agreement prior to FDA approval, we would also be forced to fund all of the development costs of Canvaxin. In the event the collaboration agreement is terminated, we may not be successful in finding another collaboration partner on favorable terms, or at all, and any failure to obtain a new partner on favorable terms could adversely affect the development, manufacture and commercialization of Canvaxin and our business.

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

In 2004, we completed the enrollment of 1,160 patients in our Phase 3 clinical trial in patients with Stage III melanoma. A total of 392 patients participating in this clinical trial must have expired before we can perform this final analysis, so a delay in the collection of follow-up information could adversely impact its timely completion. We cannot be sure that the medical institutions that conduct the clinical testing will devote sufficient resources to this

Phase 3 clinical trial. If our clinical investigators and medical institutions fail to complete the required follow-up on patients, we will be unable to complete this trial, which could prevent us from obtaining regulatory approvals for Canvaxin. In the event that we are unable to maintain our relationship with any of our clinical trial sites, or elect to terminate the participation of any of these clinical trial sites, we may experience the loss of follow-up information on patients enrolled in the Phase 3 clinical trials unless we are able to transfer the care of those patients to another clinical trial site.

We expect to commence enrollment in our Phase 2 clinical trial in patients with *in-transit* melanoma in 2005, and we currently anticipate that we will complete the target enrollment of 100 patients in 2006. We cannot be sure that we will be able to enroll an adequate number of patients to complete this Phase 2 clinical trial. In addition, we may not be able to control the amount and timing of resources that the medical institutions that conduct the clinical testing may devote to this clinical trial. If our clinical investigators and medical institutions fail to enroll a sufficient number of patients in our Phase 2 clinical trial in patients with *in-transit* melanoma, or fail to complete the required follow-up on enrolled patients, we will be unable to complete this trial.

**Table of Contents**

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

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

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

We expend significant time, money and effort in production, record keeping and quality systems to assure that Canvaxin will meet FDA-approved product specifications and other regulatory requirements. We are continuing to develop and plan to validate specialized assays to enable us to ensure the characterization, potency and consistency of our lead product candidate, Canvaxin. We are also validating our quality systems, manufacturing processes and product container closure systems. However, we have no experience producing commercial quantities of Canvaxin.

We previously modified our manufacturing process for Canvaxin and switched from a small volume flask process to a larger scale flask process in an effort to improve our manufacturing process and scale-up our manufacturing capability to produce larger quantities. We introduced Canvaxin that was manufactured using this new process into our two Phase 3 clinical trials for Stage III and Stage IV melanoma in 2003. In 2004, we initiated an expansion of our manufacturing facility for Canvaxin, which will continue in 2005. In order to increase our ability to meet anticipated demand in the event that we receive regulatory approval to market Canvaxin, we have sought and obtained guidance from the FDA and European regulatory authorities on plans to change from irradiating Canvaxin in our facility using a small-scale irradiator to having a third party irradiate the product using a commercial-scale irradiator, and our plans to change the container in which Canvaxin is stored for shipment to end users from a plastic vial to a conventional glass ampoule. If implemented, these changes would require us to successfully complete significant development and validation programs, and establish the comparability of the product following the introduction of any such changes. Significant delays in the completion or validation of the expanded manufacturing facility, in the change to and validation of the commercial irradiator, or in the change to and validation of the process for manufacturing Canvaxin using the glass ampoule container, could result in an inability to meet the demand for Canvaxin upon our receipt of the necessary regulatory approvals and commercialization of this product candidate.

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

Table of Contents

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

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

*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 the specific active immunotherapeutic product candidates that we have licensed from that company.*

We have obtained from OFAC a license authorizing us to carry out all transactions set forth in the license agreements that we have entered into with CIMAB for the development, testing, licensing and commercialization of SAI-EGF, and with CIMAB and YM Biosciences for the two other specific active immunotherapeutic 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.

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 granted by the Commerce Department. Due to the unique status of the Republic of Cuba, technology that might otherwise be

Table of Contents

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

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

We rely on the availability and condition of our sole biologics manufacturing facility, located in the Los Angeles, California area, to manufacture Canvaxin. Our lease is scheduled to expire on August 14, 2011, although we have the option to renew the term for an additional five years, through August 2016. After that time, we may not be able to negotiate a new lease for our facility. Our manufacturing facility and our warehouse facility are located in a seismic zone, and there is the possibility of an earthquake which could be disruptive to our operations and result in a lack of supply of Canvaxin. Any lack of supply could, in turn, delay our clinical trials and any potential commercial sales. In addition, if either our manufacturing or warehouse facilities or the equipment in these facilities is significantly damaged or destroyed for any reason, we may not be able to replace our manufacturing or warehousing capacity quickly enough to avoid a materially adverse impact to our business, financial condition and results of operations.

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

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

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

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

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

Our strategy is to discover, develop and commercialize new products for the treatment of cancer. The process of successfully developing product candidates is very time-consuming, expensive and unpredictable. We have only recently begun to direct significant effort toward the expansion of our scientific staff and research capabilities to identify and develop product candidates in addition to Canvaxin. We do not know whether our planned preclinical

development or clinical trials for these other product candidates, including for the specific active immunotherapeutic product candidates that we have licensed from CIMAB, will begin on time or be completed on schedule, if at all. In addition, we do not know whether these clinical trials will result in marketable products. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials. We do not anticipate that any of our product candidates will reach the market for at least several years.

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

Table of Contents

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

In addition to our collaboration agreement with Serono for Canvaxin, we intend to rely on strategic collaborations for research, development, marketing and commercialization of our other product candidates. We have not yet marketed or sold any of our product candidates in the United States or elsewhere and we will need to continue to build our internal marketing and sales capabilities or enter into successful collaborations for these services in order to ultimately commercialize our product candidates. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of new collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. 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. For example, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

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

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

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

Specifically, we face competition from a number of companies working in the fields of specific active immunotherapy for the treatment of solid tumors including melanoma, anti-angiogenesis, signal transduction through the EGF receptor pathway, as well as companies working to develop technologies similar to the T-oligonucleotide technology to regulate cell responses as a treatment for cancer. 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. Products marketed in the United States and elsewhere for melanoma include Chiron Corporation s Proleukin(R) (IL-2), Schering-Plough Corporation s IntronA(R) (interferon alpha) and Bayer AG s chemotherapeutic agent dacarbazine. In addition, a modified form of Intron(A), which is called pegylated Intron(A) and which remains in the body longer than the non-modified form, is being tested in Phase 3 clinical trials in Europe for the treatment of patients with Stage III melanoma. Despite the side effects associated with these chemotherapy and biotherapy products, these products are currently being used in the treatment of patients with advanced-stage melanoma. A number of other potential competitors are developing immunotherapeutics and other approaches for the treatment of advanced-stage melanoma, including Progenics Pharmaceuticals, Inc. s GMK(TM), Antigenics, Inc. s Oncophage(R), and Medarex, Inc. s MDX-010, an antibody directed against the CTLA-4 molecule on T-cells that is being tested in combination with Medarex s MDX-1379, a gp100 peptide melanoma vaccine, all of which are in Phase 3 clinical trials. Vical, Inc. s Allovectin-7(R) was studied in a recently-completed Phase 2 clinical trial, and Vical is designing a Phase 3 clinical trial with high-dose Allovectin-7(R) for certain patients with metastatic melanoma. Oncophage(R) and MDX-010 are being studied in patients with metastatic melanoma, but the clinical trials of these drugs do not require that patients undergo surgical resection to remove all clinically detectable disease prior to the initiation of their treatment. This is in contrast to patients who are being studied in Canvaxin s Phase 3 clinical trial in Stage III melanoma, who have their primary tumors and all clinically detectable metastases resected prior to receiving Canvaxin. In March 2004, Celgene Corporation announced that it was discontinuing its Phase 3 clinical trial studying Revlimid(R) as a monotherapy for the treatment of patients with melanoma, but that it plans to conduct clinical trials for Revlimid(R) in combination with other treatments for melanoma. In May 2004, Genta, Inc., announced that the FDA s oncologic drug advisory committee determined that the clinical trial results provided to it by Genta did not provide enough evidence of effectiveness to outweigh the increased toxicity of administering the drug in combination with dacarbazine for the treatment of patients with advanced malignant melanoma. In September 2004, Maxim Pharmaceutical, Inc. announced that its Phase 3 clinical trial of Ceplene(TM) for the treatment of advanced malignant melanoma patients with liver metastases failed to demonstrate improvement in overall patient survival. If we receive approval to market and sell Canvaxin, 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 melanoma and other forms of cancer, and new discoveries may lead to new technologies for treatment. As a result, Canvaxin, or any other product candidates that we may develop, may be rendered obsolete and noncompetitive.

Several products that target the EGF receptor 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(TM)(gefitinib), an EGF receptor-targeted tyrosine kinase inhibitor for refractory Stage IV NSCLC, ImClone Systems, Inc. s Erbitux(TM)(cetuximab), an EGF receptor monoclonal antibody for Stage IV refractory colorectal cancer, and Genentech, Inc. and OSI Pharmaceuticals, Inc. s EGF receptor-targeted tyrosine kinase inhibitor, Tarceva(TM) (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(TM) 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(TM) 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 EGF receptor and HER-2, which is being studied in patients with advanced metastatic breast cancer whose disease progressed on Herceptin(R) (trastuzumab) therapy, and Abgenix, Inc. and Amgen, Inc. s panitumumab (ABX-EGF), a fully human monoclonal antibody targeting the EGF, which is being studied in patients with advanced colorectal and renal cell cancer. Several

other monoclonal antibodies and tyrosine kinase inhibitors targeting the EGF receptor 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 EGF receptor 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, and working to develop technologies similar to our T-oligonucleotide technology that use internal cellular mechanisms to regulate cell responses to treat cancer. We expect that competition among such products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position. As a result, any product candidates that we may develop may be rendered obsolete and noncompetitive.

Table of Contents

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.

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

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

our ability to generate revenues and achieve profitability;

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

the availability of capital.

In certain foreign markets, the pricing of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. For example, legislation was enacted on December 8, 2003, which provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. While we cannot predict the full effects of the implementation of this new legislation or whether any legislative or regulatory proposals affecting our business will be adopted, the implementation of this legislation or announcement or adoption of these proposals could have a material and adverse effect on our business, financial condition and results of operations.

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

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

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

our ability to provide acceptable evidence of safety and efficacy;

convenience and ease of administration;

prevalence and severity of adverse side effects;

availability of alternative treatments;

cost effectiveness;

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

Table of Contents

publicity concerning our products or competitive products; and

our ability to obtain third-party coverage or reimbursement.

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

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

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

To date, we have no experience as a company in selling, marketing or distributing biological products. If we are successful in developing and obtaining regulatory approvals for Canvaxin or our other product candidates, we will need to establish sales, marketing and distribution capabilities. We intend to market and sell Canvaxin in the United States with our co-promotion partner, Serono. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for Canvaxin or our other product candidates. Although we have established a strategic collaboration with Serono for the commercialization of Canvaxin outside the United States, we have not established collaborations to market our other product candidates outside the United States. If we are unable to establish such collaborations or if our collaboration agreement with Serono is terminated, we may be required to market our product candidates outside of the United States directly, or to find another collaboration partner. In the event that we must market our product outside of the United States directly, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

We currently plan to distribute Canvaxin from our manufacturing facility in liquid nitrogen storage containers, which will require that any distribution service we retain will need to comply with exacting standards and precise specifications in order to preserve Canvaxin in the appropriate form for administration to patients. Although there are several distributors that could potentially meet our requirements for the handling, storage and distribution of Canvaxin, we may be unable to obtain distribution services on economically viable terms, or at all. Any failure to comply with the precise handling and storage requirements for Canvaxin by our distribution service or any medical facility that may store Canvaxin prior to administration to patients could adversely affect its quality and, as a result, materially and adversely affect our results of operations.

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

We are currently dependent on a sole source supplier, Organon Teknika Corporation, for the BCG product that we administer to patients with the first two doses of Canvaxin. Our supply agreement with Organon Teknika had an initial term of one year beginning in April 1998, with automatic renewals for successive one-year terms. Under some circumstances, Organon Teknika can terminate the agreement if we fail to purchase BCG for specified periods of time. However, in 2004 we purchased BCG, which should preserve our agreement with Organon Teknika for the foreseeable future. The FDA and other regulatory authorities may require that if the manufacturing source of BCG is changed, comparability be demonstrated before patients may be administered BCG from an alternative source with Canvaxin. If required, the demonstration of comparability may require additional clinical trials to be conducted. There may be similar requirements if we change our suppliers for other components. We may not be able to demonstrate

comparability and the effort to do so may require significant expenditures of time and money, which could have a material and adverse effect on our results of operations.

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

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

We will need to expand and effectively manage our organization, operations and facilities in order to successfully pursue our research, development and commercialization efforts and secure collaborations to market and distribute our products. We increased the number of our full-time employees from 22 as of December 31, 2000 to 187 as of March 31, 2005, and we expect the number of employees to continue to grow to meet our strategic objectives. If we continue to grow, it is possible that our management and scientific personnel, systems and facilities currently in place may not be adequate. Our need to effectively manage our operations, growth and various projects requires that we continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

*If we 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.*

The loss of the services of any principal member of our management and scientific staff, including David F. Hale, our President and Chief Executive Officer, and John Petricciani, M.D., our Senior Vice President, Medical and Regulatory Affairs, could significantly delay or prevent the achievement of our scientific and business objectives. Mr. Hale s employment agreement expires in October 2005, and Dr. Petricciani s employment agreement expires in January 2009. Competition among biotechnology companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to our success. We may be unable to attract and retain key personnel on acceptable terms, if at all.

We 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 Canvaxin and our other product candidates. In addition, Dr. Morton has retained the right to use the cell lines in Canvaxin for the diagnosis or detection of cancer.

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

*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

Table of Contents

with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for damages or penalized with fines, and this liability could exceed our resources. We may have to incur significant costs to comply with future environmental laws and regulations.

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

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

Product liability claims may stem from side effects that are associated with Canvaxin, including blistering, stinging, itching and redness at the site of injection and a decrease in energy. Some patients have experienced flu-like symptoms, including headache, muscle aches, joint aches, fever, nausea, diarrhea, vomiting, cough, chills and loss of appetite, as well as irritation and ulceration at the injection sites. A small number of patients who received Canvaxin have had a drop in the number of white blood cells in their blood or developed white patches on their skin. Two patients out of approximately 3,000 who have received Canvaxin experienced degeneration of part of their retinas. The cause of this condition, which is known as melanoma-associated retinopathy, is unknown, but it may occur spontaneously in patients with melanoma who have not received Canvaxin. In addition, although Canvaxin is treated with radiation to prevent the melanoma cells in Canvaxin from replicating when administered to patients, there is a theoretical possibility that these cells may develop into a tumor after injection. There is also a small possibility that Canvaxin may contain unidentified agents, such as bacteria or viruses, which could cause infections or other diseases, or that patients could have a localized skin reaction to Canvaxin. Side effects may also be associated with BCG, which we administer to patients with the first two doses of Canvaxin. BCG is also used to prevent tuberculosis and some patients treated with BCG have developed serious complications such as an infection with BCG or a severe muscle and nerve weakness known as Guillain Barre syndrome. To date, neither of these complications has been reported in patients who received BCG with Canvaxin. However, both Canvaxin and BCG are investigational for treating metastatic melanoma and may, along with our other product candidates, have other side effects that have not been seen or predicted. While we would expect to provide adequate disclosure to patients of the potential for adverse side effects, we cannot be sure that we will be able to do so or that we will be able to avoid the cost and expense of defending product liability claims.

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

*Risks Related to Our Financial Results and Need for Financing*

*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 $157.0 million in net losses from our inception through March 31, 2005. We expect to increase our operating expenses over the next several years as we prepare for the potential commercialization of Canvaxin if this product candidate is approved by regulatory authorities, advance our other product candidates into clinical trials, expand our research and development activities, acquire or license new technologies and product candidates and scale-up our manufacturing and quality operations. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with

our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

*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 may borrow an aggregate of $18.0 million. 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 intend to use 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. 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.

Table of Contents

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 and cash equivalents 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.

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.

*If we fail to obtain the capital necessary to fund our operations, we will be unable to develop or commercialize Canvaxin or other product candidates 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 March 31, 2005, pre-commercialization cost-sharing payments from Serono and additional borrowings under our $18.0 million bank credit facility will be sufficient to meet our projected operating requirements through June 30, 2006. We intend to raise additional funds to meet our working capital and capital expenditure needs, potentially through the sale of up to $80 million of common stock under our S-3 shelf registration statement, declared effective by the Securities and Exchange Commission on December 9, 2004, additional debt financing or through additional strategic collaboration agreements. In addition, we will need to raise additional capital in order to expand the clinical trials for Canvaxin, initiate clinical trials with our specific active immunotherapeutic product candidates that target the EGFR signaling

Table of Contents

pathway, advance other product candidates into clinical trials and expand our research and development activities. Our ability to scale-up our manufacturing and quality operations and respond to competitive pressures could be significantly limited if we are unable to obtain the necessary capital. We do not know whether additional financing will be available when needed, or whether it will be available on favorable terms or at all. 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:

- the completion of clinical testing for Canvaxin in Stage III and *in-transit* melanoma, potential clinical testing of Canvaxin in other indications, and the initiation of clinical trials for our specific active immunotherapeutic product candidates that target the EGFR signaling pathway and for one of our humanized, anti-angiogenic monoclonal antibodies;

- progress in preclinical development and clinical trials for our other product candidates;

- the time and costs involved in obtaining and maintaining regulatory approvals for Canvaxin and our other product candidates;

- progress in, and the costs of, our research and development programs;

- the scope, prioritization and number of programs we pursue;

- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;

- the costs of expanding our manufacturing capabilities;

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

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

- competing technological and market developments.

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

*We 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.*

Our ability to generate revenue depends on a number of factors, including our ability to successfully complete our ongoing Phase 3 clinical trial for Canvaxin in Stage III melanoma and obtain regulatory approvals to commercialize this product candidate as well as others. 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, including sales of Canvaxin. Even if Canvaxin receives regulatory approvals, we will need to establish and maintain sales, marketing and distribution capabilities. We plan to rely on Serono to help generate revenues in markets outside of the United States, and to co-promote Canvaxin in the United States, and we cannot be sure that this collaboration will be successful. Even if we are able to commercialize Canvaxin, we may not achieve profitability for at least several years after generating material revenue. If we are unable to become profitable, we may be unable to continue our operations.

*Our quarterly operating results and stock price may fluctuate significantly.*

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

the status of development of Canvaxin and our other product candidates;

the time at which we enter into research and license agreements with strategic collaborators that provide for payments to us, and the timing and accounting treatment of payments to us, if any, under those agreements;

Table of Contents

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 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.

Table of Contents

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

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

We hold exclusive rights through two agreements with CIMAB to develop and commercialize within a specific territory, which includes the U.S., Canada, Japan, Australia, New Zealand, Mexico and certain countries in Europe, SAI-EGF, a Phase 2 specific active immunotherapeutic product candidate that targets the EGF receptor 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-á, 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.

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 specific active immunotherapeutics 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. We hold rights to certain T-oligonucelotide technology under a sublicense agreement from SemaCo, which can be terminated if we fail to perform any of the obligations that we are required to perform under that agreement, including using commercially reasonable efforts to develop commercially viable products based on the licensed technology.

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 two of our 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

Table of Contents

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

- we might not have been the first to make the inventions covered by each of our 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;
- 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 specific active immunotherapeutic product candidates that target the EGF receptor 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.

Table of Contents

In particular, before we obtained commercial development rights to Canvaxin and related technology, development of some of the related technology was carried out at UCLA Medical Center and JWCI over a period of about 15 years. While we have agreements with these parties designed to protect our trade secrets and know-how, these agreements may not be sufficient to prevent all parties who have had access to this proprietary information over the years from using this information to compete with us.

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

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. In particular, we cannot be certain that Dr. Morton, from whom we have acquired the patent rights for Canvaxin, was the first to make his inventions or to file patent applications for those inventions. 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.

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

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

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

While we prevailed in the opposition proceeding and the appeal by Boehringer Ingelheim, 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.

Table of Contents

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

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

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

Our current stockholders hold a substantial number of shares of our common stock that they will be able to sell in the public market. 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:

- changes in the regulatory status of our product candidates, including results of our clinical trials for Canvaxin, for our specific active immunotherapeutic product candidates targeting the EGFR signaling pathway, and for our humanized, anti-angiogenic monoclonal antibodies, 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;

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

Table of Contents

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 secured in December 2004 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 long-term 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 March 31, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

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

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

Through March 31, 2005, we have used approximately $63.4 million of the net proceeds from the public offering primarily to continue the development and prepare for the commercialization of our specific active immunotherapeutic product candidate, Canvaxin, including scale-up of our manufacturing operations and quality systems, advance the development of our other product candidates and fund other working capital and general corporate purposes.

Table of Contents

**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(3) | Fourth Amendment to Lease entered into as of January 18, 2005, between Marina Business Center, LLC and CancerVax Corporation |
| 10.2(4)# | CancerVax 2005 Management Incentive Compensation Plan |
| 10.3# | Form of Restricted Stock Award Agreement (Performance Vesting) |
| 10.4# | Form of Option Agreement (Time Vesting) |
| 10.5# | Form of Option Agreement (Performance Vesting) |
| 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.

(3) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 20, 2005.

(4) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2005.

# 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: May 6, 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)*