CANCERVAX CORP
Form 10-K
March 15, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K
FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the year ended December 31, 2004

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 0-50440
CancerVax Corporation
(Exact name of registrant as specified in its charter)

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

(760) 494-4200
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
None	None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.00004 per share

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past

90 days. Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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

As of June 30, 2004, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $132.1 million, based on the closing price of the registrant s common stock on the Nasdaq National Market.

The number of outstanding shares of the registrant s common stock, par value $0.00004 per share, as of February 1, 2005 was 27,809,748.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after registrant s fiscal year end December 31, 2004 are incorporated by reference into Part III of this report.

CANCERVAX CORPORATION
FORM 10-K ANNUAL REPORT
For the Year Ended December 31, 2004
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PART I

Forward-Looking Statements

Any statements in this report and the information incorporated herein by reference about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue, anticipate, intend, seek, plan, expect, should, or would. Among cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, statements about the progress and timing of our clinical trials; difficulties or delays in development, testing, obtaining regulatory approvals, producing and marketing our products; unexpected adverse side effects or inadequate therapeutic efficacy of our products that could delay or prevent product development or commercialization, or that could result in product recalls or product liability claims; the scope and validity of patent protection for our products; competition from other pharmaceutical or biotechnology companies; our ability to obtain additional financing to support our operations; and other risks detailed below under the caption Business 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.

Corporate Information

Unless the context requires otherwise, in this report the terms we, us and our refer to CancerVax Corporation and its wholly owned or indirect subsidiaries, Cell-Matrix, Inc., Tarcanta, Inc., and Tarcanta, Ltd., and their predecessors.

We have registered the CancerVax® trademark and also use Canvaxin™ and our logo as trademarks in the United States and other countries. All other brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Item 1. Business

Overview

We are a biotechnology company focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. We were incorporated in Delaware in June 1998 and commenced substantial operations in the third quarter of 2000. Our lead product candidate, Canvaxin, is one of a new class of products being developed in the area of specific active immunotherapy, also known as therapeutic cancer vaccines. Canvaxin, which is currently being studied in two Phase 3 clinical trials at 80 sites worldwide for the treatment of patients with Stage III and Stage IV, or advanced-stage, melanoma, the deadliest form of skin cancer. Canvaxin has received fast track designation from the Food and Drug Administration, or FDA, for the treatment of patients with advanced-stage melanoma and orphan drug designation from the FDA for the treatment of invasive melanoma.

In September 2004 we completed the target enrollment of 1,118 patients in the Phase 3 clinical trial in patients with Stage III melanoma. An additional 42 patients who had consented to participate in this clinical trial prior to the time that we reached the target enrollment were also enrolled, bringing the total enrollment to 1,160 patients. As of March 1, 2005, 485 patients out of a planned total enrollment of 670 patients had been enrolled in the Phase 3 clinical trial in Stage IV melanoma, which is being conducted at approximately 70 clinical trial sites. If the FDA and foreign regulatory authorities accept a positive result in a single Phase 3 clinical trial as sufficient for approval, and if our manufacturing processes and facility are approved by the FDA and European regulatory authorities in connection with our

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marketing applications, we anticipate launching Canvaxin for advanced-stage melanoma in the United States and in Europe in 2007.

In December 2004, we announced an exclusive worldwide collaboration with Serono Technologies, S.A., a Swiss corporation, for the development and commercialization of Canvaxin. Serono made an initial cash payment of $37 million to us, which included a $25 million up-front license fee, received in January 2005, and $12 million for the purchase of 1 million shares of our common stock, which was received in December 2004. Serono also agreed to make up to $253 million in additional payments to us, which are dependent on the achievement of specified development, regulatory and commercial milestones. The portion of these milestone payments related to the receipt of marketing authorization for Canvaxin solely in Stage III and Stage IV melanoma in the United States and the European Union, or EU, could amount to $100 million. Under the collaboration agreement, we will jointly develop Canvaxin with Serono for melanoma, as well as for other indications. We will share equally the costs of developing and seeking regulatory approvals for Canvaxin from the date of our collaboration agreement going forward. We will co-promote Canvaxin in the United States with Serono, and share equally specified expenses and profits. We will distribute Canvaxin to customers and record sales in the United States, if any. Outside the United States, Serono will have the exclusive right to commercialize Canvaxin and will pay royalties to us based on its sales of the product, if any. Initially, we will manufacture Canvaxin for supply throughout the world, although Serono may eventually establish a second manufacturing site for Canvaxin to supply, primarily, markets outside of the United States.

In retrospective analyses of pooled data from Phase 2 clinical trials in patients with melanoma, Canvaxin demonstrated:

- a statistically significant improvement in survival in a matched pair analysis of 739 patients who received Canvaxin at JWCI or UCLA for Stage III melanoma versus 739 historical control patients with Stage III melanoma who were treated at JWCI or UCLA but did not receive Canvaxin. These results were published in the October 2002 issue of the *Annals of Surgery*;

- a statistically significant improvement in survival in a matched pair analysis of 107 patients who received Canvaxin at JWCI or UCLA for Stage IV melanoma versus 107 historical control patients with Stage IV melanoma who were treated at JWCI or UCLA but did not receive Canvaxin. These results were published in the December 2002 issue of the *Journal of Clinical Oncology*; and

- a favorable safety and side effect profile relative to existing therapies for the treatment of patients with advanced-stage melanoma.

In addition to Canvaxin, we have one product candidate in clinical development and a number of product candidates in research and preclinical development for the treatment or prevention of cancer, including three specific active immunotherapeutic product candidates that target the epidermal growth factor, or EGF, receptor signal transduction pathway, humanized monoclonal antibodies and peptides that use extracellular matrix approaches to inhibit tumor angiogenesis, and T-oligonucleotides, which are short DNA sequences that appear to activate natural protective pathways in cells that cause malignant cells to stop growing and die.

We are targeting large disease markets with significant unmet medical needs. Melanoma is the sixth most commonly diagnosed cancer in the United States, and existing therapeutic alternatives have had inconsistent efficacy results and involve serious toxicity. We manufacture clinical supplies of Canvaxin at our biologics manufacturing facility, which is being expanded to provide sufficient capacity to satisfy anticipated commercial demand for Canvaxin for several years after launch.

Industry Background

Cancer

The World Health Organization estimated that more than 10 million people were diagnosed with cancer worldwide in the year 2000 and that this number will increase to 15 million by 2020. In addition, the World Health Organization estimated that 6 million people died from the disease in 2000. The American Cancer Society estimated that over 1.3 million people in the United States were diagnosed with

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cancer in 2004 and over 500,000 people died from the disease. In 2004, the American Cancer Society announced that cancer has become the leading cause of death in people over age 85.

As the incidence of cancer grows, it is estimated that revenues from cancer drugs will increase in the United States, from $7 billion in 2001 to $11 billion in 2006, a 9% compounded annual growth rate. On a world-wide basis, revenues from cancer drugs are estimated to grow from $15 billion in 2001 to $25 billion in 2006, an 11% compounded annual growth rate.

Melanoma

The World Health Organization reports the worldwide incidence, or number of newly diagnosed cases, of melanoma in 2000 was 132,600, with 37,000 people dying of the disease. According to the American Cancer Society, melanoma is the sixth most commonly diagnosed cancer in the United States. The American Cancer Society estimated that in the United States, approximately 55,000 people were diagnosed with melanoma in 2004 and 7,900 died as a result of the disease. The American Cancer Society also estimated that in 2000, over 510,000 patients in the United States were alive who had been diagnosed with melanoma. For the years 1998 to 2000, the National Cancer Institute s Statistical Research and Applications Branch calculated the lifetime risk of developing melanoma in the United States as 1 in 55 for men, and 1 in 82 for women. Furthermore, according to the National Cancer Institute, since 1997 the incidence of new melanoma cases in the United States has increased at an average rate of more than 5% per year, one of the highest growth rates for any type of cancer. Melanoma is classified into four stages, which are based on well-defined criteria, including characteristics of the primary tumors, presence of disease in regional lymph nodes and presence or absence of metastases. When melanoma is discovered and treated in the early stages, where the cancer is confined to a local area, patients have a relatively high rate of survival. According to an August 2001 study in the *Journal of Clinical Oncology*, Stage I patients have a five-year survival rate of over 90%. Once melanoma has advanced to Stage III, where the cancer has spread to the regional lymph nodes, or Stage IV, where the cancer has spread to distant organs, the prognosis for patients is much worse. The August 2001 study found five-year survival rates for patients with Stage IV melanoma are between 7% and 19%. In 2001, the American Joint Committee on Cancer estimated that approximately 15% of patients with melanoma were initially diagnosed with advanced-stage melanoma, which consists of Stage III and IV melanoma. However, recent scientific articles suggest that increased use of more sensitive diagnostic techniques may increase this percentage. In a February 2003 study in the *Journal of American College of Surgeons*, approximately 38% of 175 patients originally diagnosed with Stage I or Stage II melanoma should have been categorized as having Stage III melanoma.

Surgery is widely-accepted as the standard of care for patients with Stage III melanoma. For patients with Stage IV melanoma, surgery is generally of limited benefit because, in many patients, not all tumors can be removed. Careful patient selection is critical to successful curative surgical resection in patients with Stage IV melanoma.

Although interferon alpha-2b is approved for patients with metastatic melanoma, its use has been limited due to significant toxicity and inconsistent efficacy results in clinical trials. Dacarbazine and Proleukin, or IL-2, have been approved for the treatment of patients with Stage IV melanoma, but neither of these drugs has been shown to increase overall survival in these patients and both drugs are associated with significant toxicity.

Non-small-cell Lung Cancer

According to the World Health Organization, lung cancer is the most frequently diagnosed cancer in the world, with over 1.2 million cases reported in 2000, and is the leading cause of cancer deaths, with over 1.1 million deaths reported in 2000. The American Cancer Society estimates that more than 173,000 cases of lung cancer were diagnosed in the United States in 2004. The National Cancer Institute reports that non-small-cell lung cancer, or NSCLC, represents approximately 80% of all cases of lung cancer in the United States, and represents a significant, unmet medical need. The five-year overall survival of patients with all stages of NSCLC is approximately 15%.

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Immunotherapy for the Treatment of Cancer

The body s immune system is a natural defense mechanism tasked with recognizing and combating cancer cells, viruses, bacteria and other disease-causing organisms. This defense is carried out mainly by white blood cells in the immune system. Specific types of white blood cells, known as T-cells and B-cells, are responsible for carrying out two types of immune responses in the body, the cell-mediated immune response, and the humoral, or antibody-based, immune response, respectively.

Cancer cells produce molecules known as tumor-associated antigens, which are present in normal cells but may be over-produced in cancer cells. The T-cells and B-cells have receptors on their surfaces that may enable them to recognize the tumor-associated antigens. For instance, once a B-cell recognizes a tumor-associated antigen, it may trigger the production of antibodies that kill the tumor cells. T-cells play more diverse roles, including the identification and destruction of tumor cells.

While cancer cells may naturally trigger a T-cell-based immune response during the initial appearance of the disease, the immune system response may not be sufficiently robust to eradicate the cancer. The human body has developed numerous immune suppression mechanisms to prevent the immune system from destroying the body s normal tissues. Cancer cells have been shown to utilize these mechanisms to suppress the body s immune response against cancer cells. Even with an activated immune system, the number and size of tumors can overwhelm the immune system.

Research focused on the activation of the immune system in the treatment of cancer has increased significantly in recent years. Unlike traditional chemotherapeutic or radiotherapeutic approaches to cancer treatment that are designed to kill cancer cells directly, immunotherapy approaches to cancer are intended to activate and stimulate the body s immune system to fight the cancer. For example, data published in the 1998 issue of the *Journal of Clinical Oncology* indicated that Canvaxin, which is a whole cell-based specific active immunotherapeutic that expresses a number of tumor-associated antigens, elicited an immune response in over 85% of patients to whom it was administered.

The immune system may also be harnessed to inactivate tumor-promoting signaling pathways, such as the EGF receptor signaling pathway, which may interfere with cancer cell growth, and to target specific molecules in the bloodstream or receptors on the surface of cells. EGF is one of several molecules that bind to the EGF receptor, and may be responsible for activating a series of intracellular processes that stimulate cell growth, enhance metastasis, and protect the tumor cells from cell death from treatments such as chemotherapy. While many cells in the human body express the EGF receptor, most solid tumor cell types express the EGF receptor in excessive quantities. By targeting EGF or the EGF receptor with specific active immunotherapies, cancer cell growth and proliferation may be suppressed or eliminated.

Immunotherapy approaches for treating cancer generally fall into three categories:

Passive immunotherapy generally relies on the direct administration of monoclonal antibodies designed to target a specific receptor on the surface of a cell or a secreted protein. Administering the antibodies to patients interferes with the functioning of cancer cells or binds to cancer cells and activates various cytotoxic mechanisms that may help destroy the cancer.

Non-specific active immunotherapy elicits a general immune system response to cancer and includes the use of stimulatory proteins, known as cytokines, such as interferons and interleukins. Cytokines that have been approved for treating cancer in humans to date have been associated with significant side effects. Non-specific active immunotherapy also includes immune stimulatory agents such as bacillus Calmette-Guérin, known as BCG.

Specific active immunotherapy, such as Canvaxin, generates targeted, cell-mediated and antibody-mediated immune responses focused on specific antigens expressed by cancer cells, on specific proteins that may activate tumor-promoting signaling pathways, or on specific receptors found on cancer or normal cells. Specific active immunotherapy is an emerging immunotherapeutic approach to the treatment of cancer that includes the use of whole cells, peptides, antigens, cell fragments and viral vectors.

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Anti-Angiogenesis for the Treatment of Cancer

In a process known as angiogenesis, cancer cells stimulate the formation of new blood vessels in order to bring oxygen and nutrients to rapidly-growing tumor tissue. Angiogenesis involves proliferation of cells that form new blood vessels and are involved in the remodeling of the extracellular matrix, a dense protein network that provides support and growth signals to blood vessels and tumors, and regulates cellular processes such as adhesion, migration, gene expression and differentiation.

During angiogenesis, cancer cells secrete growth factors that activate endothelial cells on the blood vessels supplying the tumor. Activation of these endothelial cells results in growth and proliferation of new blood vessels. In addition, the extracellular matrix is degraded by proteolytic enzymes. Degradation of the extracellular matrix contributes to the release of additional growth factors, facilitates the movement of activated endothelial cells, and supports the growth of new blood vessels. These processes encourage tumor growth through nourishment of the existing tumor, as well as by creating pathways for metastasis of the tumor. By inhibiting the angiogenesis process, it may be possible to restrict blood supply to a tumor and limit its ability to grow and metastasize.

Telomere Signaling Disruption in the Treatment of Cancer

Genetic information communicated through DNA is organized into strands called chromosomes, which end in long, repeating, single strand chains of a specific nucleotide sequence, called the telomere. The proximal end of the telomere is tucked within the DNA to form a loop. In normal cells, disruption of this telomere loop may signal DNA damage or aging, which activates natural protective pathways to prevent excessive replication of compromised cells. In cancer cells, however, these responses are impaired, and cells with gross DNA abnormalities continue to proliferate. Telomere homolog oligonucleotides, or T-oligonucleotides, are short DNA sequences that appear to mimic the effect of telomere loop disruption. It is hypothesized that treatment of cancer cells with T-oligonucleotides may activate natural protective pathways in the cell that cause malignant cells to stop growing and die.

Our Pipeline

The table below lists our principal product candidates:

Product Candidates	Targeted Disease	Status	Commercialization Rights
Specific Active Immunotherapy			
Canvaxin	Stage III melanoma	Phase 3	CancerVax/Serono(a)
Canvaxin	Stage IV melanoma	Phase 3	CancerVax/Serono(a)
SAI-EGF	Non-small-cell lung cancer	Phase 1/2	CancerVax(b)
SAI-TGF-a	Solid tumors	Preclinical	CancerVax(b)
SAI-EGFR-ECD	Solid tumors	Preclinical	CancerVax(b)
Anti-Angiogenesis			
Humanized monoclonal antibodies	Solid tumors, ophthalmic diseases	Preclinical	CancerVax
Various peptides	Solid tumors, ophthalmic diseases	Research	CancerVax
T-oligonucleotides	Cancer	Research	CancerVax

(a) Serono has the right to co-promote Canvaxin with CancerVax in the United States, and to exclusively commercialize Canvaxin outside the United States.

(b) CancerVax has the right to commercialize SAI-EGF, SAI-TGF-a and SAI-EGFR-ECD in the United States, Canada, Japan, Australia, New Zealand, Mexico and specified countries in Europe, including Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands,

Norway, Poland, Portugal, Spain, Sweden, and the United Kingdom.

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Specific Active Immunotherapy Programs

Canvaxin Specific Active Immunotherapy Product Candidates

Canvaxin, initially developed by our founder, Donald L. Morton, M.D., is a specific active immunotherapy designed to stimulate a patient s immune system to fight cancer. Canvaxin is composed of three carefully selected human tumor cell lines that contain a broad array of tumor-related antigens and invoke a strong immune response in most patients with melanoma. Since 1984, over 2,600 patients have been treated with Canvaxin in a number of Phase 1 and Phase 2 clinical trials, primarily supported by the National Institutes of Health through peer-reviewed grants.

Published data indicate that non-patient specific, or allogeneic, melanoma cells can induce an immune response to tumor antigens by both indirect presentation of tumor antigens by host dendritic cells and direct presentation of antigens to host T-cells. Canvaxin is administered with BCG, an immunologic adjuvant, for the first two doses to boost the immune system s ability to mount an immune response to Canvaxin. The anti-tumor immune response that occurs following administration of Canvaxin may result in the destruction of tumor cells that persist or recur following surgery.

Canvaxin can be conveniently administered in an outpatient setting as an injection within the layers of the skin, which is referred to as an intradermal injection. Dendritic cells, which are important in presenting antigens to the immune system, are found in high concentrations below the skin and therefore may be activated upon administration of Canvaxin to these sites. Unlike many other active immunotherapy approaches, which require the removal of tissue from the patient s tumor to manufacture the immunotherapeutic, it is not necessary to remove tumor tissue from patients to manufacture Canvaxin. Therefore, Canvaxin can be manufactured for use by any patient using standardized cell culture process.

Canvaxin is manufactured in our biologics manufacturing facility in the Los Angeles, California area, and manufacturing-related materials are stored in a nearby warehouse facility. Both facilities are operated according to the FDA s current good manufacturing practices, or cGMP regulations. In 2004, we initiated a program to expand our production capabilities, which we plan to complete in 2005.

Advantages of Our Specific Active Immunotherapy Platform

Our specific active immunotherapy technology, on which Canvaxin is based, is a proprietary platform that can potentially be applied to treat a number of solid tumor cancers. We believe our technology may be effective because of the following characteristics:

Use of Whole Cells. This technology uses whole cells that are irradiated during the manufacturing process to prevent replication when administered to patients, but that continue to produce antigens and stimulate the immune system for a period of days to weeks after they have been injected into a patient as they undergo apoptosis, or cell death. We believe that whole cell approaches such as that taken with Canvaxin, may stimulate a more enduring response than cell fragments, peptides and antigens. The use of whole cells may enhance Canvaxin s ability to stimulate a cross reactive immune response against the patient s own tumor cells.

Polyvalence. Administering a polyvalent technology exposes the patient s immune system to multiple antigens that are associated with a wide range of solid tumors. These antigens appear in unpredictable patterns and concentrations among different people and within an individual as their cancer evolves over time. We believe the presentation of numerous antigens, termed polyvalence, is an important element in eliciting a therapeutic immune response in most patients and reducing a tumor cell s ability to escape the immune response. Canvaxin contains at least 38 antigens that may be associated with tumors and may induce an immune response. Other approaches based upon a single tumor-associated antigen or a few tumor-associated antigens may not demonstrate therapeutic value if they do not stimulate a sufficiently broad immune response to cross react with the patient s own tumor, particularly as the tumor changes over time.

Allogeneity. This technology employs non-patient-specific, or allogeneic, tumor cell lines selected for their ability to elicit an immune response and their expression of a large number of tumor-

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associated antigens. This is distinct from the autologous, or patient-specific, approach in which a specific active immunotherapy product is created from cells extracted from a patient s own tumor. Because it relies on cells harvested from the patient, the autologous approach may result in the availability of only a limited number of doses for administration to the patient. We believe there are numerous other potential advantages to our allogeneic approach, including a standardized manufacturing procedure, reduced costs, simplified distribution and improved quality control. Additionally, since allogeneic specific active immunotherapeutics contain a different profile of antigens than the profile to which a recipient has previously been exposed, we believe that these allogeneic immunotherapeutics may induce a stronger anti-tumor immune response than autologous immunotherapeutics.

Canvaxin for the Treatment of Patients with Melanoma

On-Going Phase 3 Clinical Trials for Advanced-Stage Melanoma

Canvaxin is currently being evaluated in two Phase 3 clinical trials for Stage III and Stage IV melanoma at 80 sites worldwide, including many of the leading melanoma treatment centers in the United States, Europe and Australia. In September 2004 we completed the target enrollment of 1,118 patients in the Phase 3 clinical trial in patients with Stage III melanoma. An additional 42 patients who had consented to participate in this clinical trial prior to the time that we reached the target enrollment were also enrolled, bringing the total enrollment to 1,160 patients. We continue to make progress in our Phase 3 clinical trial in patients with Stage IV melanoma and, as of March 1 2005, 485 out of a planned total enrollment of 670 patients had been enrolled in this clinical trial.

The Phase 3 clinical trials are randomized, double-blind, placebo-controlled studies designed to detect a statistically significant increase in overall survival in patients treated with Canvaxin plus BCG, an immunologic adjuvant, compared to those treated with a placebo plus BCG. An immunologic adjuvant is a substance that is administered with another therapy, such as Canvaxin, to enhance the immune response. In the protocols for both clinical trials, patients are required to have their primary tumor and all clinically detectable metastases surgically removed prior to randomization. The treatment protocols call for a total of 33 doses of Canvaxin over a five-year course of therapy, with 15 doses administered in the first year, six in the second year and four doses in each of the third, fourth and fifth years of treatment. In these clinical trials, Canvaxin is administered along with BCG with the first two doses of therapy.

Both Phase 3 clinical trials were designed with three interim analyses. At each interim analysis, an independent DSMB will review unblinded data from one of the clinical trials, primarily to determine whether there are any unexpected safety issues with the product being tested, and to consider whether the clinical trial should continue as originally designed, should be changed, or should be closed early based on these data. The DSMB consists of experts in medical and surgical oncology, statistics and medical ethics who are not participating in our clinical trials, whose primary responsibility is to oversee the studies and safeguard the interests of current and future patients in the trials. If the DSMB recommends that a study be closed early due to demonstration of efficacy at an interim analysis, the FDA must be consulted before a decision is made to do so, since consideration may still need to be given to the regulatory and scientific implications of that decision, such as the adequacy of data with regard to safety, duration of benefit, outcomes in important subgroups, and secondary endpoints. Strict confidentiality must be maintained during these discussions and, pending FDA consultation and review, it is likely that the DSMB would recommend continuation of the clinical trial. In the event that statistical significance in the efficacy of Canvaxin is observed, and if the FDA agrees that we should stop the clinical trials, we would discuss filing a biologics license application, or BLA, with the FDA based on the clinical data accumulated at that time. It is possible that in connection with any of the interim analyses or at any other stage of the trials, the DSMB may determine that there are safety risks associated with Canvaxin, that it is not sufficiently efficacious to continue the trials, or 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. The DSMB may also recommend the discontinuation of the trials for safety reasons at any other time.

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In February 2004, the independent DSMB completed its planned, second interim analysis of our Phase 3 clinical trial of Canvaxin in Stage III melanoma. The interim analysis was conducted on data from 842 patients enrolled in the trial. The DSMB recommended that we continue the trial as planned. We anticipate that the 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 in the third quarter of 2005, and that the final analysis of this data will occur in mid-2006. We also expect that the DSMB will complete its review of the planned, second interim analysis of data from our Phase 3 clinical trial of Canvaxin in patients with Stage IV melanoma in the first quarter of 2005, that the third interim analysis will be reviewed by the DSMB in early 2006, and that the final analysis of this data will occur by mid-2007. The interim analyses of data from our Phase 3 clinical trials may only be performed after the required number of patients participating in each of these clinical trials has expired. Thus, these dates are only estimates based on our periodic analyses of the rate of patient deaths in each of these clinical trials, and may be delayed or accelerated if these rates change.

Analysis of Phase 2 Data

Canvaxin has been studied in over 2,600 patients in Phase 1 and Phase 2 clinical trials at JWCI and UCLA, primarily in patients with advanced-stage melanoma and also in a small number of patients with advanced-stage colorectal cancer. A database has been compiled by JWCI of approximately 11,000 patients with melanoma treated at JWCI and UCLA, including over 2,600 patients who received Canvaxin. Using this database, clinicians and statisticians at JWCI and other institutions performed a number of analyses comparing the difference in survival of patients who received Canvaxin to patients who did not receive Canvaxin. Several analyses were recently published in the *Annals of Surgery* and the *Journal of Clinical Oncology*. The following chart depicts the results from the principal retrospective survival analyses:

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Patients Treated with Canvaxin vs. Patients Not Treated with Canvaxin

Disease Stage		Number of Patients		Patient Population	Median Overall Survival *(p-vales)*(1)	Five-Year Survival
Melanoma	Stage III	Canvaxin	935	All patients(2)	56.4 vs. 31.9 mos. *(p-value = 0.0001)*	49% vs. 37%
		Non-Canvaxin	1,667			
		Total	2,602			
Melanoma	Stage III	Canvaxin	739	All patients matched	55.3 vs. 31.6 mos.	48.8% vs. 36.8%
		Non-Canvaxin	739	according to key	*(p-value = 0.0001)*	
		Total	1,478	prognostic factors(2)		
Melanoma	Stage IV	Canvaxin	150	All patients(3)	36 vs. 18 mos. *(p-value = 0.0001)*	39% vs. 19%
		Non-Canvaxin	113			
		Total	263			
Melanoma	Stage IV	Canvaxin	107	All patients matched	38 vs. 19 mos. *(p-value = 0.0009)*	39% vs. 20%
		Non-Canvaxin	107	according to key		
		Total	214	prognostic factors(3)		

(1) P-values indicate the likelihood that the results were due to random statistical fluctuations rather than a true cause and effect relationship. The lower the p-value, the more likely there is a true cause and effect relationship. Therefore, p-values provide a sense of the reliability of the results of the study in question, however, the significance of p-values is dependent on the underlying study. When the underlying study is a retrospective analysis of pooled data, the p-value is of more limited significance than for a prospective, controlled study. Typically, the FDA requires a p-value of less than 0.05 to establish the statistical significance of a clinical trial.

(2) All patients with Stage III melanoma who were included in the JWCI database and had their primary tumor and regional lymph nodes resected, or removed, between 1971 and 1998 were included in the analysis. Historical control patients in the Canvaxin-treated group received the product candidate between 1984 and 1998. The 1,478 patients that were matched according to key prognostic factors are a subset of the 2,602 total patient population with Stage III melanoma.

(3)

All patients with Stage IV melanoma who were included in the JWCI database and had their primary tumor and all known metastases resected between 1971 and 1997 are included in the analysis. Patients in the Canvaxin-treated group received the product candidate between 1984 and 1997. The 214 patients that were matched according to key prognostic factors are a subset of the 263 total patient population with surgically resected Stage IV melanoma.

Results of these analyses suggest that Canvaxin may have a favorable safety and side effect profile relative to existing therapies for the treatment of patients with advanced-stage melanoma. Canvaxin is generally well tolerated by patients and the most common adverse event is injection site reaction which is more severe with the first two injections that are administered with BCG. Other common side effects include fatigue, chills, myalgia and headaches, but these are usually mild.

Retrospective analyses are not generally deemed sufficient by the FDA and most foreign regulatory authorities as a basis for approval. Such approvals require prospective, randomized, double-blinded, placebo-controlled clinical trials.

Stage III Melanoma. A series of retrospective analyses was published in the *Annals of Surgery* in October 2002 comparing the survival of post-surgical patients with Stage III melanoma who received Canvaxin with historical control patients treated at JWCI or UCLA who did not receive Canvaxin.

One analysis evaluated survival in patients with Stage III melanoma who underwent surgery to completely remove their primary tumors and regional lymph nodes at UCLA and JWCI between 1971 and 1998. In this analysis, 935 patients received Canvaxin and 1,667 historical control patients treated at JWCI or UCLA did not receive Canvaxin. The median overall survival was 56.4 months for patients who received Canvaxin compared to 31.9 months for patients who did not receive Canvaxin. This increase in median overall survival of 24.5 months for patients who received Canvaxin is statistically significant, with a p-value of 0.0001.

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The survival benefit suggested by this analysis of Canvaxin in the treatment of patients with Stage III melanoma was also assessed in a matched-pair analysis, where patients who received Canvaxin were matched on a one-to-one basis by a computer program with historical control patients treated at JWCI or UCLA who did not receive Canvaxin. Patients were matched according to the following six key prognostic factors: the number and degree of palpability of lymph node metastases, ulceration status, primary tumor stage, and the patient s age and gender. We believe that melanoma is particularly well suited for retrospective matched-pair analyses because the key prognostic factors have been thoroughly studied and documented by the American Joint Committee on Cancer based on analyses of over 17,000 patients, which was published in the *Journal of Clinical Oncology* in August, 2001. In this matched-pair analysis using the JWCI database, patients were evaluated after surgical removal of their primary tumors and regional lymph nodes. Results comparing 739 patients who received Canvaxin to the same number of historical control patients treated at JWCI or UCLA who did not receive Canvaxin indicated an increase in median overall survival of 23.7 months, with a p-value of 0.0001. The median overall survival for the Canvaxin-treated group was 55.3 months compared to 31.6 months for the group of historical control patients treated at JWCI or UCLA who had not received Canvaxin. In addition, the five-year survival rate in the Canvaxin-treated group was 48.8% compared to 36.8% in historical control patients treated at JWCI or UCLA who had not received Canvaxin. In these analyses, survival was measured from the time of surgery. The following chart depicts the overall survival rate for the patients studied in the matched-pair analysis:

Stage III Melanoma Matched Pair Survival Analysis

Additionally, a regression analysis was used to calculate the relative impact of various factors on a patient s risk of dying, which is known as a hazard ratio. In this analysis, patients receiving Canvaxin in Phase 2 clinical trials had a hazard ratio of 0.64 relative to patients who did not receive Canvaxin, which means that patients in this analysis who did not receive Canvaxin had a 56% increased risk of death compared to the historical control patients treated at JWCI or UCLA who did receive Canvaxin. These results were statistically significant, with a p-value of 0.0001.

Stage IV Melanoma. Similar retrospective analyses for patients with Stage IV melanoma who received Canvaxin in Phase 2 clinical trials were presented in the *Journal of Clinical Oncology* in December 2002. In an analysis of 263 patients from the JWCI database with Stage IV melanoma who had their tumors removed between 1971 and 1997, those patients who received Canvaxin demonstrated approximately a doubling in median overall survival versus historical control patients treated at JWCI or UCLA who did not receive Canvaxin, 36 months for Canvaxin-treated patients compared to 18 months for non-treated patients. These results were statistically significant, with a p-value of 0.0001.

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A further survival analysis was performed on this group of 263 patients by matching patients according to three prognostic factors: gender, site of initial distant metastases and number of involved sites. Using a computerized program, 107 pairs of patients were matched according to these prognostic factors. Results of this retrospective matched-pair analysis comparing 107 patients with Stage IV melanoma who received Canvaxin in Phase 2 clinical trials to the same number of historical control patients from the JWCI database who did not receive Canvaxin indicated that those patients who received Canvaxin experienced an approximate doubling in median overall survival when compared to similar historical control patients treated at JWCI or UCLA who did not receive Canvaxin. The median overall survival for the Canvaxin-treated group was 38 months compared to 19 months for the patients who did not receive Canvaxin. The results were statistically significant, with a p-value of 0.0009. The five-year survival rate in the Canvaxin-treated group was 39% compared to 20% in the historical control patient group treated at JWCI or UCLA that did not receive Canvaxin. In these analyses, survival of the Canvaxin-treated group was measured from the time of the first administration of Canvaxin following surgery, while survival of the non-Canvaxin-treated historical control group treated at JWCI or UCLA was measured from the time of surgery. The following chart depicts the overall survival rate for the patients studied in the matched-pair analysis:

Stage IV Melanoma Matched Pair Survival Analysis

Tumor Response Data. Canvaxin s ability to produce an immune response that causes melanoma tumors to regress was demonstrated in patients with *in-transit* melanoma who received Canvaxin in Phase 2 clinical trials. *In-transit* melanoma is a rare condition in which multiple subcutaneous or intradermal metastases are visible. As a result, tumor responses in these patients can be readily assessed.

As reported in the May 1999 edition of *Cancer*, 54 patients with *in-transit* melanoma were treated at JWCI with Canvaxin between 1985 and 1997. In this patient population, 41% of patients treated with Canvaxin experienced stabilization of their disease or an improvement in their disease status, including 13% who demonstrated a complete response, with a median duration of complete response greater than 22 months.

Immune Response Data. In the September 1998 *Journal of Clinical Oncology*, it was reported that approximately 85% of patients generated an immune response to Canvaxin that correlated with improved overall survival. This study demonstrated that patients who generated both cellular and humoral immune responses to Canvaxin had a longer survival rate than patients who did not generate an immune response. In addition, patients who had only a cellular or a humoral immune response demonstrated a decreased overall survival rate when compared with patients who demonstrated both. Patients who did not generate an immune response to Canvaxin experienced the shortest overall survival rate of the three groups.

High-Dose Interferon Data. A multi-center, randomized Phase 3 clinical trial of Canvaxin was initiated in the treatment of patients with Stage III melanoma compared to patients who received high-dose interferon. As a result of the substantial toxicity of high-dose interferon, many patients who were

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randomized to the high-dose interferon arm dropped out of the clinical trial. In agreement with the National Cancer Institute and the FDA, enrollment in the clinical trial was discontinued and the design was modified to the current Phase 3 clinical trial design, which compares patients treated with Canvaxin and BCG to patients who receive a placebo and BCG. Prior to the change in the protocol, 43 patients were enrolled at six clinical trial sites. The survival data for patients who received Canvaxin in this clinical trial were consistent with the survival trends observed for patients who received Canvaxin in a retrospective matched-pair analysis of JWCI data from Phase 2 clinical trials in patients with Stage III melanoma, described above.

Canvaxin with GM-CSF. In association with JWCI, we recently completed a randomized Phase 2 clinical trial to determine whether administering granulocyte macrophage colony stimulating factor, or GM-CSF, an immune system stimulatory protein, with Canvaxin and BCG could significantly amplify Canvaxin-induced immune responses in patients with various stages of melanoma. Patients with Stage II, III or IV melanoma were included who were not eligible for our ongoing Phase 3 clinical trials. In this trial, 97 patients were randomized to receive Canvaxin and BCG, or Canvaxin, BCG and GM-CSF. BCG was administered to all patients during the first two doses of therapy. GM-CSF, a stimulatory protein, was administered in addition to Canvaxin and BCG during the first four months to patients randomized to that arm of the study. This clinical trial was supported, in part, by a grant to JWCI from the National Cancer Institute. A delayed-type hypersensitivity, or DTH, skin test for response to Canvaxin was performed at each treatment dose and measured 48 hours later. The level of antibodies developed by each patient against the tumor-associated glycoprotein, or TA90, antigen were also evaluated in serum samples obtained from patients during treatment. Logistic regression showed that the addition of GM-CSF to the Canvaxin/ BCG treatment regimen did not significantly change maximal DTH response to Canvaxin, but it did increase maximal IgM response to the TA90 antigen. Adverse events were generally mild and consistent with known GM-CSF side effects. The investigators concluded that the addition of GM-CSF to Canvaxin/ BCG does not appear to change the DTH cellular immune response to Canvaxin immunotherapy, but may enhance the initial humoral immune response to Canvaxin, as suggested by the enhanced IgM anti-TA90 antibody response.

We plan to study Canvaxin in conjunction with other adjuvants and co-stimulatory molecules to determine whether these approaches may enhance the efficacy of Canvaxin.

Non-Resectable Stage IV Melanoma. At the same 2003 American Society of Clinical Oncologists meeting, Dr. Morton also presented data from a retrospective matched-pair analysis comparing 203 patients with Stage IV melanoma whose disease was not fully surgically resectable. Patients were matched in the analysis by gender, specific site of metastasis and number of tumor-involved organ sites. Median overall survival was significantly higher in patients who received Canvaxin compared to historical control patients treated at JWCI or UCLA who did not receive Canvaxin. The median overall survival rates for the Canvaxin-treated population was 11 months versus 7 months for the historical control patient group who did not receive Canvaxin. The one-year, two-year and three-year overall survival rates in the Canvaxin-treated group were 45%, 20% and 12%, respectively, compared to survival rates in the patient group who did not receive Canvaxin, which were 29%, 13% and 9%, respectively. The results were statistically significant, with a p-value of 0.006.

Canvaxin for the Treatment of Patients with Other Indications

Phase 1/2 Results for Patients with Stage IV Colorectal Cancer

Based on the number of shared antigens between colorectal cancer and Canvaxin, a Phase 1/2 clinical trial was conducted at JWCI to evaluate immune responses to Canvaxin in patients with Stage IV

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colorectal cancer. Results of this study were published in the May 2001 *Annals of Surgical Oncology.* The study demonstrated that Canvaxin induced both a cell-mediated and antibody response in many patients. While a preliminary analysis of data from this 27-patient study indicated that patients who had a clearly defined immune response also experienced a statistically significant improvement in overall survival from 13 months to 31 months, a later analysis of the results showed that while patients who demonstrated an immune response had greater survival, the difference was no longer statistically significant. Although the group of patients in this clinical trial is too small to be predictive of survival, we believe that the immune response elicited by Canvaxin may result in an improved prognosis in patients with colorectal cancer.

Other Indications

Based on the antigen expression profile of Canvaxin, we believe that Canvaxin may be effective in tumors other than melanoma. We plan to evaluate potential options for the expansion of Canvaxin into other tumor types, such as renal, prostate, breast, pancreatic and brain cancers.

Additional Proprietary Tumor Cell Targeting Specific Active Immunotherapy Programs

In addition to our current research and clinical development programs for melanoma, we plan to assess the efficacy of other product candidates developed with our proprietary specific active immunotherapy development platform in other cancers. We also plan to conduct a research program to screen, test and incorporate additional tumor cell lines into our specific active immunotherapy development platform that may be beneficial for solid tumors other than melanoma.

Specific Active Immunotherapy Product Candidates Targeting the EGF Receptor Signaling Pathway

In July 2004 we signed an agreement with CIMAB, S.A., a Cuban Company, whereby we obtained the exclusive rights to develop and commercialize in a specific territory, which includes the United States, 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 signed an agreement with CIMAB and YM BioSciences, Inc., a Canadian company, to obtain the exclusive rights to develop and commercialize, within the same territory, SAI-TGF- , 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.

EGF Receptor Pathway Role in Regulating Tumor Growth

Dysregulation of the EGF receptor signaling pathway is associated with tumor growth and metastasis, decreased effectiveness of chemotherapy and radiotherapy, and decreased overall survival. EGF and TGF- are molecules that bind to and activate the EGF receptor. Increased stimulation, as a direct result of over-expression of the EGF receptor, EGF or TGF- , may contribute to dysregulation of the EGF receptor pathway. In addition, cancerous cells may secrete EGF and TGF- , which in turn fuels their growth and proliferation by increased activation of the EGF receptor pathway.

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Interference with signaling through the EGF receptor pathway represents a therapeutic approach with potentially broad clinical applications. Over-stimulation of this pathway has been documented in breast, colorectal, brain, head and neck, non-small-cell lung, ovarian, pancreatic and prostate cancers.

Tumors	% EGFR Expression
Breast	**14-91**
Colorectal	**25-77**
Brain	**40-60**
Head & neck	**95**
Non-small-cell lung cancer	**40-80**
Ovarian	**35-70**
Pancreatic	**30-50**
Prostate	**62-71**

Salomon et al. Crit Rev Oncol Hematol. 1995;19:183; Moscatello et al. Cancer Res. 1995;55:5536; Garcia de Palazzo et al. Cancer Res. 1993;53:3217; Kumar et al. Cancer Lett. 1998;134:177; Nagane et al. Cancer Lett. 2001;162:S17.

Advantages of Specific Active Immunotherapy Targeting the EGF Receptor Pathway

The three specific active immunotherapy product candidates that we have licensed are designed to stimulate the immune system to produce antibodies to EGF, TGF- and the extracellular domain of EGF receptor, and ultimately reduce signaling through the EGF receptor. Since each of these product candidates targets a different aspect of the EGF receptor pathway, it is possible that they may be used as single agents, in combination with each other, or in combination with other EGF receptor-targeted therapies. In addition, we anticipate that they may also be used with cytotoxics or other novel therapies for the treatment of cancer.

Phase 1/2 Results with SAI-EGF

SAI-EGF is an investigational specific active immunotherapy composed of recombinant human EGF that has been coupled to a proprietary immunogenic carrier protein, known as p64K. SAI-EGF, which is administered with a general immune system stimulant known as an immunologic adjuvant, stimulates the immune system to produce antibodies that target EGF. The anti-EGF antibodies bind to EGF circulating in the patient s bloodstream and interrupt EGF receptor signaling. This approach differs from existing EGF receptor inhibitors, such as monoclonal antibodies and tyrosine kinase inhibitors, in two important ways. First, it utilizes the body s own defense mechanisms to target the EGF receptor pathway, and second, it targets circulating EGF, which activates the EGF receptor, as opposed to targeting the receptor itself.

The SAI-EGF product candidate has been studied in Phase 1 and Phase 2 clinical trials conducted in Canada, the United Kingdom and Cuba. Data from several of these studies were published in the *Annals of Oncology* (Volume 14, 2003) and presented at the June 2004 American Society of Clinical Oncology annual meeting. The results suggested

treatment with SAI-EGF was well-tolerated, resulted in measurable immune responses, and may increase survival in patients with advanced-stage non-small-cell lung cancer, or NSCLC. In a trial of 50 advanced-stage NSCLC patients who received first line chemotherapy and then were randomized to treatment with SAI-EGF or best supportive care, survival was significantly greater (p-value equal to or less than 0.05) in patients receiving SAI-EGF compared with randomized controls (mean: 19.54 vs. 13.35 months, respectively; median: 17.33 vs. 10.27 months, respectively). In addition, a significant survival benefit (p-value equal to or less than 0.006) was reported in patients with a good antibody response, defined as at least 1:4000 anti-EGF antibody titers and a fourfold increase in anti-EGF antibody titers from baseline, compared with patients with a lesser antibody response (mean: 23.93

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vs. 13.07 months, respectively; median: not reached vs. 10.53 months, respectively). Combined data from three pilot clinical studies evaluating a total of 75 patients with advanced-stage NSCLC who received SAI-EGF suggests that immunized patients experienced a significant increase in survival compared to non-randomized control patients with a history of late-stage NSCLC who did not receive SAI-EGF (mean: 9.13 vs. 4.85 months, respectively; median: 12.43 vs. 4.83 months, respectively). Further, reduction of serum EGF concentration to 7 pg/mL or less was associated with increased survival compared with patients having greater serum EGF concentrations (mean: 14.54 vs. 5.23, respectively; median: 12.43 vs. 4.83 months, respectively). The results in these studies also suggested SAI-EGF was well tolerated by patients.

Proposed Phase 2 Clinical Trial of SAI-EGF in Patients with NSCLC

In late 2005 or early 2006, we plan to initiate a Phase 2 clinical trial of the SAI-EGF product candidate in patients with NSCLC.

SAI-TGF- (preclinical)

SAI-TGF- is an investigational specific active immunotherapeutic product candidate that may stimulate the immune system to develop anti-TGF- antibodies, another common molecule that activates the EGF receptor. Blocking TGF- may provide a therapeutic benefit in certain cancers and may also enhance the therapeutic effect when used in combination with other EGF receptor inhibitors. We also plan to evaluate the potential combination of SAI-TGF- with SAI-EGF to more effectively inhibit the activation of the EGF receptor.

SAI-EGFR-ECD (preclinical)

SAI-EGFR-ECD is an investigational specific active immunotherapeutic product candidate that may stimulate the immune system to develop antibodies that target a portion of the EGF receptor that resides outside of the cell membrane, i.e. the extracellular domain. Stimulating the immune system with a specific active immunotherapy directed against the receptor itself may offer a unique approach to targeting the EGF receptor pathway.

Anti-Angiogenesis Programs

Through our January 2002 acquisition of Cell-Matrix, Inc., we acquired unique therapeutic and diagnostic anti-angiogenesis technology and several product candidates. To complement this technology, in June 2003, we licensed from New York University the rights to several peptides that may also inhibit angiogenesis. We believe that these product candidates have a mechanism of action that is distinct from Avastin^{tm} (bevacizumab; Genenetch), a product approved for metastatic colorectal cancer that targets the vascular endothelial growth factor, and from other anti-angiogenesis product candidates currently in development by other companies. We believe that these antibodies and peptides will provide us with an opportunity to develop products that may be beneficial for the treatment of various solid tumors.

Advantages of Our Anti-Angiogenesis Platform

Our anti-angiogenesis platform targets proteins such as collagen and laminin that comprise the extracellular matrix but are altered at sites of tumor growth. Our monoclonal antibodies and peptides bind specifically to hidden, or cryptic, binding sites on extracellular matrix proteins that become exposed as a result of the denaturation of collagen that occurs during tumor formation. Binding of our monoclonal antibodies or peptides to these degraded or denatured extracellular matrix proteins may inhibit angiogenesis and the growth, proliferation and metastasis of tumor cells.

This approach to inhibiting angiogenesis may have several therapeutic advantages. Because our monoclonal antibodies and proteins bind preferentially to extracellular matrix proteins that have been denatured during angiogenesis rather than to the native, undenatured forms of collagen or laminin, we believe that these product candidates may have greater tumor site specificity than other therapies, especially those characterized by broad biologic activity or the ability to bind to multiple targets. Additionally, the denatured proteins in the extracellular matrix may provide a better long-term therapeutic

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target than binding sites found directly on tumor cells since the proteins in the extracellular matrix represent a stable structure and are less likely to undergo mutations typical of cancer cells. Due to the unique mechanism through which our monoclonal antibodies and proteins inhibit angiogenesis, they may have the potential to be used in combination with other anti-angiogenic agents or with treatments such as chemotherapy, specific active immunotherapy and radiation.

Anti-Angiogenesis Product Candidates

Several of our anti-angiogenesis product candidates are in preclinical development, and we are currently selecting a lead antibody to be evaluated in clinical trials. Preclinical results in tumor models suggest that targeting extracellular matrix proteins that are denatured during tumor formation may be an effective therapeutic approach for the treatment of solid tumors.

In a poster presented at the 2004 American Association of Cancer Research, or AACR, annual meeting, we demonstrated that humanized monoclonal antibodies targeting unique sites on denatured collagen reduced angiogenesis and inhibited tumor growth in *in vivo* models. In a murine model using human melanoma cells, antibodies D93 and H8, which target sites on denatured collagen, inhibited tumor growth by 56% and 63%, respectively. Most notably, the D93 antibody also inhibited human breast tumor growth by 84% using an orthotopic animal model, which is designed to more closely mimic breast cancer by generating human breast carcinomas in mouse mammary pads.

In a separate poster, data were presented at the 2004 AACR annual meeting that demonstrated binding of a novel peptide to a cryptic, or hidden, epitope in laminin. In *in vitro* studies, this peptide was shown to bind to denatured laminin while having little effect on normal laminin. Using an *in vivo* chick embryo model, this peptide inhibited angiogenesis and melanoma metastasis by 90% and 70%, respectively.

Our approach may be useful in other pathological conditions associated with angiogenesis such as choroidal neovascularization, or CNV, an ophthalmologic condition caused by excess growth of blood vessels within the eye that is the major cause of severe visual loss in patients with age-related macular degeneration. Data presented during the 2004 Annual Meeting of the Association for Research in Vision and Ophthalmology demonstrated that in a murine model of CNV, the H8 monoclonal antibody preferentially recognized areas of new vascular growth but not existing normal vasculature and inhibited angiogenesis in a dose-dependent manner.

We plan to submit an IND application for a clinical trial of one of our humanized anti-angiogenic monoclonal antibodies in early 2006.

Telomere Signaling T-Oligonucleotide Technology

In March 2004, we sublicensed the exclusive worldwide commercialization rights from SemaCo, Inc., to certain telomere signaling T-oligonucleotide technology to develop product candidates for the prevention, treatment, control, prognosis and diagnosis of cancer. We believe this technology represents a novel approach that uses inherent biological processes to effectively halt the proliferation of, or destroy, cancer cells. As a result of this activity, the T-oligonucleotide technology may have therapeutic potential for the treatment of cancer and, potentially, for the prevention of cancerous conditions. This technology may complement existing cancer therapies and enhance our pipeline of biological treatments for cancer.

T-oligonucleotide Approaches to the Treatment of Cancer

Genetic information communicated through DNA is organized into strands called chromosomes that end in telomeres, which are tandem repeats of a short nucleotide sequence several thousand base pairs long. In humans, the 3 strand is a repeat of TTAGGG nucleotides and extends beyond the complementary strand as an overhang. This telomere overhang is tucked within the DNA to form a loop. In normal cells, disruption of this telomere loop with exposure of the TTAGGG overhang sequence appears to signal DNA damage or aging, which activates natural protective pathways to prevent excessive replication of compromised cells. In cancer cells, however, these responses are impaired, and cells with gross DNA abnormalities continue to proliferate. T-oligonucleotides are short DNA sequences that appear

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to mimic telomere loop disruption. It is hypothesized that T-oligonucleotides activate natural protective pathways in the cell that cause malignant cells to stop growing and/or die.

Administration of T-oligonucleotides in *in vitro* studies has demonstrated inhibitory effects on the growth and replication of multiple tumor cell lines including breast, ovarian, pancreatic and squamous cell carcinomas, melanoma, fibrosarcoma, osteosarcoma, and lymphoma. In an article published in the March 1, 2004 issue of the *Proceedings of the National Academy of Sciences*, preclinical studies in murine models of several types of cancers suggested inhibition of tumor growth by T-oligonucleotides may be due to the activation of defense mechanisms used by healthy cells to stop tumor cell growth and replication, and cause cancer cell death. Additional work was published in the September issue of the *Federation of American Societies for Experimental Biology* Journal (Vol. 18, No. 12) showing that treatment of mice with an 11-nucleotide T-oligonucleotide inhibited melanoma tumor growth and reduced the size and number of metastases in preclinical studies. In these studies, the T-oligonucleotide was administered to mice with established melanoma tumors, either directly to the tumor or intraperitoneally. The growth of these tumors was reduced by 85-90% without detectable toxicity. In the preclinical model of metastasis, when melanoma cells were exposed to the T-oligonucleotide and then injected into immuno-compromised mice, the resulting metastatic tumors were 80-85% smaller and 90-95% fewer in number than tumors in mice injected with melanoma cells not exposed to the T-oligonucleotide. Importantly, results presented in this paper showed *in vitro* treatment with the T-oligonucleotide selectively induced apoptosis, a natural process resulting in cell death, of melanoma cells but not of normal human melanocytes, which are melanin-containing skin cells.

Our Strategy

Our objective is to establish our position as a leader in the development and marketing of specific active immunotherapy and other biological products for the treatment and control of cancer. Key aspects of our corporate strategy include the following:

Obtain Regulatory Approval of Canvaxin for the Treatment of Patients with Advanced-Stage Melanoma. We are working with Serono to complete our Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma and launch Canvaxin as promptly as practicable. If the data from the Phase 3 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 the launch of Canvaxin in the United States and in Europe to occur in 2007.

Co-Promote Canvaxin with Serono in the United States and Support Serono in its Efforts to Commercialize Canvaxin Abroad. We plan to build a specialty sales force to co-promote Canvaxin with Serono to medical and surgical oncologists and dermatologists in the United States and, through our development efforts, to support Serono s efforts to commercialize Canvaxin in Europe, Australia and elsewhere.

Leverage Our In-House Manufacturing Capabilities to Support the Commercialization of Canvaxin and Our Other Product Candidates. We have built our own biologics manufacturing facility and are developing a standardized manufacturing process for Canvaxin to further our ability to commercialize Canvaxin, and are expanding that facility to meet the anticipated demand for Canvaxin during the initial years following its launch. We intend to outsource the manufacture of our other product candidates during the early stages of development, and to leverage the experience that we have gained from developing the manufacturing process for Canvaxin to these product candidates.

Advance the Development of Our Clinical Stage Product Candidate Targeting the EGF Receptor Signaling Pathway. We plan to initiate a Phase 1/2 clinical trial with SAI-EGF, our specific active immunotherapy that targets EGF, in the treatment of patients with advanced non-small-cell lung cancer in late 2005 or early 2006.

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Advance the Development of Our Preclinical Product Candidates. We plan to initiate a clinical trial with one of our anti-angiogenic, humanized monoclonal antibodies in early 2006, and to continue the development of our other preclinical anti-angiogenesis antibodies and peptides, telomere-signaling T-oligonucleotide technology, and our preclinical specific active immunotherapy candidates targeting TGF- and the extracellular domain of the EGF receptor signaling pathway.

Identify Additional Product Candidates Based on Our Anti-Angiogenesis Technology Platform. We plan to leverage our research and preclinical experience in anti-angiogenesis to identify additional product candidates that will interact with sites exposed during the denaturation and remodeling of the extracellular matrix. In addition, we intend to explore using our anti-angiogenesis product candidates in combination with other therapies such as immunotherapy, chemotherapy and radiation.

Expand Our Product Pipeline and Technologies Through Acquisitions and Licensing. In addition to our internal development efforts, we plan to selectively license and acquire product opportunities, technologies and businesses that complement our target markets.

Create Additional Product Candidates Using Our Proprietary Specific Active Immunotherapy Platform. We plan to evaluate the applicability of our proprietary specific active immunotherapy technology platform to a number of other solid tumors, such as renal, prostate, breast, pancreatic and brain cancers.

Marketing

We intend to market and sell Canvaxin with our co-promotion partner, Serono, in the United States. The groups of clinicians that are primarily involved in the diagnosis and treatment of melanoma are medical oncologists, surgeons, surgical oncologists and dermatologists. As a result, we believe that a small, focused sales and marketing organization will enable us to effectively penetrate our target markets. We plan to build a sales force to launch Canvaxin for advanced-stage melanoma in the United States, which will be complemented by a number of Serono sales representatives. Outside of the United States, Serono will be responsible for the commercialization of Canvaxin under the terms of our collaboration agreement.

We may enter into collaboration agreements with third parties with respect to other cancer therapeutics that we may develop, which may include co-marketing or co-promotion arrangements. Alternatively, we may grant exclusive marketing rights to our strategic collaborators in exchange for up-front fees, milestone payments and royalties on future sales, if any.

Manufacturing and Supply

We produce Canvaxin in our biologics manufacturing facility for use in our clinical trials and plan to manufacture commercial quantities at the same facility. This facility is operated in accordance with the FDA s current good manufacturing practices, known as CGMPs. We have initiated an expansion of the production capacity of our biologics manufacturing facility, which we anticipate completing in 2005. Total capital expenditures associated with this expansion are estimated to be approximately $18 million, of which $5.9 million has been invested through December 31, 2004. We intend to fund a significant portion of these capital expenditures through our $18.0 million bank credit facility secured in December 2004.

We use standard biologics manufacturing processes to produce Canvaxin. We separately grow the individual cell lines, which are then harvested, pooled and dispensed into individual vials for storage in the vapor phase of liquid nitrogen. Next, Canvaxin is irradiated to ensure that the cells are unable to replicate following administration to patients. Prior to shipment, each lot of Canvaxin is tested to ensure that the quality, purity and potency of the product conform to all applicable performance standards. We take these steps in an effort to ensure that each released lot of Canvaxin meets specifications that have been accepted by the FDA and other regulatory agencies.

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 of this product candidate. We introduced

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Canvaxin manufactured with this new process in our two Phase 3 clinical trials for advanced-stage melanoma in 2003.

We obtain BCG, an adjuvant that we administer to patients with the first two doses of Canvaxin, from a single source of supply, Organon Teknika Corporation. Our supply agreement with Organon Teknika, which was assigned to us in July 2000, had an initial term of one year beginning in April 1998, with automatic renewals for successive one-year terms. However, under some circumstances, Organon Teknika can terminate the agreement if we fail to purchase BCG under the agreement for specified periods of time. If the manufacturing source of BCG is changed, the FDA may require us to conduct a comparability study before patients can be administered BCG from the alternate source with Canvaxin.

CIMAB will supply our newly licensed specific active immunotherapeutic product candidates that target the EGF receptor 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, and we will manufacture or outsource the manufacture of these product candidates for Phase 3 clinical trials and commercialization in the United States, Canada and Mexico. We intend to outsource the manufacture of our other product candidates during the early stages of development.

Collaborations

We engage in collaborations with private industry and academic institutions in the course of conducting our research and clinical studies, including the following.

Serono

In December 2004, we entered into a collaboration agreement with Serono. Pursuant to the agreement, 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.

Under the agreement, the parties will use commercially reasonable efforts to jointly develop Canvaxin worldwide. The parties will use commercially reasonable efforts to jointly commercialize and co-promote Canvaxin in the United States, subject to certain minimum sales force and detail requirements, with our company recording sales and distributing Canvaxin. Serono has the right, and must use commercially reasonable efforts, to commercialize Canvaxin outside the United States. We will initially supply Canvaxin for commercial sale worldwide. Serono may later establish a second manufacturing site, primarily to source Canvaxin for sales outside the United States.

In consideration for the arrangements under the agreement, Serono paid us $25.0 million up-front, and Serono B.V., a Netherlands corporation and an affiliate of Serono, purchased 1.0 million shares of our common stock, for an aggregate purchase price of $12.0 million. We may also receive up to $253.0 million in milestone payments from Serono upon the achievement of certain development-, regulatory- and sales-based goals. Profits from sales of Canvaxin in the United States, as well as certain expenses, will be shared equally between the parties. Serono will pay us a royalty on net sales of Canvaxin outside the United States. This royalty is subject to reduction by up to a set percentage upon the occurrence of certain events. In addition, Serono has granted us a license to certain Serono trademarks, patents and know-how that may be necessary or useful in connection with Canvaxin.

We have deferred the $25.0 million up-front license fee from Serono and will initially recognize it as revenue on a straight-line basis over approximately 3.3 years, which primarily represents the estimated period until regulatory approval and commercialization of Canvaxin in Stage IV melanoma in the United States. In 2004, we recognized $0.3 million of the up-front license fee as license fee revenue. Additionally, we recognized $1.2 million of collaborative agreement revenue in 2004, representing Serono s share of Canvaxin pre-commercialization expenses under the agreement, which were incurred by us after the effective date of the collaboration agreement.

We will retain control over our Canvaxin patent portfolio. In addition, we will retain responsibility for United States regulatory filings, including biologic license applications for Canvaxin. Neither party may

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develop or commercialize certain categories of competing products for a defined term. The parties will conduct activities under the agreement pursuant to agreed plans and budgets. Dispute resolution procedures provide for each party to have a casting vote on certain matters; however, certain key elements of the agreement must be agreed by the parties without resort to such procedures.

Serono has the right to terminate the agreement for convenience upon 180 days prior notice. Either party may terminate for the material breach or bankruptcy of the other. The development or commercialization by Serono of a competing product gives us a right to terminate the agreement; however, the development or commercialization by us of a competing product does not give Serono the right to terminate the agreement, but instead results in us forfeiting our right to co-promote Canvaxin in the United States, although we would receive royalties on net sales of Canvaxin in the United States by Serono. In the event of a termination of the agreement, rights to Canvaxin will revert to us. In certain circumstances, we will retain our license to the Serono technology upon termination of the agreement.

CIMAB and YM BioSciences

In July 2004 we signed an agreement with CIMAB, whereby we obtained the exclusive rights to develop and commercialize in a specific territory, which includes the United States, Canada, Japan, Australia, New Zealand, Mexico and certain countries in Europe, including Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, and the United Kingdom. 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 signed an agreement with CIMAB and YM BioSciences to obtain the exclusive rights to develop and commercialize, within the same territory, SAI-TGF- , 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, we will pay to CIMAB and YM BioSciences technology access 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, and royalties on future sales of commercial products, if any. Prior to the commercialization of any of the product candidates, payment of the technology transfer fees, technology access fees, and milestones owed to CIMAB under the agreements will be made entirely in United States-origin food, medicines and/or medical supplies rather than cash. Upon commercialization of a product candidate in the United States, payment of milestones and royalties owed to CIMAB under the agreements will be made 50% in cash and 50% in United States-origin food, medicines and/or medical supplies. All payments owed to YM BioSciences under the agreement will be made in cash. Through December 31, 2004, we have paid approximately $2.8 million to CIMAB and YM Biosciences under the agreements for technology access and transfer fees.

The agreements terminate upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreements or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreements. CIMAB may terminate the agreements if we have not used reasonable commercial efforts to file an 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 technology access and transfer fees. In addition, if CIMAB does not receive payments under the agreements due to changes in United States law, actions by the United States government or by order of any United States 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 United States and Canada. We may terminate the agreement for any reason following 180 days written notice to CIMAB.

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John Wayne Cancer Institute

JWCI is a leading cancer treatment and research center located in Santa Monica, California. Our founder, Donald L. Morton, M.D., is currently Medical Director and Surgeon-in-Chief and a member of the board of directors of JWCI.

In 2001, we entered into a clinical trial services agreement under which JWCI transferred the Investigational New Drug application, or IND, for the Phase 3 clinical trials of Canvaxin in advanced-stage melanoma to us. Under the terms of this agreement, JWCI performs clinical trial services for us, including review of patient eligibility. We are required to reimburse JWCI for all approved payments to clinical trial study sites that are not covered by National Cancer Institute grants. In addition, we agreed to reimburse JWCI for expenses and disbursements actually incurred up to $5,000 per month, plus a 25% administrative fee on specified expenses. We also agreed to pay JWCI $25,000 per year during the time period when payments to the clinical trial study sites are covered by the National Cancer Institute grants and $50,000 per year thereafter, or such greater amounts incurred by JWCI in connection with the Phase 3 clinical trials. In July 2002, this agreement was amended to require us to directly reimburse the clinical trial study sites for the approved payments that are not covered by National Cancer Institute grants, as opposed to reimbursing such amounts to JWCI. Once we assumed responsibility for the IND, we discontinued enrolling patients into the Phase 3 clinical trials at JWCI to avoid the appearance of a conflict of interest. We continue to work with JWCI on various clinical trials involving Canvaxin.

Pursuant to a cross-license agreement with JWCI, under which JWCI transferred to us the rights to certain ancillary technology developed at JWCI related to Canvaxin, as well as certain other technology, we committed to pay upfront and periodic payments totaling $1,250,000 and to issue to JWCI a specified ownership interest in us. In August 2000, we satisfied the ownership commitment by issuing to JWCI 284,090 shares of common stock, which represented approximately 4.8% of our outstanding capital stock at the time of issuance. The value of the common stock was estimated to be $306,817, or $1.08 per share. The $1.08 was the then estimated fair market value of the common stock, as determined by the board of directors. For accounting purposes, no value was assigned to the common stock because the carrying value of the assets acquired was zero. As of December 31, 2004, we have paid JWCI installments totaling $1.0 million, and we are obligated to pay two additional installments to JWCI of $125,000 each in 2005 and 2006. We also 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. The cross-license agreement terminates upon the later of the expiration of the last to expire of the patent rights covered by the agreement, which is currently November 24, 2015, or ten years from the date of the agreement. If either party commits a material breach of the agreement, the other party has the right to terminate the license rights it has granted under the agreement upon 90 days written notice to the breaching party unless such breach has been cured within that time. Any such termination by JWCI would affect only the ancillary technology that is the subject of the cross-license agreement and not our core patents related to Canvaxin.

Applied Molecular Evolution

In November 1999, we entered into a collaboration agreement with Applied Molecular Evolution, Inc., or AME, in San Diego, California to have AME humanize two of our murine monoclonal antibodies. A humanized monoclonal antibody is constructed by replacing portions, known as peptides, of the antibody of a non-human species with peptide sequences that match the human sequence. This process reduces the likelihood of an immune response against the antibody when the antibody is administered to the patient. In consideration for humanizing the monoclonal antibodies, AME received a fixed fee of $0.5 million for each of the two humanized monoclonal antibodies. In addition, AME is entitled to certain milestone payments, up to a maximum of $3.3 million per therapeutic product developed using these humanized monoclonal antibodies and $1.3 million per diagnostic product developed using these humanized monoclonal antibodies, as well as royalties on net sales of products, if any, developed using these humanized monoclonal antibodies. Prior to January 2002, the date we acquired Cell-Matrix and assumed this agreement, AME earned and received milestone payments totaling $1.5 million. From January 2002,

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through December 31, 2004, we have paid an additional approximately $0.3 million to AME under the agreement for the reimbursement of certain patent expenses and a milestone payment in connection with the amendment of the agreement as described below. The agreement expires ten years after the date of the first commercial sale of the last product that incorporates or is derived from one or more of the humanized monoclonal antibodies that are the subject of the agreement. If we fail to make milestone or royalty payments to AME or if we fail to file an IND application for one or more products that incorporate or are derived from one or more of the humanized monoclonal antibodies that are the subject of the agreement by a specified date or fail to meet certain other specified commercial development obligations, then AME has the right to terminate the agreement. In the event of such termination, we will be required to grant to AME an exclusive license under all of our patent rights relating to the humanized monoclonal antibodies that are the subject of the 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 and will have to assign and deliver copies of all related regulatory filings. In exchange for this exclusive license, we would be entitled to royalties on both future net sales and payments received as consideration for the grant of a sublicense, if any. We have no future obligation to humanize additional monoclonal antibodies with AME.

In October 2004, we, along with AME, which is now a wholly owned subsidiary of Eli Lilly and Company, amended and restated the agreement, pursuant to which the time periods by which we must use our best efforts to file an IND application to begin clinical testing and obtain regulatory approval to market one or more products in the United States were extended. The amended and restated agreement also gives AME 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 product subject to the agreement should we decide to negotiate with or seek a collaborator for the commercialization of such product. The amended and restated agreement also obligates us to pay for the preparation, filing, prosecution, maintenance and enforcement of all patent applications directed at the antibodies that are the subject of the 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 agreement.

University of Southern California

We hold exclusive, worldwide licenses to specified technology originating from the University of Southern California, or USC. We entered into license agreements with USC in September 1999 and May 2000 for specific anti-angiogenesis technology. In consideration for these technology licenses, USC received up-front license fees of $0.5 million for the September 1999 license agreement and $0.3 million for the May 2000 license agreement and will receive royalties on future net sales of products relating to our licenses, subject to a minimum annual royalty payment of $10,000 for each of the two agreements commencing on the third anniversary of the agreements. From January 2002, the date we acquired Cell-Matrix and assumed these agreements, through December 31, 2004, we have paid an additional approximately $0.2 million to USC under the license agreements for minimum annual royalties and reimbursement of certain patent expenses. The license agreements terminate upon the later of the expiration of the last of any patent rights to licensed products that are developed under the applicable agreement or 15 years from the effective date of the applicable agreement. We may terminate the USC license agreements for any reason following 30 days written notice to USC.

SemaCo

In March 2004, we signed an agreement with SemaCo, Inc. whereby we obtained an exclusive, worldwide sublicense from SemaCo to develop and commercialize novel technology using T-oligonucleotides for the potential treatment or prevention of cancer. In exchange, we made upfront payments totaling $0.5 million for the acquisition of the technology rights and a $0.3 million payment for the reimbursement of certain patent costs. Additionally, we will make research support payments totaling $1.2 million over the three-year period commencing on the effective date of the agreement, of which we have paid $0.4 million through December 31, 2004. We are also obligated to make future milestone payments upon meeting certain regulatory and clinical objectives and royalties on sales of commercial

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products, if any. The agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreement or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreement. We may terminate this agreement for any reason following 60 days written notice to SemaCo.

Scripps Research Institute

We hold exclusive, worldwide licenses to specified technology originating from The Scripps Research Institute. We entered into a license agreement with Scripps in 2001 for technology related to angiogenesis, including anti-angiogenic diagnostic applications. In consideration for these technology licenses, Scripps received up-front license fees of $50,000, and will receive royalties on future net sales of products relating to our licenses, subject to a minimum annual royalty payment of $10,000 commencing on the third anniversary of the agreement. In addition, Scripps will receive milestone payments, up to a maximum of $1.2 million per therapeutic product and $0.4 million per diagnostic product, based on meeting certain regulatory and clinical milestones. From January 2002, the date we acquired Cell-Matrix and assumed this agreement, through December 31, 2004, we have paid an additional approximately $4,000 to Scripps under the license agreement for the reimbursement of certain patent expenses. The license agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreement or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreement.

Eyetech Pharmaceuticals

By letter received February 8, 2005, Eyetech Pharmaceuticals, Inc. gave notice to our Cell-Matrix subsidiary, that the Development and Sublicense Agreement, effective as of March 5, 2001, between Eyetech and Cell-Matrix is terminated, effective May 9, 2005. The notice did not state a reason for the termination. Pursuant to the terms of the Agreement, we had licensed several antibodies and related technology for ophthalmic indications to Eyetech. In the event that the Agreement had not been terminated, Eyetech would have been obligated to pay us milestone payments, up to a maximum of $20.0 million per therapeutic product and $2.4 million per diagnostic product developed under the Agreement, based on meeting specified regulatory and clinical milestones and royalties on future net sales of products, if any. Upon termination of the Agreement, the license to Eyetech will terminate, and all rights to the licensed technology will revert to us. We will not incur any early termination penalties as a result of the termination of the Agreement.

New York University

In June 2003, we licensed from New York University, or NYU, the exclusive worldwide commercial rights to several peptides that appear to inhibit angiogenesis in preclinical models. Pursuant to our licensing arrangement, NYU will receive an initial license fee of $0.2 million, payable in three equal annual installments, and subsequent annual license maintenance fees of $15,000. We are also obligated to pay milestone payments, up to a maximum of $0.8 million per product relating to the licenses, based on regulatory and clinical milestones and royalties on both future net sales of products relating to the licenses and payments received as consideration for the grant of a sublicense, if any. Through December 31, 2004, we have paid approximately $0.2 million to NYU under the agreement representing two installments of the initial license fee and reimbursement of certain patent expenses. The agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under this agreement, or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreement. We may terminate the agreement for any reason following 180 days written notice to NYU. This agreement may be terminated by NYU if we fail to meet specified commercial development obligations under the agreement and we do not materially cure this failure in one year.

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Patents and Proprietary Technology

Our success will depend in large part on our ability to:

- maintain and obtain patent and other proprietary protection for cell lines, antigens, antibodies and delivery systems;
- defend patents;
- preserve trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

We intend to seek appropriate patent protection for our proprietary technologies by filing patent applications when possible in the United States and selected other countries. Our policy is to seek patent protection for the inventions that we consider important to the development of our business. As of December 31, 2004 we had exclusive rights to develop for commercial therapeutic purposes cancer vaccines under five patents issued to Donald L. Morton, M.D., in the United States, with additional patents issued in Europe and Australia. In addition, a related patent application has been published in Japan, another related application is pending in Canada, and additional applications are pending in the United States. The patents include composition of matter and process claims, as well as method of treatment claims. The issued patents in the United States expire during 2010 and 2015, and our issued patents in Europe and Australia expire in 2010. We intend to continue using our scientific expertise to pursue and file patent applications on new developments with respect to uses, methods and compositions to enhance our intellectual property position in the field of cancer treatment.

We own the exclusive rights to commercialize for use in cancer treatment the three human melanoma cell lines that comprise Canvaxin, which are designated as M10, M101, M24. We own 20 additional cell lines derived from human tumors. Although we believe our rights under patents and patent applications provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop further patentable products or processes, and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us.

Any patents or patent rights that we obtain may be circumvented, challenged or invalidated by our competitors. For example, Boehringer Ingelheim GmbH filed an opposition to one of the patents related to our product candidates and technology in Europe. While we prevailed in the opposition proceeding and the appeal by Boehringer Ingelheim was rejected, our patents may be the subject of other challenges by our competitors in Europe, the United States and elsewhere.

Additionally, because it is not possible to predict with certainty what patent claims may issue from pending applications and because patent prosecution can proceed in secret prior to issuance of a patent, third parties may obtain patents with claims of unknown scope relating to our product candidates which they could attempt to assert against us. Further, as we develop our products, we may infringe the current patents of third parties or patents that may issue in the future.

Although we believe that our product candidates, production methods and other activities do not currently infringe the valid and enforceable intellectual property rights of any third parties, we cannot be certain that a third party will not challenge our position in the future. 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 biopharmaceutical and pharmaceutical industries regarding patent and other intellectual property rights. As noted above, we believe that our pre-commercialization activities fall within the scope of 35 U.S.C. §271(e). We also believe that our subsequent manufacture of Canvaxin will also not require the license of any patents known to us.

Nevertheless, 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

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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.

Additionally, to enforce patents issued to us or to determine the scope and validity of other parties proprietary rights, we may also become involved in litigation or in interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial costs to us or an adverse decision as to the priority of our inventions. We may be involved in interference and/or opposition proceedings in the future.

We are party to several license agreements that give us rights to use technologies in our research and development, including intellectual property for technology related to Canvaxin from Cancer Diagnostics Laboratories, Inc. and JWCI, to our specific active immunotherapeutic product candidates that target the EGF signaling pathway from CIMAB, to our angiogenesis and anti-angiogenesis technology from USC, Scripps, NYU and AME, to our human antibody technology from M-Tech Therapeutics, and to our T-oligonucleotide technology from SemaCo. These parties have been responsible for filing various patent applications, including patents and patent applications containing composition claims that encompass the three cancer cell lines used for Canvaxin, patent applications directed towards the specific active immunotherapeutic product candidates that target the EGF signaling pathway, patent applications directed to Cell-Matrix s angiogenesis technology, and patent applications covering our T-oligonucleotide technology. We may be unable to maintain our licenses and may be unable to secure additional licenses in the future. Therefore, we may be forced to abandon certain product areas or develop alternative methods for operating in those areas.

We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. However, trade secrets are difficult to protect. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions agreement before beginning their employment, consulting or advisory relationship with us obligating them not to disclose our confidential information. 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.

Competition

We face competition from a number of companies that are evaluating various technologies and approaches to the treatment of cancer.

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 more resources than 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® (IL-2), Schering-Plough Corporation s IntronA® (interferon alpha) and Bayer AG s

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chemotherapeutic agent dacarbazine. Despite the side effects associated with these chemotherapy and biotherapy products, these products are currently being used in the treatment of patients with advanced-stage melanoma. In addition, Corixa Corporation s Melacine® has been approved in Canada for the treatment of patients with Stage IV melanoma, however, Corixa recently announced that it is discontinuing the development of Melacine in the United States for melanoma. A number of other potential competitors are developing immunotherapeutics and other approaches for the treatment of advanced-stage melanoma, including Progenics Pharmaceuticals, Inc. s GMK™, Antigenics, Inc. s Oncophage®, 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® was studied in a recently-completed Phase 2 clinical trial, and Vical is designing a Phase 3 clinical trial with high-dose Allovectin-7® for certain patients with metastatic melanoma. Oncophage® 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, in contrast to patients who are being studied in Canvaxin s Phase 3 clinical trials, 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® as a monotherapy for the treatment of patients with melanoma, but that it plans to conduct clinical trials for Revlimid® in combination with other treatments for melanoma. In May 2004, Genta, 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™ 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™ (gefitinib), an EGF receptor-targeted tyrosine kinase inhibitor for refractory Stage IV non-small-cell lung cancer, ImClone Systems, Inc. s Erbitux™ (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™ (erlotinib HCl), for the treatment of patients with locally advanced or metastatic non-small-cell lung cancer after failure of at least one prior chemotherapy regimen. Subsequent to its approval for the treatment of NSCLC in the United States, a phase IV clinical study of Iressa™ failed to demonstrate a survival benefit. As a result, AstraZeneca has withdrawn its request for approval of this product in the European Union, and has suspended its promotion of Iressa™ in the United States. 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® (trastuzumab) therapy, and Abgenix, Inc. and Amgen, Inc. s panitumumab (ABX-EGF), a fully human monoclonal antibody targeting EGF receptor, which is being studied in patients with advanced colorectal and renal cell cancer.

We also face competition from a number of companies working in the fields of anti-angiogenesis and specific active immunotherapy for the treatment of other solid tumors, and working to develop technologies similar to 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.

Additionally, we may encounter competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and private research organizations in recruiting and retaining

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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.

Government Regulation and Product Approval

General

Governmental authorities in the United States and other countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of biologic products. In the United States, the FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations subjects pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our product candidates and products, and we may be criminally prosecuted. The FDA also has the authority to revoke previously granted marketing authorizations if we fail to comply with regulatory standards or if we encounter problems following initial marketing.

In April 2002, the FDA placed our two Phase 3 clinical trials of Canvaxin in advanced-stage melanoma on partial clinical hold. The partial clinical hold was not the result of safety or clinical practice concerns, but rather because of questions regarding the production, testing and characterization of Canvaxin. 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 similar requests for additional information sent to all holders of IND applications for products involving somatic cell or gene therapies. During the partial clinical hold, we were allowed to continue treating patients who were already enrolled in the Phase 3 clinical trials but were not allowed to enroll new patients. The FDA removed the partial clinical hold in April 2003 after reviewing and accepting our responses to the issues raised, and we resumed enrolling patients in our Phase 3 clinical trials soon afterwards.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests and preclinical and clinical trials. This testing and the preparation of necessary applications and processing of those applications by the FDA are expensive and typically take many years to complete. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing any products we may develop. The FDA also may require post-marketing testing and surveillance to monitor the safety and efficacy of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems at any time following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit the products or technologies.

The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following: completion of preclinical laboratory and animal testing; submission of an IND, which must become effective before human clinical trials may begin; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use; and submission and approval of a New Drug Application, or NDA, for a drug, or a Biologics License Application, or BLA, for a biologic. The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase 1 clinical trials, the product

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is tested in a small number of patients or healthy volunteers, primarily for safety at one or more doses. In Phase 2, in addition to safety, the sponsor evaluates the efficacy of the product in targeted indications, and identifies possible adverse effects and safety risks, in a patient population that is usually larger than Phase 1 clinical trials. Phase 3 clinical trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically-dispersed clinical trial sites. Clinical trials must be conducted in accordance with the FDA s Good Clinical Practices requirements. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at one of the clinical trial sites. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The ethics committee at each clinical site may also require the clinical trial at that site to be halted, either temporarily or permanently, for the same reasons.

The sponsor must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product, in the form of a new drug application, or NDA, or, in the case of a biologic, a BLA. The FDA is regulating our specific active immunotherapy product candidate, Canvaxin, and may regulate additional specific active immunotherapy product candidates we may develop as biologics. Therefore, we will be submitting BLAs to obtain approval of our product candidates. However, our monoclonal antibody product candidates will be regulated as drugs. In a process that may take from several months to several years, the FDA reviews these applications and, when and if it decides that adequate data are available to show that the new compound is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. The amount of time taken for this approval process is a function of a number of variables, including whether the product has received a fast track designation, the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of the disease in question, and the workload at the FDA. It is possible that our product candidates will not successfully proceed through this approval process or that the FDA will not approve them in any specific period of time, or at all.

The FDA may, during its review of a NDA or BLA, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase 4 studies, to monitor the safety and effectiveness of the product. In addition, the FDA may in some circumstances impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials.

We will also be subject to a variety of regulations governing clinical trials and sales of our products outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries and regions must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from one regulatory authority to another and the time may be longer or shorter than that required for FDA approval. In the European Union, Canada, and Australia, regulatory requirements and approval processes are similar, in principle, to those in the United States.

Fast Track Designation

We received fast track designation from the FDA for Canvaxin for the treatment of patients with advanced-stage melanoma in January 2003. Congress enacted the Food and Drug Administration Modernization Act of 1997, in part to ensure the availability of safe and effective drugs, biologics and medical devices by expediting the FDA review process for new products. The Modernization Act establishes a statutory program for the review of fast track products, including biologics. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the fast track program, the sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the development of the product, prior to marketing.

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The Modernization Act provides that the FDA can base approval of a marketing application for a fast track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. The FDA may condition approval of an application for a fast track product on a commitment to do post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and require prior review of all promotional materials. In addition, the FDA may withdraw approval of a fast track product on a number of grounds, including the sponsor s failure to conduct any required post-approval study in a timely manner.

If a preliminary review of clinical data suggests that a fast track product may be effective, the FDA may initiate review of entire sections of a marketing application for a fast track product before the sponsor completes the application. This rolling review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees.

In general, an NDA or BLA for a fast track product is eligible for priority review when submitted under the Prescription Drug User Fee Act. Final FDA action on a priority review NDA or BLA is expedited compared to non-priority applications.

Orphan Drug Designation

We have received orphan drug designation from the FDA for the use of Canvaxin as a treatment for invasive melanoma, which includes Stage III and Stage IV melanoma. Orphan drug designation is designed to encourage manufacturers to develop drugs intended for rare diseases or conditions affecting fewer than 200,000 individuals in the United States. Orphan drug designation qualifies us for tax credits and marketing exclusivity for seven years following the date of the drug s marketing approval if granted by the FDA.

Ongoing Regulatory Requirements

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with FDA s good manufacturing practices, or GMP, regulations which govern the manufacture, holding and distribution of a product. Manufacturers of biologics also must comply with FDA s general biological product standards. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the good manufacturing practices regulations. Manufacturers must continue to expend time, money and effort in the areas of production and quality control and record keeping and reporting to ensure full compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution.

Manufacturers are also subject to various laws and regulations governing laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of product approvals, seize or recall products, and deny or withdraw approvals.

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Employees

As of December 31, 2004, we employed 186 full-time employees, of whom approximately 69 were engaged in research, clinical development and regulatory affairs, 82 in manufacturing and quality assurance, and 35 in administration, finance, management information systems, corporate development, marketing and human resources. Twenty-two of our employees hold a Ph.D., M.D. or Pharm.D. degree and are engaged in activities relating to research and development, manufacturing, quality assurance and business development.

Available Information

We make available free of charge on or through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our Internet address is *www.cancervax.com*.

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 report, the information incorporated herein by reference and those we may make from time to time.

Risks Related to Our Business and Industry

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

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

Even if we were to ultimately receive regulatory approval, we may be unable to gain market acceptance of Canvaxin for a variety of reasons, including the treatment regimen. Under this treatment regimen, patients will require 33 doses of Canvaxin over a five-year period and will be advised against the use of other approved treatments during this period that suppress their immune systems, such as chemotherapy. In addition, the success of Canvaxin may be affected by the prevalence and severity of adverse side effects, which include blistering, stinging, itching and redness at the site of injection, flu-like symptoms and a decrease in energy. Side effects, such as a localized skin reaction, may also be associated with 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

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somatic cell or gene therapies, including Canvaxin. We cannot be certain that any of our product candidates will be shown to be safe and effective or that we will ultimately receive approval from the FDA or foreign regulatory authorities to market these products. In addition, even if granted, product approvals and designations such as fast-track and orphan drug may be withdrawn or limited at a later time.

If the data from the Phase 3 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 our clinical trial of Canvaxin in Stage IV melanoma before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin in the United States or Europe would be delayed.

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 EGF receptor 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 $125 million in development costs through 2007, when we anticipate commercializing Canvaxin. Failure can occur at any phase of clinical testing.

While Canvaxin is currently being evaluated in two Phase 3 clinical trials for advanced-stage melanoma, these trials may not produce positive results and may, under some circumstances, be terminated early. Both Phase 3 clinical trials for Canvaxin in advanced-stage melanoma were designed with three interim analyses prior to the final analysis at the planned completion of the clinical trials. At each interim analysis, an independent data and safety monitoring board, or DSMB, reviews unblinded data from the clinical trials primarily to evaluate the safety of Canvaxin.

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In February 2004, the independent DSMB responsible for providing oversight of our Phase 3 clinical trials completed its planned, second interim analysis of our Phase 3 clinical trial of Canvaxin in Stage III melanoma. Based upon its review of data from 842 patients enrolled in the trial, the DSMB recommended that we continue both of the Phase 3 clinical trials as planned. We anticipate that the 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 in the third quarter of 2005, and that the final analysis of this data will occur in mid-2006. We also expect that the DSMB will complete its review of the planned, second interim analysis of data from our Phase 3 clinical trial of Canvaxin in patients with Stage IV melanoma in the first quarter of 2005, that the third interim analysis will be reviewed by the DSMB in early 2006, and that the final analysis of this data will occur by mid-2007. The interim analyses of data from our Phase 3 clinical trials may only be performed after the required number of patients participating in each of these clinical trials has expired. Thus, these dates are only estimates based on our periodic analyses of the rate of patient deaths in each of these clinical trials, and may be delayed or accelerated if these rates change.

It is possible that in connection with the interim analyses, the DSMB may determine that there are safety risks associated with Canvaxin, that it is not sufficiently efficacious to continue the trials, or 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. 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 advanced-stage melanoma on partial clinical hold. The FDA s action with respect to our Phase 3 clinical trials was consistent with clinical holds placed on other companies immunotherapy products, and with requests for additional information sent to us and all other holders of IND applications for products involving somatic cell or gene therapies. The partial clinical hold was the result of questions regarding the production, testing and characterization of Canvaxin. During the partial clinical hold, we were allowed to continue treating patients who were already enrolled in our Phase 3 clinical trials but were not allowed to enroll new patients. The FDA removed the partial clinical hold in April 2003 and we resumed enrolling patients in the Phase 3 clinical trials. Our clinical trials of Canvaxin and our other product candidates may be subject to additional clinical holds imposed by the FDA or other regulatory authorities in the future.

We may also encounter difficulties related to the clinical trials of the specific active immunotherapeutic product candidates that target the EGF receptor 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 EGF receptor 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

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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 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

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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.

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

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

Of the approximately 2,600 patients who have been administered Canvaxin in Phase 1 and Phase 2 clinical trials, fewer than 50 of those patients received Canvaxin at locations other than JWCI and UCLA. As of December 31, 2004, 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. We have undertaken two international Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma based on the positive results of the Phase 1 and Phase 2 clinical trials conducted by Dr. Morton and other investigators at JWCI and UCLA. If it is determined that the results of these Phase 1 and Phase 2 clinical trials are affected by a bias or conflict of interest and we fail to obtain satisfactory Phase 3 clinical trial results, our development of Canvaxin would be significantly delayed or may be terminated.

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

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

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analyses by other groups. Differences in survival rates between studies in patients with Stage III and Stage IV melanoma are affected by the following factors:

- time from which survival of patients is initially calculated, such as the time of diagnosis, the time of surgery or time of treatment;
- definitions of mortality, such as all causes mortality or disease-specific mortality;
- diagnosis status of patients, such as initial diagnosis or recurrent disease; and
- severity of disease, such as size of tumors and number of metastases.

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

We 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.

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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 Stage III melanoma. As of March 1, 2005, 485 patients out of a planned total enrollment of 670 patients had been enrolled in our Phase 3 clinical trial in Stage IV melanoma. From March 2004 through the end of February 2005, the rate of patient enrollment has been between 6 and 18 patients per month for the clinical trial in patients with Stage IV melanoma. Enrollment in our Phase 3 clinical trial in patients with stage IV melanoma is currently anticipated to be completed in the first half of 2006. We cannot be sure that we will be able to enroll an adequate number of patients to complete the Phase 3 clinical trial in patients with Stage IV melanoma. 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 either of our Phase 3 clinical trials. If these clinical investigators and medical institutions fail to enroll a sufficient number of patients in our Phase 3 clinical trial in patients with Stage IV melanoma, or fail to complete the required follow-up on patients already enrolled in both clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for Canvaxin. In addition, the interim and final analyses of the data from both of these clinical trials may not be performed until a specified number of patients in each of these clinical trials have died, so a delay in enrollment will adversely impact the timely completion of these clinical trials. A total of 392 patients participating in the Phase 3 clinical trial in patients with Stage III melanoma, and a total of 390 patients participating in the Phase 3 clinical trial in patients with Stage IV melanoma, respectively, must have expired before we can perform the final analyses on these clinical trials. Approximately 70 clinical trial sites that have participated in our Phase 3 clinical trials are planning to continue to enroll patients in the clinical trial in Stage IV melanoma. 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. Any delays could significantly slow the pace of our patient enrollment activities and the ultimate development of Canvaxin.

We contract with Synteract, Inc. to perform data collection, data management and data analysis for our two Phase 3 clinical trials in advanced-stage melanoma as well as for specified Phase 1 and Phase 2 clinical trials. Our agreement with Synteract for the Phase 3 clinical trials 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.

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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 advanced-stage 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.

Under the licensing agreements for our specific active immunotherapeutic product candidates that target the EGF receptor 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

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

If we are unable to 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.

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

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

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

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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® (IL-2), Schering-Plough Corporation s IntronA® (interferon alpha) and Bayer AG s chemotherapeutic agent dacarbazine. Despite the side effects associated with these chemotherapy and biotherapy products, these products are currently being used in the treatment of patients with advanced-stage melanoma. In addition, Corixa Corporation s Melacine® has been approved in Canada for the treatment of patients with Stage IV melanoma, however, Corixa recently announced that it is discontinuing the development of Melacine in the United States for melanoma. A number of other potential competitors are developing immunotherapeutics and other approaches for the treatment of advanced-stage melanoma, including Progenics Pharmaceuticals, Inc. s GMK™, Antigenics, Inc. s Oncophage®, 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® was studied in a recently-completed Phase 2 clinical trial, and Vical is designing a Phase 3 clinical trial with high-dose Allovectin-7® for certain patients with metastatic melanoma. Oncophage® 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 trials, 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® as a monotherapy for the treatment of patients with melanoma, but that it plans to conduct clinical trials for Revlimid® in combination with other treatments for melanoma. In May 2004, Genta, 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™ 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.

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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™ (gefitinib), an EGF receptor-targeted tyrosine kinase inhibitor for refractory Stage IV NSCLC, ImClone Systems, Inc. s Erbitux™ (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™ (erlotinib HCl), for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Subsequent to its approval for the treatment of NSCLC in the U.S., a phase IV clinical study of Iressa™ failed to demonstrate a survival benefit. As a result, AstraZeneca has withdrawn its request for approval of this product in the European Union, and has suspended its promotion of Iressa™ in the U.S. Two other products that are currently being evaluated in Phase 3 clinical trials are GlaxoSmithKline s lapatinib (GW572016), a tyrosine kinase dual inhibitor of EGF receptor and HER-2, which is being studied in patients with advanced metastatic breast cancer whose disease progressed on Herceptin® (trastuzumab) therapy, and Abgenix, Inc. and Amgen, Inc. s panitumumab (ABX-EGF), a fully human monoclonal antibody targeting the EGF, which is being studied in patients with advanced colorectal and renal cell cancer.

We also face competition from a number of companies working in the fields of anti-angiogenesis and specific active immunotherapy for the treatment of other solid tumors, and working to develop technologies similar to 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.

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

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

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

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

our ability to provide acceptable evidence of safety and efficacy;

convenience and ease of administration;

prevalence and severity of adverse side effects;

availability of alternative treatments;

cost effectiveness;

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

publicity concerning our products or competitive products; and

our ability to obtain third-party coverage or reimbursement.

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

In the event Canvaxin does not achieve market acceptance for one indication, such as advanced-stage melanoma, it may be even more difficult to promote Canvaxin for other indications, such as colon cancer, if 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

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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 186 as of December 31, 2004, and we expect the number of employees to continue to grow to meet our strategic objectives. If we continue to grow, it is possible that our management and scientific personnel, systems and facilities currently in place may not be adequate. Our need to effectively manage our operations, growth and various projects requires that we continue to improve our operational,

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financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to developing acquired technologies;
- increased amortization expenses;
- higher than expected acquisition and integration costs;
- difficulty and cost in combining the operations and personnel of acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of acquired businesses due to changes in management and ownership;
- inability to retain key employees of acquired businesses; and
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions.

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

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

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.

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

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

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

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

Product liability claims may stem from side effects that are associated with Canvaxin, including blistering, stinging, itching and redness at the site of injection and a decrease in energy. Some patients have experienced flu-like symptoms, including headache, muscle aches, joint aches, fever, nausea, diarrhea, vomiting, cough, chills and loss of appetite, as well as irritation and ulceration at the injection sites. A small number of patients who received Canvaxin have had a drop in the number of white blood cells in their blood or developed white patches on their skin. Two patients out of approximately 3,000 who have received Canvaxin experienced degeneration of part of their retinas. 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 $150.4 million in net losses from our inception through December 31, 2004. We expect to increase our operating expenses over the next several years as we expand the clinical trials for Canvaxin, advance other product candidates into clinical trials, expand our research and development activities, acquire or license new technologies and product candidates and scale-up our manufacturing and quality operations. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our product

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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.

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;

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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 December 31, 2004, the $25.0 million up-front license fee received from Serono in January 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 EGF receptor signaling pathway, advance other product candidates into clinical trials and expand our research and development activities. Our ability to scale-up our manufacturing and quality operations and respond to competitive pressures could be significantly limited if we are unable to obtain the necessary capital. We do not know whether additional financing will be available when needed, or whether it will be available on favorable terms or at all. 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 advanced-stage 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 EGF receptor signaling pathway;

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

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

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

the scope, prioritization and number of programs we pursue;

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

the costs of expanding our manufacturing capabilities;

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

our acquisition and development of technologies and product candidates; and

competing technological and market developments.

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

We 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 trials for Canvaxin and obtain regulatory approvals to commercialize this product candidate as well as others. We have not yet completed the development, including obtaining

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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;
- 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, which is effective for fiscal periods beginning after June 15, 2005 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. 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 2005 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

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attempt to protect our intellectual property position by filing United States patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We cannot be certain that any of the patents or patent applications related to our products and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we can:

- obtain and maintain patents to protect our product candidates and the related underlying technology;
- obtain and maintain licenses to use certain technologies of third parties, which may be protected by patents or subject to U.S. regulation;
- maintain our patents, and, along with our collaborators and licensors, those of our collaborators and our licensors, that we use in our business;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

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

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- , 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.

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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 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

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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.

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

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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.

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

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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 and our specific active immunotherapeutic product candidates targeting the EGF receptor signaling pathway, 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

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 December 31, 2004, our officers and directors beneficially owned approximately 37.2% of our common stock. As a result, these stockholders, acting together, can significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always

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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.

Item 2. Properties

Our corporate headquarters and research and development facility of approximately 60,000 square feet located in Carlsbad, California is leased under a ten-year operating lease that commenced in July 2002. We have options to renew this lease for two additional periods of five years each. We believe that this facility will suffice for our anticipated future corporate headquarters and research and development requirements through 2005.

Our biologics manufacturing facility consists of approximately 51,000 square feet of space located in the Los Angeles, California, area. JWCI entered into an original operating lease for 25,600 square feet of space in July 1999, with a commencement date in August 1999, which was subsequently assigned to us. We entered into an amendment to our lease to add 25,150 square feet of space at the same address on October 1, 2001. Our lease is scheduled to expire on August 14, 2011. We have an option to renew this lease for an additional term of five years.

We have initiated an expansion of the production capacity of our biologics manufacturing facility, which we anticipate completing in 2005. Total capital expenditures associated with this expansion are estimated to be approximately $18 million, of which $5.9 million has been invested through December 31, 2004. We intend to fund a significant portion of these capital expenditures through our $18.0 million credit facility secured in December 2004. Upon completion of this expansion, we believe our biologics manufacturing facility will have sufficient capacity to satisfy anticipated commercial demand for Canvaxin for several years after the initial launch.

In August 2004, we signed a seven-year operating lease for a 42,681 square foot warehouse, laboratory and office facility located in the Los Angeles, California area, near our biologics manufacturing facility. This lease includes a renewal option for an additional five years.

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Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

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

No matters were submitted to a vote of our stockholders during the fourth quarter of the year ended December 31, 2004.

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PART II

Item 5. Market for Registrant s Common Equity and Related Stockholder Matters

Market Information

Our common stock is quoted on the Nasdaq National Market under the symbol CNVX. We completed our initial public offering in the fourth quarter of fiscal 2003. The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported on the Nasdaq National Market:

	High	Low
Year Ended December 31, 2003		
Fourth Quarter (beginning October 30, 2003)	$ 13.24	$ 8.82
Year Ended December 31, 2004		
First Quarter	$ 13.35	$ 9.25
Second Quarter	$ 12.27	$ 6.99
Third Quarter	$ 8.93	$ 5.55
Fourth Quarter	$ 11.45	$ 7.38

As of February 1, 2005, there were approximately 285 holders of record of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, our ability to pay cash dividends on our common stock is currently restricted under the terms of our bank credit facility.

Recent Sales of Unregistered Securities

In December 2004, an affiliate of Serono, Serono B.V., a Netherlands corporation, purchased 1 million shares of our common stock for an aggregate purchase price of $12 million. The offer, sale and issuance of the shares of common stock was exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 506 of Regulation D promulgated under the Securities Act, in that the issuance of these shares to Serono B.V., an accredited investor, did not involve a public offering. Serono B.V. represented its intention to acquire the shares for investment only and not with a view to or for sale in connection with any distribution thereof and an appropriate legend was affixed to the certificate for the shares.

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.

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Through December 31, 2004, we have used approximately $51.7 million of the net proceeds from the public offering to continue the development of our specific active immunotherapeutic product candidate, Canvaxin, and fund other working capital and general corporate purposes. We expect to use the majority of the balance of the net proceeds of the offering to continue the development and prepare for the commercialization of Canvaxin and to scale-up our manufacturing operations and quality systems. To a lesser extent, we anticipate using the net proceeds from the offering to:

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

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

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

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Item 6. Selected Consolidated Financial Data.

The Consolidated Statement of Operations Data and Consolidated Balance Sheet Data presented below should be read in conjunction with Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and our consolidated financial statements and related notes appearing elsewhere in this Form 10-K.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
License fee	$ 316	$	$	$	$
Collaborative agreement	1,210				
Total revenues	1,526				
Operating expenses:					
Research and development	$ 43,102	$ 27,725	$ 24,517	$ 13,910	$ 3,495
General and administrative	12,310	6,826	6,514	5,441	765
Amortization of employee stock-based compensation(1)	1,864	2,643	1,412		
Purchased in-process research and development			2,840		
Total operating expenses	57,276	37,194	35,283	19,351	4,260
Other income (expense):					
Option fee income					1,000
Interest income	920	553	691	909	147
Interest expense	(756)	(932)	(621)	(140)	
Total other income (expense)	164	(379)	70	769	1,147
Net loss	(55,586)	(37,573)	(35,213)	(18,582)	(3,113)
Accretion to redemption value of redeemable convertible preferred stock		(7,867)	(7,635)	(4,105)	
Deemed dividend resulting from beneficial conversion feature on Series C preferred stock		(14,775)			
Net loss applicable to common stockholders	$ (55,586)	$ (60,215)	$ (42,848)	$ (22,687)	$ (3,113)
Basic and diluted net loss per share(2)(3)	$ (2.08)	$ (13.30)	$ (153.85)	$ (266.02)	$ (0.58)

Weighted average shares used to compute basic and diluted net loss per share(2)(3)	26,733	4,527	279	85	5,361

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(1) Amortization of employee stock-based compensation is allocated among operating expense categories as follows for 2004, 2003 and 2002 (in thousands):

	2004	2003	2002
Research and development	$ 531	$ 838	$ 379
General and administrative	1,333	1,805	1,033
	1,864	2,643	1,412

(2) As a result of the conversion of our preferred stock into 20.1 million shares of our common stock upon completion of our initial public offering on November 4, 2003, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented. Please reference Note 1 to our consolidated financial statements included elsewhere in this Form 10-K for an unaudited pro forma basic and diluted net loss per share calculation for these periods.

(3) In December 2000, we exchanged 6.0 million shares of our common stock for shares of Junior preferred stock on a 1-for-4.4 basis.

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and securities available-for-sale	$ 65,073	$ 107,092	$ 36,201	$ 10,103	$ 29,194
Total assets	116,160	127,007	55,187	20,795	32,854
Long-term debt, net of current portion	6,355	1,811	7,379	3,353	625
Redeemable convertible preferred stock			96,582	32,455	
Accumulated deficit	(184,778)	(129,192)	(68,977)	(26,129)	(3,442)
Total stockholders equity (deficit)	71,458	112,773	(55,878)	(20,663)	1,568

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the caption Business Risk Factors. This Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Form 10-K.

Overview

We are a biotechnology company focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. Our lead product candidate, Canvaxin, is one of a new class of products being developed in the area of specific active immunotherapy, also known as therapeutic cancer vaccines, and is being developed in collaboration with Serono. Canvaxin is currently being studied in two Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma. In September 2004, we completed our target enrollment of 1,118 patients in our Phase 3 clinical trial in patients with Stage III melanoma. An additional 42 patients who had consented to participate in this clinical trial prior to the time that we reached target enrollment were also enrolled, bringing the total enrollment to 1,160 patients. We continue to enroll patients in our Phase 3 clinical trial in Stage IV melanoma and as of March 1, 2005, 485 patients had been enrolled in the trial. Approximately seventy of the eighty clinical trial sites that have participated in our Phase 3 clinical trials are continuing to enroll patients in the clinical trial in Stage IV melanoma. Canvaxin is based on our proprietary specific active immunotherapy development platform that uses human tumor cell lines that express a broad array of tumor-related antigens. We are dependent on the success of Canvaxin and we cannot be certain that it will be approved by regulatory authorities or that it will be commercialized. If we fail to commercialize Canvaxin, our business, financial condition and results of operations will be materially and adversely affected.

In July 2004, we in-licensed from CIMAB and YM BioSciences three specific active immunotherapeutic product candidates targeting the EGFR signaling pathway for the treatment of cancer, including one product candidate that has been evaluated in Phase 2 clinical trials. We plan to initiate a Phase 2 clinical trial with SAI-EGF, the most advanced of these three new product candidates, in patients with advanced non-small-cell lung cancer in late 2005 or early 2006, and to continue pre-clinical development of the other two product candidates. We also have a number of other product candidates in research and preclinical development, including four humanized monoclonal antibodies and several peptides that potentially target various solid tumors. We also plan to identify and develop new product candidates based on our proprietary specific active immunotherapy, anti-angiogenesis, and T-oligonucleotide technologies. Our efforts to identify, develop and commercialize these product candidates, 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.

We were incorporated in Delaware in June 1998 and have incurred net losses since inception. As of December 31, 2004, our accumulated deficit was approximately $184.8 million. We expect to incur substantial and increasing losses for the next several years as we:

- continue the development and prepare for the commercialization of our lead specific active immunotherapy product candidate, Canvaxin, in advanced-stage melanoma, and explore the potential for clinical testing of Canvaxin in other indications;
- scale-up and validate our manufacturing operations and improve our quality systems;
- advance the development of our specific active immunotherapeutic product candidates that target the EGFR signaling pathway;
- advance our preclinical anti-angiogenesis and telomere signaling t-oligonucleotide product candidates into clinical development;

expand our research and development programs; and

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

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

In December 2004, we entered into a collaboration and license agreement with Serono for the worldwide development and commercialization of Canvaxin. We will jointly commercialize and co-promote Canvaxin in the United States while Serono has the exclusive right to commercialize Canvaxin outside the United States. The costs to develop and commercialize Canvaxin in the United States, excluding the costs associated with the recruitment, compensation and deployment of a Canvaxin salesforce, and the operating profits from the sale of Canvaxin in the United States (as defined in the agreement) will be shared equally by us and Serono. Serono is responsible for the costs of commercializing Canvaxin outside the United States and will pay us royalties on net sales of Canvaxin outside the United States. We will initially supply Canvaxin for commercial sale worldwide and Serono will reimburse us for our costs to manufacture and distribute Canvaxin for sales outside the United States. Serono may later establish a second manufacturing site primarily to source Canvaxin for sales outside the United States. Serono may terminate the collaboration agreement for convenience upon 180 days prior notice.

We manufacture Canvaxin at our biologics manufacturing facility located in the Los Angeles, California area. We have initiated an expansion of the production capacity at our biologics manufacturing facility which we anticipate completing in 2005. Total capital expenditures associated with this expansion are estimated to be approximately $18 million, of which $5.9 million has been invested through December 31, 2004. We will fund a significant portion of these capital expenditures through our $18.0 million bank credit facility secured in December 2004. Upon completion of this expansion, we believe our biologics manufacturing facility will have sufficient capacity to satisfy anticipated commercial demand for Canvaxin for several years after the initial launch. Significant delays in the completion or validation of the expanded manufacturing facility could result in an inability to meet commercial demand for Canvaxin, if commercialized. 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.

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

Research and Development

Our research and development expenses consist primarily of costs associated with the clinical trials of Canvaxin for advanced-stage melanoma, including costs associated with the production of Canvaxin for use in these clinical trials, manufacturing process and quality systems development for Canvaxin, research and preclinical development, including compensation and other personnel expenses, supplies and materials, costs for consultants and related contract research, facility costs, license fees and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on clinical trials of Canvaxin for advanced-stage melanoma, the development of additional indications for Canvaxin, and the development of product candidates based on our proprietary specific active immunotherapy, anti-angiogenesis and T-oligonucleotide technologies. We are also developing three specific active immunotherapeutic product candidates targeting the EGFR signaling pathway, including one product candidate that has been evaluated in Phase 2 clinical trials for the treatment of non-small-cell lung cancer.

From our inception through December 31, 2004, we incurred costs of approximately $103.2 million associated with the research and development of Canvaxin, representing over 91% of our total research and development expenses. Included in the costs associated with the research and development of Canvaxin are certain external costs of our Phase 3 clinical trials for Canvaxin, including payments made to clinical sites participating in the trials and payments to third parties for data collection, management and analysis

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services, clinical trial monitoring services and clinical sample collection and storage, all of which are recognized as research and development expenses. Under our collaboration agreement with Serono, the ongoing costs to develop Canvaxin will be shared equally by us and Serono. While difficult to predict, we estimate that we and Serono will incur at least an additional $125 million in development costs, including internal costs, through 2007, when we anticipate commercializing Canvaxin. Any delays in the development and commercialization of Canvaxin, including delays in obtaining regulatory approvals, could cause a material increase in Canvaxin development costs. If Serono were to terminate the collaboration agreement prior to the commercialization of Canvaxin, we would be forced to fund all of the development costs of Canvaxin or seek new collaboration partners for Canvaxin.

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

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

The costs and timing for developing and obtaining regulatory approvals of our product candidates vary significantly for each product candidate and are difficult to estimate. The expenditure of substantial resources will be required for the lengthy process of clinical development and obtaining regulatory approvals as well as to comply with applicable regulations. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We anticipate launching Canvaxin in the United States and Europe in 2007 if the data from either of our two ongoing Phase 3 clinical trials is positive, if the FDA and European regulatory authorities accept a positive result in one of our Phase 3 clinical trials as sufficient for marketing approval, and if our manufacturing processes and facility are approved by the FDA and European regulatory authorities in connection with our marketing applications. Although the FDA and European regulatory authorities typically require successful results in two Phase 3 clinical trials to support marketing approval, both agencies have, on several occasions, approved products based on a single Phase 3 clinical trial that demonstrates a high level of statistical significance and where there is an unmet need for a life-threatening condition. In the event that the FDA or European regulatory authorities require the results of our Phase 3 clinical trial in patients with Stage IV melanoma before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin in the United States or Europe, respectively, would be delayed. Our ability to generate net cash inflows from Canvaxin or any of our other development projects is dependent upon our ability to obtain regulatory approval.

In February 2004, the independent DSMB with oversight responsibility for the Phase 3 clinical trials of Canvaxin completed its review of the planned, second interim analysis of data from our clinical trial of Canvaxin in Stage III melanoma. The DSMB recommended that we continue the trial as planned. We completed our target enrollment of 1,118 patients in our Phase 3 clinical trial in patients with Stage III melanoma in September 2004. We anticipate that the 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 in the third quarter of 2005, and that the final analysis of this data will occur in mid-2006. We also expect that the DSMB will complete its review of data from the planned, second interim analysis of data from our Phase 3 clinical trial of Canvaxin in patients with Stage IV melanoma in the first quarter of 2005, that the third interim analysis will be reviewed by the DSMB in early 2006, and that the final analysis of this data will occur by mid-2007. The interim analyses of data from our Phase 3 clinical trials may only be performed after the required number of patients participating in each of these clinical trials has expired. Thus, these dates are only estimates based on our periodic analyses of the rate of patient deaths in each of

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these clinical trials, and may be delayed or accelerated if these rates change. If clinical trials of Canvaxin do not produce successful results, we will be unable to commercialize this product candidate.

We cannot be sure that we will be able to accelerate clinical trial enrollment or enroll an adequate number of patients to complete the Phase 3 clinical trial in Stage IV melanoma. In addition, we may not be able to control the amount and timing of resources that the medical institutions that conduct the clinical testing may devote to these Phase 3 clinical trials. If these clinical investigators and medical institutions fail to enroll a sufficient number of patients in our Phase 3 clinical trial in Stage IV melanoma, or fail to complete the required follow-up on patients already enrolled in both Phase 3 clinical trials, we will be unable to complete this trial, which could prevent us from obtaining regulatory approvals for Canvaxin. In addition, the interim and final analyses of the data from these clinical trials may not be performed until a specified number of patients in each of these clinical trials has expired, so a delay in enrollment will adversely impact the timely completion of these clinical trials. We will be unable to commercialize Canvaxin until the successful completion of clinical trials and regulatory approval for Canvaxin is obtained.

Critical Accounting Policies and Estimates

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

Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, SAB No. 104, *Revenue Recognition, corrected copy*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Accordingly, revenue is recognized once all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Collaborative agreement revenues, representing nonrefundable amounts received for shared pre-commercialization expenses, are recognized as revenue in the period in which the related expenses are incurred, assuming that collectibility is reasonably assured and the amount is reasonably estimable. In 2004, collaborative agreement revenues represented Serono s share of Canvaxin pre-commercialization expenses under the agreement, which were incurred by us after the effective date of the collaboration agreement.

Nonrefundable up-front license fees where we have continuing involvement through research and development collaborations or other contractual obligations are initially deferred and recognized as license fee revenue over the estimated period for which we continue to have a performance obligation. In 2004, license fee revenues represented the portion of the $25.0 million up-front license fee received from Serono recognized as revenue.

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As long as the milestone achieved is considered to be substantive in nature and at-risk, the achievability of the milestone was not reasonably assured at the inception of the agreement, and the associated services are provided at fair value, nonrefundable milestone payments are recognized as revenue when earned and collectibility is reasonably assured. Otherwise, the milestone payment is deferred and recognized as revenue over the estimated period for which we continue to have a performance obligation. To date, we have not recognized revenues from milestone payments.

Our estimates of the period over which we have an ongoing performance obligation are based on the contractual terms of the underlying arrangement, the level of effort required for us to fulfill our obligation and the anticipated timing of the fulfillment of our obligation. For example, under our collaboration agreement with Serono, we are obligated to continue the development and commercialization of Canvaxin in advanced-stage melanoma. Accordingly, we have deferred the up-front license fee received from Serono and will initially recognize it as revenue on a straight-line basis over approximately 3.3 years, which primarily represents the estimated period until regulatory approval and commercialization of Canvaxin in patients with Stage IV melanoma in the United States. Our estimate of the Canvaxin commercialization period utilizes several assumptions, including the FDA and European regulatory authorities acceptance of a positive result in one of our two ongoing Phase 3 clinical trials as sufficient for marketing approval and the approval of our manufacturing processes and facility by the FDA and European regulatory authorities in connection with our marketing applications. As our product candidates move through the clinical development and regulatory approval process, our estimates of our performance obligation period may change. Changes in our estimates of our performance obligation period will be recognized prospectively over the remaining estimated performance obligation period. We regularly review our estimates of the period over which we have an ongoing performance obligation.

Impairment of Long-Lived Assets

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

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 December 31, 2004. 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.

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

Results of Operations

The following compare actual results for the applicable periods and do not reflect any pro forma adjustments for our acquisition of Cell-Matrix in January 2002.

Comparison of the Years Ended December 31, 2004 and 2003

Revenues. Total revenues were $1.5 million for the year ended December 31, 2004, compared to no revenues for the year ended December 31, 2003. Revenues for the year ended December 31, 2004 consist of $0.3 million of license fee revenues and $1.2 million of collaborative agreement revenues from our agreement with Serono. The $25.0 million up-front license fee received from Serono is being recognized as license fee revenue on a straight-line basis over approximately 3.3 years, which primarily represents the estimated period until regulatory approval and commercialization of Canvaxin in patients with Stage IV melanoma in the United States. Collaborative agreement revenues represent Serono s share of Canvaxin pre-commercialization expenses under the agreement, which were incurred by us after the effective date of the collaboration agreement.

Research and Development Expenses. Research and development expenses were $43.1 million for the year ended December 31, 2004, compared to $27.7 million for the year ended December 31, 2003. The $15.4 million increase in research and development expenses primarily reflects additional investment in

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personnel in the manufacturing, quality and research and development departments, increased clinical trial expenses associated with increased patient enrollment in our Phase 3 clinical trials of our lead product candidate, Canvaxin, including costs associated with the production of Canvaxin for use in these clinical trials, $4.3 million of technology access and transfer fees under our agreements with CIMAB and YM BioSciences, which were recognized as research and development expenses in 2004, and payments totaling $1.3 million made under our sublicense agreement with SemaCo, Inc., which were recognized as research and development expenses.

Non-cash employee stock-based compensation of $0.5 million and $0.8 million for the years ended December 31, 2004 and 2003, respectively, was excluded from research and development expenses and reported under a separate caption.

General and Administrative Expenses. General and administrative expenses were $12.3 million for the year ended December 31, 2004, compared to $6.8 million for the year ended December 31, 2003. The $5.5 million increase in general and administrative expenses primarily reflects additional investment in personnel in the finance and marketing and business development departments, increased directors and officers insurance premiums and other expenses associated with our becoming a publicly-traded company, increased legal fees and other expenses related to business development activities and increased expenses associated with marketing activities.

Non-cash employee stock-based compensation of $1.3 million and $1.8 million for the years ended December 31, 2004 and 2003, respectively, was excluded from general and administrative expenses and reported under a separate caption.

Amortization of Employee Stock-based Compensation. During the initial public offering process, we re-evaluated the historical estimated fair value of our common stock considering the anticipated initial public offering price. As a result, the exercise price of certain stock options that were previously granted to our employees and directors was deemed to be below the revised estimated fair value of the underlying common stock on the option grant date. We recorded this spread between the exercise price and the revised estimated fair value as deferred employee stock-based compensation. We amortize the deferred employee stock-based compensation as a non-cash charge to operations on an accelerated basis over the vesting period of the options. Amortization of deferred employee stock-based compensation was $1.9 million and $2.6 million for the years ended December 31, 2004 and 2003, respectively.

Interest Income. Interest income for the year ended December 31, 2004 was $0.9 million, compared to $0.6 million for the year ended December 31, 2003. The $0.3 million increase in interest income was primarily due to higher average invested balances in 2004 resulting from the proceeds from the sale of our Series C preferred stock and our initial public offering of common stock in the second half of 2003.

Interest Expense. Interest expense for the year ended December 31, 2004 was $0.8 million, compared to $0.9 million for the year ended December 31, 2003. The $0.1 million decrease was primarily due to lower long-term debt balances in 2004 due to the full repayment in January 2004 of the notes payable that were assumed in the January 2002 acquisition of Cell-Matrix, offset by the interest expense associated with the prepayment in full of certain equipment and tenant improvement loans in December 2004.

Comparison of the Years Ended December 31, 2003 and 2002

Research and Development Expenses. Research and development expenses were $27.7 million for the year ended December 31, 2003, compared to $24.5 million for the year ended December 31, 2002. The $3.2 million increase in research and development expenses primarily reflects additional investment in personnel in the clinical affairs, manufacturing, quality and research and development departments, higher manufacturing expenses for our lead product candidate, Canvaxin, due to the resumption of patient enrollment in our Phase 3 clinical trials and the full year effect of an increase in facility expenses due to the need for a larger facility to support our growth and the expansion of our research, analytical and clinical development capabilities.

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Non-cash employee stock-based compensation of $0.8 million and $0.4 million for the years ended December 31, 2003 and 2002, respectively, was excluded from research and development expenses and reported under a separate caption.

General and Administrative Expenses. General and administrative expenses were $6.8 million for the year ended December 31, 2003 compared to $6.5 million for the year ended December 31, 2002. The $0.3 million increase in general and administrative expenses was primarily due to a general increase in compensation costs.

Non-cash employee stock-based compensation of $1.8 million and $1.0 million for the years ended December 31, 2003 and 2002, respectively, was excluded from general and administrative expenses and reported under a separate caption.

Amortization of Employee Stock-based Compensation. During the initial public offering process, we re-evaluated the historical estimated fair value of our common stock considering the anticipated initial public offering price. As a result, the exercise price of certain stock options that were previously granted to our employees and directors was deemed to be below the revised estimated fair value of the underlying common stock on the option grant date. We recorded this spread between the exercise price and the revised estimated fair value as deferred employee stock-based compensation. We amortize the deferred employee stock-based compensation as a non-cash charge to operations on an accelerated basis over the vesting period of the options. For the years ended December 31, 2003 and 2002, amortization of deferred employee stock-based compensation totaled $2.6 million and $1.4 million, respectively.

Purchased In-Process Research and Development. In January 2002, we completed the acquisition of Cell-Matrix, Inc. in a transaction accounted for as a purchase. Upon completion of the acquisition, we recognized a $2.8 million charge for the write-off of the fair value of the acquired in-process research and development. The amount of the charge represents the estimated fair value of acquired in-process research and development programs that had not reached technological feasibility and had no alternative future use. The principal technology acquired related to anti-angiogenic monoclonal antibodies and peptides that were in preclinical research and development. The fair value of the in-process research and development technology was based on a cost approach that attempts to estimate the cost of replicating the technology, including outside contracted services, the level of full-time employees and lab supplies that would be required in the development effort, net of tax. As of December 31, 2004, due to the inherent uncertainty and lengthy development life of the underlying monoclonal antibodies, we cannot estimate with any certainty the costs that will be incurred, or the anticipated completion dates, in the continued development of these monoclonal antibodies.

Interest Income. Interest income for the year ended December 31, 2003 was $0.6 million, compared to $0.7 million for the year ended December 31, 2002. The $0.1 million decrease in interest income was primarily due to lower prevailing interest rates during 2003, partially offset by higher average invested balances in 2003 due to the proceeds from the sale of our Series C preferred stock and our initial public offering of common stock in the second half of 2003.

Interest Expense. Interest expense for the year ended December 31, 2003 was $0.9 million, compared to $0.6 million for the year ended December 31, 2002. The $0.3 million increase in interest expense was primarily due to higher debt balances in 2003 related to the financing of equipment and leasehold improvements in the second half of 2002.

Liquidity and Capital Resources

As of December 31, 2004, we had $65.1 million in cash, cash equivalents and securities available-for-sale as compared to $107.1 million as of December 31, 2003, a decrease of $42.0 million. This decrease was primarily due to the use of cash to fund ongoing operations and payments on long-term debt. Cash, cash equivalents and securities available-for-sale as of December 31, 2004 excludes the $25.0 million up-front license fee received from Serono in January 2005.

Net cash used in operating activities was $46.1 million for the year ended December 31, 2004, compared to $30.9 million for the year ended December 31, 2003. The increase in net cash used in

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operating activities was primarily due to the increase in our operating expenses as we expanded our research and development activities.

Net cash used in investing activities was $26.4 million for the year ended December 31, 2004, compared to net cash provided by investing activities of $2.3 million for the year ended December 31, 2003. Significant components of cash flows from investing activities for the year ended December 31, 2004 included a $19.6 million net increase in our securities available-for-sale portfolio, $7.2 million of purchases of property and equipment and a $0.7 million decrease in restricted cash. Significant components of cash flows from investing activities for the year ended December 31, 2003 included a $4.5 million net decrease in our securities available-for-sale portfolio, $1.6 million of purchases of property and equipment and a $0.5 million increase in restricted cash.

Net cash provided by financing activities was $11.4 million for the year ended December 31, 2004, compared to $104.1 million for the year ended December 31, 2003. Significant components of cash flows from financing activities for the year ended December 31, 2004 included the $12.0 million proceeds from the issuance of 1.0 million shares of our common stock to Serono in December 2004 and net payments on long-term debt of $1.0 million. Significant components of cash flows from financing activities for the year ended December 31, 2003 included $65.1 million in net proceeds from our initial public offering of common stock on November 4, 2003, $41.2 million in net proceeds from the sale of our Series C preferred stock in August 2003 and net payments on long-term debt of $2.4 million.

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 financing 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. 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 this covenant as of December 31, 2004.

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As of December 31, 2004, we have borrowed $6.2 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 $4.9 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 December 31, 2004 bear interest at the greater of the bank s prime rate or 4.75% (5.25% at December 31, 2004) with interest-only payments due through 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 $5.9 million has been invested through December 31, 2004. We will fund a significant portion of these capital expenditures through our $18.0 million bank credit facility secured in December 2004. Of the capital expenditures invested in the expansion through December 31, 2004, $4.6 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 December 31, 2004, we have received aggregate net proceeds of approximately $208.6 million from the sale of equity securities. In addition, through December 31, 2004, we have borrowed an aggregate of approximately $15.5 million under certain credit facilities primarily to finance the purchase of equipment and leasehold improvements, of which $6.6 million is our current obligation under our existing credit facilities as of December 31, 2004. Of our existing borrowings as of December 31, 2004, $6.2 million represent borrowings under our $18.0 million bank credit facility secured in December 2004 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 December 31, 2004, the $25.0 million up-front license fee received from Serono in January 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, 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.

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Contractual Obligations

The following summarizes our long-term contractual obligations as of December 31, 2004 (in thousands):

		Payments Due by Period			
Contractual Obligations	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	$ 21,140	$ 2,697	$ 5,601	$ 5,989	$ 6,853
Contractual payments under licensing and research and development agreements	4,600	2,980	1,110	110	400
Equipment and tenant improvement loans	6,630	400	2,952	3,278	
Installment obligation due to JWCI	250	125	125		
	$ 32,620	$ 6,202	$ 9,788	$ 9,377	$ 7,253

We have entered into three irrevocable standby letters of credit in connection with the operating leases for our three primary facilities. The amount of the letter of credit related to the operating lease for our corporate headquarters and research and development facility is $0.4 million, varying up to a maximum of $1.9 million based on our cash position. The amount of the letter of credit related to the operating lease for our manufacturing facility is $0.6 million, decreasing through the end of the lease term. The amount of the letter of credit related to the operating lease for our warehouse, laboratory and office facility is $0.3 million. At December 31, 2004 and 2003, the amounts of the letters of credit totaled $1.3 million and $2.0 million, respectively. To secure the letters of credit, we pledged twelve-month certificates of deposit for similar amounts as of December 31, 2004 and 2003 which have been classified as restricted cash in our consolidated balance sheets.

We have entered into licensing and research and development agreements with various universities, research organizations and other third parties under which we have received licenses to certain intellectual property, scientific know-how and technology. In consideration for the licenses received, we are required to pay license and research support fees, milestone payments upon the achievement of certain success-based objectives and/or royalties on future sales of commercialized products, if any. We may also be required to pay minimum annual royalties and the costs associated with the prosecution and maintenance of the patents covering the licensed technology. If all potential product candidates under these agreements were successfully developed and commercialized, the aggregate amount of milestone payments we would be required to pay is at least $56 million over the terms of the related agreements as well as royalties on net sales of each commercialized product.

Related Party Transactions

For a description of our related party transactions, see Note 4 to our consolidated financial statements included elsewhere in this Form 10-K.

Off-Balance Sheet Arrangements

Through December 31, 2004, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships. We do not have relationships or transactions with persons or entities that derive benefits from their non-independent relationship with us or our related parties other than what is disclosed in Note 4 to our consolidated financial statements included elsewhere in this Form 10-K.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R. SFAS No. 123R, which will be effective for

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our fiscal third quarter of 2005, requires that employee stock-based compensation is measured based on its fair-value on the grant date and is treated as an expense that is reflected in the financial statements over the related service period. SFAS No. 123R applies to all employee equity awards granted after adoption and to the unvested portion of equity awards outstanding as of adoption. We currently anticipate adopting SFAS No. 123R using the modified-prospective method effective July 1, 2005. While we are currently evaluating the impact on our consolidated financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS No. 123R will have a significant impact on our results of operations for 2005 and future periods although our overall financial position will not be effected.

In March 2004, the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF Issue No. 03-1 requires certain quantitative and qualitative disclosures with respect to securities in an unrealized loss position accounted for under SFAS No. 115 and SFAS No. 124 and for cost method investments. We have provided the disclosure information required by EITF Issue No. 03-1 in Note 3 to our consolidated financial statements included elsewhere in this Form 10-K. EITF Issue No. 03-1 also describes a three-step model to measure and recognize other-than-temporary impairments of investments in marketable securities, however, the effectiveness of the measurement and recognition guidance of EITF Issue No. 03-1 has been indefinitely delayed. We do not expect that the adoption of the measurement and recognition guidance of EITF Issue No. 03-1, as currently contemplated, will have a material impact on our operating results and financial position.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2004 and 2003, 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 8. Financial Statements and Supplementary Data

See the list of financial statements filed with this report under Item 15 below.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None.

Item 9A. 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

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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 December 31, 2004.

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.

Management s Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

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Ernst & Young LLP, independent registered public accounting firm, has audited management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 as stated in their attestation report which is set forth below.

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

The Board of Directors and Stockholders
CancerVax Corporation:

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that CancerVax Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). CancerVax Corporation s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that CancerVax Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, CancerVax Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CancerVax Corporation as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity (deficit) and

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cash flows for each of the three years in the period ended December 31, 2004 of CancerVax Corporation and our report dated March 4, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 4, 2005

Item 9B. Other Information

None.

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PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders (the Proxy Statement), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2004, and is incorporated in this report by reference.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) *Documents filed as part of this report.*

1. Financial Statements: The index to the financial statements is located on page F-1 of this report.

2. Financial Statement Schedules: All schedules have been omitted because they are not applicable or the required information is included in the financial statements or notes thereto.

3. Exhibits Required By Item 601 of Regulation S-K: See Item 15(c) below.

(b) *Exhibits.* The following exhibits are filed as a part of this report:

Exhibit Number	Description
2.01(1)	Agreement and Plan of Merger, dated January 8, 2002, by and among CancerVax Corporation, CMI Acquisition Corp. and Cell-Matrix, Inc.
3.01(2)	Amended and Restated Certificate of Incorporation
3.02(2)	Amended and Restated Bylaws
3.03(3)	Certificate of Designations for Series A Junior Participating Preferred Stock of CancerVax Corporation
4.01(4)	Form of Specimen Common Stock Certificate
4.02(5)	Third Amended and Restated Investors Rights Agreement, dated as of December 15, 2004, by and between CancerVax Corporation, Serono B.V. and the investors listed on Schedule A thereto
4.03(1)	Form of Warrant to Purchase Vendor Preferred Stock, Series 1
4.04(1)	Warrant to Purchase Vendor Preferred Stock, Series 2, dated September 6, 2002, issued to Venture Lending & Leasing III, LLC
4.05(1)	Form of Incidental Registration Rights Agreement
4.06(3)	Rights Agreement, dated as of November 3, 2004, between CancerVax Corporation and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of CancerVax Corporation as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C
10.01(1)	Standard Industrial/Commercial Single-Tenant Lease-Net, dated August 31, 2001, between Blackmore Airport Centre and CancerVax Corporation
10.02(1)	Lease, made as of July 22, 1999, between Spieker Properties, L.P. and John Wayne Cancer Institute
10.03(1)	Agreement of Lease Assignment, dated as of August 4, 2000, between John Wayne Cancer Institute and CancerVax Corporation
10.04(1)	First Amendment to Lease, entered into as of October 1, 2001, between EOP Marina Business Center, L.L.C. (as successor in interest to Spieker Properties, L.P.) and CancerVax Corporation (as successor in interest to John Wayne Cancer Institute)
10.05(1)	Second Amendment to Lease, entered into as of September 4, 2002, between EOP Marina Business Center, L.L.C. (as successor in interest to Spieker Properties, L.P.) and CancerVax Corporation (as successor in interest to John Wayne Cancer Institute)
10.06(6)	Third Amendment to Lease, entered into as of November 14, 2003, between CA-Marina Business Center Limited Partnership and CancerVax Corporation
10.07(7)	Fourth Amendment to Lease entered into as of January 18, 2005, between Marina Business Center, LLC and CancerVax Corporation
10.08(8)	

Standard Industrial/ Commercial Multi-Tenant Lease Net for 18120 Central Avenue, Los Angeles, California, executed as of August 18, 2004

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Exhibit Number	Description
10.09(1)#	Third Amended and Restated 2000 Stock Incentive Plan
10.10(1)#	2003 Employee Stock Purchase Plan
10.11(9)#	CancerVax 2004 Management Incentive Compensation Plan
10.12(9)#	CancerVax 2005 Management Incentive Compensation Plan
10.13(1)#	Form of Indemnification Agreement entered into by CancerVax Corporation with its directors and executive officers
10.14(8)#	Form of Amended and Restated Employment Agreement, dated as of November 15, 2004, between CancerVax Corporation and its executive officers
10.15(8)#	Amended and Restated Employment Agreement, dated as of November 15, 2004, between CancerVax Corporation and David F. Hale
10.16(1)	Assignment of Cross-License Agreement, dated as of July 31, 2000, by and among 3DLM, Inc., the John Wayne Cancer Institute and CancerVax Corporation
10.17(1)	Cross-License Agreement, dated as of July 24, 1998, by and between CancerVax, Inc. and the John Wayne Cancer Institute
10.18(1)	Agreement, dated as July 31, 2000, by and between Cancer Diagnostic Laboratories, Inc. and CancerVax Corporation
10.19(1)	Amendment No. 1 to CDL Agreement, dated as of December 15, 2000, by and between Cancer Diagnostic Laboratories, Inc. and CancerVax Corporation
10.20(1)	Second Amendment to CDL Agreement, dated as of May 1, 2002, between Cancer Diagnostic Laboratories, Inc. and CancerVax Corporation
10.21(1)	Contribution of Technology and Exchange Agreement, dated as of December 15, 2000, by and between Donald L. Morton, M.D. and CancerVax Corporation
10.22(1)	First Amendment to Contribution of Technology and Exchange Agreement, entered into as of May 1, 2002, between Donald L. Morton, M.D. and CancerVax Corporation
10.23(1)	Fetal Antigen License Agreement, dated as of December 15, 2000, by and between Donald L. Morton, M.D. and CancerVax Corporation
10.24(1)	License Agreement, dated May 23, 2000, by and between the University of Southern California and Bio-Management, Inc.
10.25(1)	License Agreement, dated September 19, 1999, by and between the University of Southern California and Bio-Management, Inc.
10.26(1)	Development and Sublicensing Agreement, effective as of March 5, 2001, by and among EyeTech Pharmaceuticals, Inc. and Cell-Matrix, Inc.
10.27(1)	License Agreement, dated October 26, 2001, by and between The Scripps Research Institute and Cell-Matrix, Inc.
10.28(1)	License Agreement, effective as of June 2, 2003, between New York University and Cell-Matrix, Inc.
10.29(1)	Assignment of Supply Agreement, entered into as of July 31, 2000, between 3DLM, Inc., f/k/a CancerVax, Inc., and CancerVax Corporation
10.30(1)	Supply Agreement, entered into as of April 15, 1998, between CancerVax, Inc. and Organon Teknika Corporation
10.31(1)	Letter Agreement, entered into as of January 22, 2002, between the John Wayne Cancer Institute and CancerVax Corporation
10.32(10)	Sublicense Agreement, dated as of March 10, 2004, by and among SemaCo, Inc., Barbara Gilchrest, M.D. and CancerVax Corporation
10.33(11)	

	TGF- HER-1 Vaccine License, Development, Manufacturing and Supply Agreement, dated July 13, 2004, by and among Tarcanta, Inc., Tarcanta, Ltd., CIMAB, S.A., YM BioSciences, Inc. and CIMYM, Inc.
10.34(11)	EGF Vaccine License, Development, Manufacturing and Supply Agreement, dated July 13, 2004, by and among Tarcanta, Inc., Tarcanta, Ltd. and CIMAB, S.A.

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Exhibit Number	Description
10.35(12)	Amended and Restated Collaboration Agreement, dated as of October 15, 2004, by and between Cell-Matrix, Inc., and Applied Molecular Evolution
10.36(5)+	Collaboration and License Agreement, dated as of December 15, 2004, by and between CancerVax Corporation and Serono Technologies S.A.
10.37(5)	Stock Purchase Agreement, dated as of December 15, 2004, by and between CancerVax Corporation and Serono B.V.
10.38(6)	Loan and Security Agreement, dated December 23, 2004, entered into between CancerVax Corporation and Silicon Valley Bank
10.39(13)#	CancerVax Corporation Amended and Restated 2003 Equity Incentive Award Plan
10.40(13)#	Form of Time Based Vesting Option Agreement under the CancerVax Corporation Amended and Restated 2003 Equity Incentive Award Plan
21.01(14)	List of Subsidiaries
23.01	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to CancerVax Corporation s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 24, 2003.

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

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

(4) Incorporated by reference to CancerVax Corporation s Registration Statement on Form S-3 filed with the Securities and Exchange Commission on December 9, 2004.

(5) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2004.

(6) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 29, 2004.

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

(8)

Incorporated by reference to CancerVax Corporation s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 15, 2004.

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

(10) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 15, 2004.

(11) Incorporated by reference to CancerVax Corporation s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2004.

(12) Incorporated by reference to CancerVax Corporation s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2004.

(13) Incorporated by reference to CancerVax Corporation s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on November 17, 2004.

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(14) Incorporated by reference to CancerVax Corporation s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2004.

# Indicates management contract or compensatory plan.

CancerVax Corporation has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been filed separately with the Securities and Exchange Commission.

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

* These certifications are being furnished solely to accompany this annual 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.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

CancerVax Corporation

Dated: March 15, 2005

By: /s/ David F. Hale

David F. Hale
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ David F. Hale David F. Hale	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 15, 2005
/s/ William R. LaRue William R. LaRue	Senior Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 15, 2005
/s/ Ivor Royston Ivor Royston	Director *(Chairman of the Board of Directors)*	March 15, 2005
/s/ Michael G. Carter Michael G. Carter	Director	March 15, 2005
/s/ Cam L. Garner Cam L. Garner	Director	March 15, 2005
/s/ Clayburn La Force, Jr. Clayburn La Force, Jr.	Director	March 15, 2005
/s/ Donald L. Morton Donald L. Morton	Director	March 15, 2005
/s/ Barclay A. Phillips Barclay A. Phillips	Director	March 15, 2005

/s/ Phillip M. Schneider	Director	March 15, 2005
Phillip M. Schneider		
	Director	March 15, 2005
Gail S. Schoettler		

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CANCERVAX CORPORATION
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
CancerVax Corporation:

We have audited the accompanying consolidated balance sheets of CancerVax Corporation (the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of CancerVax Corporation at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of CancerVax Corporation s internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 4, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 4, 2005

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CANCERVAX CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value amounts)

	December 31,	
	2004	**2003**
Assets		
Current assets:		
Cash and cash equivalents	$ 40,588	$ 101,681
Securities available-for-sale	24,485	5,411
Restricted cash		1,000
Receivables under collaborative agreement	26,210	
Other current assets	1,573	917
Total current assets	92,856	109,009
Property and equipment, net	15,650	10,529
Goodwill	5,381	5,381
Intangibles, net	625	519
Restricted cash	1,280	1,000
Other assets	368	569
Total assets	$ 116,160	$ 127,007
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 11,354	$ 5,650
Current portion of deferred revenue	7,595	
Current portion of long-term debt	525	6,091
Total current liabilities	19,474	11,741
Deferred revenue, net of current portion	17,139	
Long-term debt, net of current portion	6,355	1,811
Other liabilities	1,734	682
Commitments		
Stockholders equity:		
Preferred stock, $.00004 par value; 10,000 shares authorized; no shares issued and outstanding		
Common stock, $.00004 par value; 75,000 shares authorized; 27,808 and 26,736 shares issued and outstanding at December 31, 2004 and 2003, respectively	1	1
Additional paid-in capital	257,582	245,314
Accumulated other comprehensive income (loss)	(71)	3
Deferred compensation	(1,276)	(3,353)
Accumulated deficit	(184,778)	(129,192)
Total stockholders equity	71,458	112,773

Total liabilities and stockholders equity	$ 116,160	$ 127,007

See accompanying notes to consolidated financial statements.

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CANCERVAX CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended December 31,		
	2004	**2003**	**2002**
Revenues:			
License fee	$ 316	$	$
Collaborative agreement	1,210		
Total revenues	1,526		
Operating expenses:			
Research and development	43,102	27,725	24,517
General and administrative	12,310	6,826	6,514
Amortization of employee stock-based compensation	1,864	2,643	1,412
Purchased in-process research and development			2,840
Total operating expenses	57,276	37,194	35,283
Other income (expense):			
Interest income	920	553	691
Interest expense	(756)	(932)	(621)
Total other income (expense)	164	(379)	70
Net loss	(55,586)	(37,573)	(35,213)
Accretion to redemption value of redeemable convertible preferred stock		(7,867)	(7,635)
Deemed dividend resulting from beneficial conversion feature on Series C preferred stock		(14,775)	
Net loss applicable to common stockholders	$ (55,586)	$ (60,215)	$ (42,848)
Basic and diluted net loss per share(1)	$ (2.08)	$ (13.30)	$ (153.85)
Weighted averaged shares used to compute basic and diluted net loss per share(1)	26,733	4,527	279
The allocation of employee stock-based compensation is as follows:			
Research and development	$ 531	$ 838	$ 379
General and administrative	1,333	1,805	1,033
	$ 1,864	$ 2,643	$ 1,412

(1) As a result of the conversion of our preferred stock into 20.1 million shares of our common stock upon completion of our initial public offering on November 4, 2003, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented above. Please reference Note 1 for an unaudited pro forma basic and diluted net loss per share calculation for the periods presented.

See accompanying notes to consolidated financial statements.

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CANCERVAX CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)
(In thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Compensation	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balance at December 31, 2001	25,046	$ 1	358	$	$ 5,466	$	$	$ (26,129)	$ (20,662)
Issuance of common stock under equity compensation plans, net			138		182				182
Deferred employee stock-based compensation					2,740		(2,740)		
Amortization of deferred employee stock-based compensation, net					(60)		1,472		1,412
Issuance of stock options to consultants					41				41
Issuance of warrants in conjunction with debt and facility lease					319				319
Issuance of preferred stock in conjunction with Cell-Matrix acquisition	2,143				5,721				5,721
Accretion to redemption value of redeemable convertible preferred stock								(7,635)	(7,635)
Comprehensive loss:									
Net loss								(35,213)	(35,213)
Unrealized loss on securities available-for-sale						(43)			(43)
Total comprehensive loss									(35,256)

Balance at December 31, 2002	27,189	1	496		14,409	(43)	(1,268)	(68,977)	(55,878)
Issuance of common stock under equity compensation plans and upon exercise of warrants			133		263				263
Deferred employee stock-based compensation					4,999		(4,999)		
Amortization of deferred employee stock-based compensation, net					(271)		2,914		2,643
Issuance of stock options to consultants					131				131
Issuance of warrants in conjunction with a research consulting agreement					245				245
Issuance of common stock in initial public offering			6,000		65,139				65,139
Conversion of redeemable convertible preferred stock into common stock			13,892	1	145,623				145,624
Conversion of convertible preferred stock into common stock	(27,189)	(1)	6,215		1				
Deemed dividend resulting from beneficial conversion feature on Series C redeemable convertible preferred stock					14,775			(14,775)	

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	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Compensation	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount					
Accretion to redemption value of redeemable convertible preferred stock								(7,867)	(7,867)
Comprehensive loss:									
Net loss								(37,573)	(37,573)
Unrealized gain on securities available-for-sale						46			46
Total comprehensive loss									(37,527)
Balance at December 31, 2003			26,736	1	245,314	3	(3,353)	(129,192)	112,773
Issuance of common stock under equity compensation plans, net			72		376				376
Amortization of deferred employee stock-based compensation, net					(213)		2,077		1,864
Issuance of stock options to consultants					105				105
Issuance of common stock in connection with collaboration agreement			1,000		12,000				12,000
Comprehensive loss:									
Net loss								(55,586)	(55,586)
Unrealized loss on securities available-for-sale						(74)			(74)
Total comprehensive loss									(55,660)
Balance at December 31, 2004	$		27,808	$ 1	$ 257,582	$ (71)	$ (1,276)	$ (184,778)	$ 71,458

See accompanying notes to consolidated financial statements.

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CANCERVAX CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2004	**2003**	**2002**
Cash flows from operating activities:			
Net loss	$ (55,586)	$ (37,573)	$ (35,213)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash stock-based compensation	2,113	2,913	1,499
Investment income from securities available-for-sale	413	216	(94)
Depreciation	2,071	1,891	1,443
Amortization of intangibles	225	252	209
Purchased in-process research and development			2,840
Deferred rent	324	446	80
Changes in operating assets and liabilities:			
Receivables under collaborative agreement	(1,210)		
Other assets	(599)	(759)	(51)
Accounts payable and accrued liabilities	6,433	1,742	500
Deferred revenue	(266)		
Net cash used in operating activities	(46,082)	(30,872)	(28,787)
Cash flows from investing activities:			
Cash paid in Cell-Matrix acquisition			(222)
Purchases of property and equipment	(7,192)	(1,575)	(4,421)
Purchases of securities available-for-sale	(56,722)	(2,942)	(10,567)
Maturities of securities available-for-sale	37,161	1,998	
Sale of securities available-for-sale		5,481	500
Increase in intangibles	(331)	(183)	(234)
(Increase) decrease in restricted cash	720	(450)	578
Net cash provided by (used in) investing activities	(26,364)	2,329	(14,366)
Cash flows from financing activities:			
Proceeds from long-term debt	6,230	462	4,901
Payments on long-term debt	(7,253)	(2,900)	(1,541)
Proceeds from equity compensation plans, net	376	263	182
Proceeds from issuance of common stock, net	12,000	65,139	
Proceeds from issuance of preferred stock, net		41,177	55,591
Net cash provided by financing activities	11,353	104,141	59,133
Increase (decrease) in cash and cash equivalents	(61,093)	75,598	15,980
Cash and cash equivalents at beginning of year	101,681	26,083	10,103
Cash and cash equivalents at end of year	$ 40,588	$ 101,681	$ 26,083
Supplemental cash flow information:			

Cash paid during the year for interest	$ 751	$ 750	$ 416
Supplemental schedule of non-cash activities:			
Unrealized gain (loss) on securities available-for-sale	$ (74)	$ 46	$ (43)
Value of stock issued in Cell-Matrix acquisition	$	$	$ 5,721
Issuance of warrants in connection with debt, facility lease and research consulting agreement	$	$ 245	$ 296
Conversion of preferred stock into common stock	$	$ 145,624	$
Deferred up-front license fee receivable under collaborative agreement	$ 24,684	$	$

See accompanying notes to consolidated financial statements.

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CANCERVAX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization and Business

We were incorporated in Delaware in June 1998 and commenced substantial operations in the third quarter of 2000. We are focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. Our lead product candidate, Canvaxin, which we are developing in collaboration with Serono Technologies, S.A., a Swiss Corporation, is currently in two worldwide Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma.

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires our management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Our management has made a number of estimates and assumptions relating to the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent assets and liabilities in conformity with accounting principles generally accepted in the United States. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and the valuation of goodwill, intangibles and other long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of highly liquid investments with an original maturity of less than three months when purchased. Our cash equivalents as of December 31, 2004 and 2003 totaled $38.7 million and $101.5 million, respectively, and consist of money market accounts.

Securities Available-for-Sale

We consider investments with a maturity date of more than three months from the date of purchase to be short-term investments and we have classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders equity. The cost of available-for-sale securities sold is determined based on the specific identification method.

Fair Value of Financial Instruments

We carry our cash and cash equivalents and securities available-for-sale at market value. The carrying amount of receivables under collaborative agreement, accounts payable and accrued liabilities are considered to be representative of their respective fair values due to their short-term nature. Our long-term debt bears interest at a variable rate based on the prime rate and therefore we believe the fair value of our long-term debt approximates its carrying value.

Concentrations of Risk

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash and cash equivalents and securities available-for-sale. We maintain deposits in federally

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CANCERVAX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

insured financial institutions in excess of federally insured limits. We do not believe we are exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, we have established guidelines regarding diversification of our investment portfolio and maturities of investments, which are designed to maintain safety and liquidity.

We rely on the availability and condition of our sole biologics manufacturing facility to manufacture Canvaxin and our warehouse facility for storage of the materials used in the manufacture of Canvaxin. Currently, we have no alternative facilities or third-party contract manufacturers approved for the manufacture of Canvaxin or for the storage of the materials used in the manufacture of Canvaxin. Any disruption in our Canvaxin manufacturing operations could result in a lack of supply of Canvaxin which, in turn, could delay our clinical trials and potential commercial sales, if any.

We obtain bacillus Calmette-Guerin, or BCG, an adjuvant that we administer to patients with Canvaxin, from a single source of supply. Our supply agreement for BCG automatically renews for successive one-year terms although the supplier may terminate the agreement if we fail to purchase BCG for specified periods of time. If we must obtain a new source for BCG, we may be required to conduct a comparability study before patients can be administered BCG from the new source. We purchased BCG in 2004, which should preserve our supply agreement for the foreseeable future.

All revenues recognized in 2004 relate to our collaboration agreement with Serono (Note 6).

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (ranging from three to seven years) using the straight-line method. Leasehold improvements are amortized over the estimated useful life of the asset or the lease term, whichever is shorter.

Patents

We capitalize the costs associated with the preparation, filing and maintenance of certain of our patents and patent applications and amortize these costs on a straight-line basis over 14 years, which represents the expected life of the patents and patent applications. Our capitalized patents are reviewed regularly for impairment in accordance with our policy regarding impairment of long-lived assets. Gross capitalized patent costs were $0.7 million and $0.4 million as of December 31, 2004 and 2003, respectively. Accumulated amortization of capitalized patent costs was $0.1 million and $0.1 million as of December 31, 2004 and 2003, respectively.

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards, or SFAS, No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets to be held and used, including property and equipment and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. 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. Long-lived assets to be disposed of are carried at fair value less costs to sell.

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

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CANCERVAX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

expected to result from the use of the Cell-Matrix asset group. We believe 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 December 31, 2004.

Goodwill

We have goodwill with a carrying value of $5.4 million at December 31, 2004 and 2003, which resulted from our acquisition of Cell-Matrix, Inc. in January 2002. We have assigned the goodwill to our Cell-Matrix reporting unit. 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 more frequently if events or changes in circumstances indicate a reduction in the fair value of the reporting unit to which the goodwill has been assigned. Goodwill is determined to be impaired if the fair value of the reporting unit to which the goodwill has been assigned is less than its carrying amount, including the goodwill. In the fourth quarter of 2004, we performed our annual goodwill impairment test in accordance with SFAS No. 142 and determined that goodwill was not impaired.

Revenue Recognition

We recognize revenue in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, SAB No. 104, *Revenue Recognition, corrected copy*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Accordingly, revenue is recognized once all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured. Any amounts received prior to satisfying these revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets.

Collaborative agreement revenues, representing nonrefundable amounts received for shared pre-commercialization expenses, are recognized as revenue in the period in which the related expenses are incurred, assuming that collectibility is reasonably assured and the amount is reasonably estimable. In 2004, collaborative agreement revenues represented Serono s share of Canvaxin pre-commercialization expenses under the agreement, which were incurred by us after the effective date of the collaboration agreement (Note 6).

Nonrefundable up-front license fees where we have continuing involvement through research and development collaborations or other contractual obligations are initially deferred and recognized as revenue over the estimated period for which we continue to have a performance obligation. In 2004, license fee revenues represented the portion of the $25.0 million up-front license fee received from Serono recognized as revenue (Note 6).

As long as the milestone achieved is considered to be substantive in nature and at-risk, the achievability of the milestone was not reasonably assured at the inception of the agreement, and the associated services are provided at fair value, nonrefundable milestone payments are recognized as revenue when earned and collectibility is reasonably assured. Otherwise, the milestone payment is deferred and recognized as revenue over the estimated period for which we continue to have a performance obligation. To date, we have not recognized revenues from milestone payments.

We regularly review our estimates of the period over which we have an ongoing performance obligation.

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CANCERVAX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development

Research and development expenses consist primarily of costs associated with the clinical trials of our product candidates, compensation and other expenses for research and development personnel, supplies and development materials, costs for consultants and related contract research, facility costs and depreciation. Expenditures relating to research and development are expensed as incurred.

Net Loss Per Share

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

The actual net loss per share amounts for 2004, 2003 and 2002 were computed based on the shares of common stock outstanding during the respective periods. The actual net loss per share for the years ended December 31, 2004 and 2003 reflects the 6.0 million shares of our common stock issued in our initial public offering on November 4, 2003 and the 20.1 million shares of our common stock issued upon conversion of our preferred stock in conjunction with the initial public offering. As a result of the issuance of these common shares on November 4, 2003, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented below. In order to provide a more relevant measure of our operating results, the following unaudited pro forma net loss per share calculation has been provided. The shares used to compute unaudited pro forma basic and diluted net loss per share represent the weighted average common shares used to calculate actual basic and diluted net loss per share, increased to include the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as-if converted method as of the beginning of each year presented or the date of issuance, if later.

	2004	2003	2002
	(In thousands, except per share amounts)		
Actual:			
Numerator:			
Net loss, as reported	$ (55,586)	$ (37,573)	$ (35,213)
Accretion to redeemable convertible preferred stock		(7,867)	(7,635)
Deemed dividend resulting from beneficial conversion feature on Series C preferred stock		(14,775)	
Net loss applicable to common stockholders, as reported	$ (55,586)	$ (60,215)	$ (42,848)
Denominator:			
Weighted average common shares outstanding	26,784	4,643	469
Weighted average unvested common shares subject to repurchase	(51)	(116)	(190)
Weighted average common shares used to calculate basic and diluted loss per share	26,733	4,527	279
Basic and diluted net loss per share	$ (2.08)	$ (13.30)	$ (153.85)

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CANCERVAX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2004	2003	2002
	(In thousands, except per share amounts)		
Pro forma:			
Numerator:			
Net loss, as reported	$ (55,586)	$ (37,573)	$ (35,213)
Deemed dividend resulting from beneficial conversion feature on Series C preferred stock		(14,775)	
Pro forma net loss applicable to common stockholders	$ (55,586)	$ (52,348)	$ (35,213)
Denominator:			
Weighted average common shares used to calculate basic and diluted loss per share	26,733	4,527	279
Pro forma adjustments to reflect weighted average effect of assumed conversion of preferred stock		14,098	13,132
Weighted average shares used to compute pro forma basic and diluted net loss per share	26,733	18,625	13,411
Pro forma basic and diluted net loss per share	$ (2.08)	$ (2.81)	$ (2.63)

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

	December 31,		
	2004	2003	2002
Preferred stock			15,431
Common stock subject to repurchase	25	91	150
Stock options	3,182	2,032	1,058
Stock warrants	86	86	66
	3,293	2,209	16,705

Stock-Based Compensation

We account for our employee stock-based compensation under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Accordingly, stock-based compensation expense related to employee stock options is recorded if, on the date of grant, the fair value of the underlying stock exceeds the exercise price of the option. In 2003 and 2002, we recorded deferred stock-based compensation of $5.0 million and $2.7 million, respectively, representing the difference between the estimated fair value of our common stock and the exercise price of the stock options on their respective grant dates. Deferred

stock-based compensation is recognized and amortized on an accelerated basis in accordance with FASB Interpretation, or FIN, No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options, which is generally four years. In 2004, 2003 and 2002, we recognized stock-based compensation expense related to employee stock option grants of $1.9 million, $2.6 million and $1.4 million, respectively.

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The following table illustrates the effect on net loss and loss per share for 2004, 2003 and 2002 if we had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-based Compensation*, as amended, to employee stock-based compensation. For purposes of the pro forma disclosures, the estimated fair value of employee stock options is amortized to expense over the vesting period of the related options using the accelerated method.

	2004	2003	2002
	(In thousands, except per share amounts)		
Net loss applicable to common stockholders, as reported	$ (55,586)	$ (60,215)	$ (42,848)
Add: Stock-based employee compensation expense included in net loss applicable to common stockholders, as reported	1,864	2,643	1,412
Deduct: Stock-based employee compensation expense determined under the fair value based method for all awards	(6,256)	(3,763)	(1,939)
Pro forma net loss applicable to common stockholders	$ (59,978)	$ (61,335)	$ (43,375)
Loss per share:			
Basic and diluted net loss per share, as reported	$ (2.08)	$ (13.30)	$ (153.85)
Pro forma basic and diluted net loss per share	$ (2.24)	$ (13.55)	$ (155.74)

The fair value of our employee stock options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	2004	2003	2002
Dividend yield	0%	0%	0%
Expected volatility	70%	70%	70%
Risk-free interest rate	3.25%	2.63%	3.81%
Expected life in years	4.89	4.85	4.97
Weighted average per share grant date fair value:			
Stock options granted with exercise prices below fair value	$	$ 7.14	$ 8.58
Stock options granted with exercise prices equal to fair value	$ 6.47	$ 6.29	$ 1.77

The fair value of our employee stock purchase plan, or ESPP, purchase rights was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for 2004: dividend yield of 0%, volatility of 70%, risk-free interest rate of 1.99% and expected life of 0.53 years. The weighted average grant date fair value of ESPP purchase rights was $3.95 per share for 2004.

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

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R. SFAS No. 123R, which will be effective for our fiscal third quarter of 2005, requires that employee stock-based compensation is measured based on its

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fair value on the grant date and is treated as an expense that is reflected in the financial statements over the related service period. SFAS No. 123R applies to all employee equity awards granted after adoption and to the unvested portion of equity awards outstanding as of adoption. We currently anticipate adopting SFAS No. 123R using the modified-prospective method effective July 1, 2005. While we are currently evaluating the impact on our consolidated financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS No. 123R will have a significant impact on our results of operations for 2005 and future periods although our overall financial position will not be effected.

We also periodically grant stock options to non-employees in exchange for services which we account for in accordance with SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*. Accordingly, the value of stock options granted to non-employees is periodically revalued as the options vest and is recognized to expense over the related service period. In 2004, 2003 and 2002, we recognized expense related to non-employee stock options of approximately $0.1 million, $0.1 million and $41,000, respectively. The fair value of the non-employee stock options was determined using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 70%, risk-free interest rates ranging from 2.84% to 5.97% and expected life equal to the remaining contractual term of the options.

Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

Segment Information

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

Guarantees

We account for guarantees in accordance with FIN No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN No. 45 requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees and requires certain disclosures to be made by a guarantor about its obligations under certain guarantees that it has issued.

In the ordinary course of our business, we enter into agreements with third parties, including corporate partners, contractors and clinical sites, which contain standard indemnification provisions. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. Although the maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. Additionally, we have insurance policies that, in most cases, would limit our exposure and enable us to recover a portion of any amounts paid. Therefore, we believe the estimated fair value of these agreements is minimal and accordingly, we have not accrued any liabilities for these agreements as of December 31, 2004.

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Effect of New Accounting Standards

In March 2004, the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF Issue No. 03-1 requires certain quantitative and qualitative disclosures with respect to securities in an unrealized loss position accounted for under SFAS No. 115 and SFAS No. 124 and for cost method investments. We have provided the disclosure information required by EITF Issue No. 03-1 in Note 3. EITF Issue No. 03-1 also describes a three-step model to measure and recognize other-than-temporary impairments of investments in marketable securities, however, the effectiveness of the measurement and recognition guidance of EITF Issue No. 03-1 has been indefinitely delayed. We do not expect that the adoption of the measurement and recognition guidance of EITF Issue No. 03-1, as currently contemplated, will have a material impact on our operating results and financial position.

2. Cell-Matrix Acquisition

On January 17, 2002, we acquired all of the outstanding common shares of Cell-Matrix, Inc. in a transaction accounted for as a purchase. Cell-Matrix is developing anti-angiogenesis technology to treat cancer and other diseases. The acquisition of Cell-Matrix allowed us to expand existing product pipelines and technologies to include anti-angiogenesis product candidates that we believe will complement and enhance our specific active immunotherapy development platform. The purchase price of the acquisition was as follows (in thousands):

Value of preferred stock issued in acquisition	$	5,721
Cash paid at acquisition		118
Acquisition-related costs		104
Assumed contractual obligations due to related parties		2,500
	$	8,443

The 2.1 million shares of Acquisition preferred stock issued to acquire Cell-Matrix converted into 0.5 million shares of common stock upon completion of our initial public offering in November 2003. In the acquisition, we assumed $2.5 million of notes payable to certain parties who became our stockholders upon completion of the acquisition. The notes and accrued interest thereon were paid in full in January 2004.

The purchase price was allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair values of assets and liabilities acquired was allocated to goodwill. The estimated fair values of the assets acquired and liabilities assumed as of the acquisition date are as follows (in thousands):

Property and equipment acquired	$	222
In-process research and development		2,840
Goodwill		5,381
	$	8,443

The principal technology acquired was monoclonal antibodies, which were in the process of being developed. Purchased in-process research and development was expensed upon acquisition, in accordance with FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, as ultimate commercialization of the antibodies acquired is uncertain and the technology has no alternative uses. The fair value of each of the in-process research and

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development projects was based on a cost approach that attempts to estimate the costs of replicating the technology including outside contracted services, the level of full time employees and lab supplies that would be required in the development effort, net of tax. Management was primarily responsible for the estimates and assumptions used in determining each of the above factors and believes that the analysis was performed based on the most relevant available data. As of December 31, 2004, due to the inherent uncertainty and lengthy development life of the underlying antibodies, we cannot estimate with any certainty the costs that will be incurred, or the anticipated completion dates, in the continued development of these antibodies. The $5.4 million of goodwill and $2.8 million of in-process research and development resulting from the acquisition are not expected to be deductible for tax purposes.

The accompanying consolidated statements of operations for 2004, 2003 and 2002 include the operating results of Cell-Matrix since the date of the acquisition. Pro forma unaudited results of operations for the year ended December 31, 2002 are not included because the operating results of Cell-Matrix prior to the January 17, 2002 acquisition date were not material.

3. Balance Sheet Details

Securities Available-For-Sale

Securities available-for-sale consists of the following (in thousands):

	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2004:					
U.S. government securities	$ 9,897	$ 90	$	$	$ 9,987
Corporate debt securities	14,468	101		(71)	14,498
	$ 24,365	$ 191	$	$ (71)	$ 24,485
December 31, 2003:					
U.S. government securities	$ 5,011	$ 101	$ 2	$	$ 5,114
Corporate debt securities	293	3	1		297
	$ 5,304	$ 104	$ 3	$	$ 5,411

All available-for-sale debt securities have contractual maturities of less than 12 months as of December 31, 2004. Our available-for-sale corporate debt securities consist of corporate bonds issued by five Fortune 500 companies, all of which were in a continuous unrealized loss position for less than 12 months as of December 31, 2004. The unrealized losses on these securities were primarily caused by recent increases in market interest rates. The contractual terms of these securities do not permit settlement at a price less than the amortized cost. Based on an evaluation of the credit standing of each issuer, we believe it is probable that we will be able to collect all amounts due according to the contractual terms of each security. Therefore, we do not expect the bonds to be settled at a price less than amortized cost. Because we have the ability and intent to hold these securities until a recovery of fair value, which may be at maturity, we do not consider these securities to be other-than-temporarily impaired as of December 31, 2004.

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Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,	
	2004	2003
Leasehold improvements	$ 10,335	$ 6,450
Manufacturing and lab equipment	6,364	5,265
Office equipment and furniture	1,735	1,519
Computer equipment	1,362	1,053
Construction in progress	1,908	226
	21,704	14,513
Less accumulated depreciation and amortization	(6,054)	(3,984)
	$ 15,650	$ 10,529

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consists of the following (in thousands):

	December 31,	
	2004	2003
Accounts payable	$ 4,963	$ 2,445
Accrued employee benefits	2,967	2,041
Accrued clinical trial patient costs	1,047	591
Accrued technology access fees (Note 6)	800	
Other accrued liabilities and expenses	1,577	573
	$ 11,354	$ 5,650

4. Related Party Transactions

We were founded in 1998 by Donald L. Morton, M.D., who is currently Medical Director and Surgeon-in-Chief and a member of the board of directors of the John Wayne Cancer Institute, or JWCI, a cancer research institute located in Santa Monica, California. Dr. Morton is a member of our board of directors and a significant stockholder. Since our inception in 1998, we have entered into various transactions with Dr. Morton and entities affiliated with Dr. Morton, including JWCI.

JWCI provides us with certain services related to our Canvaxin Phase 3 clinical trials under a clinical trial services agreement and is a participating site in the clinical trials. Under the terms of the clinical trial services agreement, as amended, we will make annual payments of $25,000 to JWCI while payments to the clinical trial sites are covered by National Cancer Institute grants and thereafter an annual amount equal to the greater of actual amounts incurred by JWCI in connection with the Canvaxin Phase 3 clinical trials or $50,000. We also will reimburse JWCI for certain

expenses incurred. In 2004, 2003 and 2002, we paid to JWCI $0.3 million, $0.4 million and $0.3 million, respectively, for services provided under the clinical trial services agreement, participation in the clinical trials and certain other services.

We had a consulting and non-compete agreement with Dr. Morton that expired in December 2004. Under the terms of the agreement, we paid Dr. Morton $150,000 per year to provide consulting services related to the development and commercialization of Canvaxin and our other product candidates as well as consult on medical and technical matters as requested. We are currently negotiating an extension of

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Dr. Morton s consulting and non-compete agreement with modified terms, however, we cannot be certain that the agreement will be renewed.

In 2000, we entered into an agreement with OncoVac, Inc., an entity owned by Dr. Morton, under which we were assigned the rights to certain patents and patent applications, cell banks and manufacturing know-how related to Canvaxin that were originally cross-licensed from JWCI by OncoVac. In exchange for the cross-license, we issued 284,090 shares of our common stock to JWCI and agreed to pay an aggregate of $1,250,000 to JWCI, of which $500,000 was paid upfront and the remainder is due in annual installments of $125,000 through June 2006. Of the total amount, $250,000 remains unpaid as of December 31, 2004 (Note 5). Under the cross-license agreement, we are also obligated to pay to JWCI 50% of the initial net royalties we receive on sales of Canvaxin, if any, by our sublicensees, up to $3.5 million. Subsequently, we are obligated to pay to JWCI a 1% royalty on net sales, if any, of Canvaxin to third parties by us, our sublicensees and affiliates. Under separate agreements entered into with OncoVac in 2000, we were assigned the cross-license agreement with JWCI, a supply agreement and a trademark in exchange for the issuance of 408,163 shares of Series A preferred stock. We also entered into a contribution of technology and exchange agreement with Dr. Morton in 2000 under which we acquired three Canvaxin cell lines and certain patent rights in exchange for a cash payment of $550,000 and the conversion of certain preferred shares owned by Dr. Morton.

In 2000, we also entered into an agreement with Cancer Diagnostics Laboratories, Inc., or CDL, which is also controlled by Dr. Morton, under which we acquired 20 cell lines and licenses to certain patent rights and related technology in exchange for $750,000 and assumed CDL s obligation to pay a royalty of up to 2% of net sales of any commercialized products that include the acquired cell lines. We capitalized the acquired cell lines and licensed technology rights as an intangible asset at their acquired cost and amortized the asset on a straight-line basis over four years. Accumulated amortization of the asset was $750,000 and $562,500 as of December 31, 2004 and 2003, respectively.

5. Debt Obligations and Lease Commitments

Debt Obligations

Debt consists of the following (in thousands):

	December 31,	
	2004	**2003**
Equipment and tenant improvement loans	$ 6,630	$ 4,802
Notes payable to related parties (Note 2)		2,725
Installment obligations due to JWCI (Note 4)	250	375
	6,880	7,902
Current portion of debt	(525)	(6,091)
Long-term debt, less current portion	$ 6,355	$ 1,811

In December 2004, we entered into an $18.0 million loan and security agreement with a financing 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

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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. 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 this covenant as of December 31, 2004.

As of December 31, 2004, we have borrowed $6.2 million under this credit facility, of which $1.3 million was used to repay our outstanding borrowings under the credit facility secured in 2002. The remaining $4.9 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 manufacturing facility. The interest rate on the outstanding borrowings under this credit facility was 5.25% as of December 31, 2004.

During 2002, we entered into a $6.0 million loan and security agreement with a financing institution to finance eligible equipment and tenant improvements. The outstanding borrowings under this credit facility were repaid in full in December 2004 using borrowings under the $18.0 million bank credit facility secured in December 2004. We issued warrants in connection with this loan as discussed in Note 7.

During 2001, we entered into a $4.0 million loan and security agreement with a financing institution pursuant to which we drew down the entire line of $4.0 million to finance certain capital expenditures. As the credit facility was utilized, separate promissory notes were executed. Each promissory note has monthly payments ranging from 36 to 42 months with the interest rate being fixed at the funding date of each promissory note (9.34% to 10.41%). Each promissory note is collateralized by the related equipment acquired with the loan. We issued warrants in connection with this loan as discussed in Note 7. As of December 31, 2004, borrowings of $0.4 million remain unpaid under this credit facility, which will be repaid in full in 2005.

Lease Commitments

We lease our manufacturing facility under an operating lease which expires in August 2011 with options to renew under varying terms. We also have a ten-year lease for our corporate headquarters and research and development facility that commenced in July 2002 and has two renewal options for five years each. We issued warrants in connection with this lease agreement as discussed in Note 7. In August 2004, we signed a seven-year lease for a warehouse, laboratory and office facility near our manufacturing facility with an option to renew for an additional five years. We also lease certain equipment under operating leases which expire through 2009.

For accounting purposes, we recognize rent expense on a straight-line basis over the term of the related operating leases. Rent expense recognized in excess of rent paid is reflected as a deferred rent liability, which is included in other liabilities in the accompanying consolidated balance sheets. In 2004, 2003 and 2002, rent expense totaled $3.2 million, $3.0 million and $2.1 million, respectively.

We have entered into three irrevocable standby letters of credit in connection with the operating leases for our three primary facilities. The amount of the letter of credit related to the operating lease for our corporate headquarters and research and development facility is $0.4 million, varying up to a maximum of $1.9 million based on our cash position. The amount of the letter of credit related to the operating lease for our manufacturing facility is $0.6 million, decreasing through the end of the lease term. The amount of the letter of credit related to the operating lease for our warehouse, laboratory and office facility is $0.3 million. At December 31, 2004 and 2003, the amounts of the letters of credit totaled $1.3 million and $2.0 million, respectively. To secure the letters of credit, we pledged twelve-month

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certificates of deposit for similar amounts as of December 31, 2004 and 2003 which have been classified as restricted cash in the accompanying consolidated balance sheets.

Annual principal payments due under our debt obligations and annual future minimum payments under our lease commitments are as follows at December 31, 2004 (in thousands):

	Equipment and Tenant Improvement Loans	Installment Obligation Due to JWCI	Operating Leases
2005	$ 400	$ 125	$ 2,697
2006	1,437	125	2,757
2007	1,515		2,844
2008	1,596		2,942
2009	1,682		3,047
Thereafter			6,853
	$ 6,630	$ 250	$ 21,140

6. Collaborative Research and Development and Licensing Agreements

Serono

In December 2004, we entered into a collaboration and license agreement with Serono for the worldwide development and commercialization of Canvaxin. We will jointly commercialize and co-promote Canvaxin in the United States, while Serono has the exclusive right to commercialize Canvaxin outside the United States. The costs to develop and commercialize Canvaxin in the United States, excluding the costs associated with the recruitment, compensation and deployment of a Canvaxin salesforce, and the operating profits from the sale of Canvaxin in the United States, as defined in the agreement, will be shared equally by us and Serono. Serono is responsible for the costs of commercializing Canvaxin outside the United States and will pay us royalties on net sales of Canvaxin outside the United States. We will initially supply Canvaxin for commercial sale worldwide and Serono will reimburse us for our costs to manufacture and distribute Canvaxin for sales outside the United States. Serono may later establish a second manufacturing site, primarily to source Canvaxin for sales outside the United States.

Under the agreement, we received from Serono a $12.0 million payment in December 2004 for the purchase of 1.0 million shares of our common stock and a non-refundable up-front license fee of $25.0 million in January 2005. We may also receive in the future up to $253.0 million of non-refundable milestone payments upon the achievement of certain development, regulatory and sales based objectives and we will share equally with Serono certain costs to develop and commercialize Canvaxin in the United States. We recorded a receivable for the $25.0 million up-front license fee in December 2004 as we had no further obligations to Serono for the receipt of payment and collectibility was reasonably assured. We have deferred the up-front license fee and will initially recognize it as revenue on a straight-line basis over approximately 3.3 years, which primarily represents the estimated period until regulatory approval and commercialization of Canvaxin in patients with Stage IV melanoma in the United States. In 2004, we recognized $0.3 million of the up-front license fee as license fee revenue. Additionally, we recognized $1.2 million of collaborative agreement revenue in 2004 representing Serono s share of Canvaxin pre-commercialization expenses under the agreement, which were incurred by us after the effective date of the collaboration agreement.

Serono may terminate the agreement for convenience upon 180 days prior notice. We may terminate the agreement if Serono develops or commercializes a competing product. We forfeit our right to co-promote Canvaxin in the United States if we were to develop or commercialize a competing product,

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although we would receive royalties on net sales of Canvaxin in the United States by Serono. Either party may terminate the agreement for the material breach or bankruptcy of the other party. In the event of a termination of the agreement, rights to Canvaxin will revert to us.

CIMAB, S.A. and YM BioSciences, Inc.

In July 2004, we signed agreements with CIMAB, S.A., a Cuban corporation, and YM BioSciences, Inc., a Canadian corporation, whereby we obtained the exclusive rights to develop and commercialize in a specific territory, which includes the U.S., Canada, Japan, Australia, New Zealand, Mexico and certain countries in Europe, three specific active immunotherapeutic product candidates that target the epidermal growth factor receptor, or EGFR, signaling pathway for the treatment of cancer. In exchange, we will pay to CIMAB and YM BioSciences technology access and transfer fees totaling $5.7 million, to be paid over the 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, and royalties on future sales of commercial products, if any. Prior to the commercialization of any of the product candidates, payment of the technology transfer fees, technology access fees, and milestones owed to CIMAB under the agreements will be made entirely in United States-origin food, medicines and/or medical supplies rather than cash. Upon commercialization of a product candidate in the United States, payment of milestones and royalties owed to CIMAB under the agreements will be made 50% in cash and 50% in United States-origin food, medicines and/or medical supplies. All payments owed to YM BioSciences under the agreement will be made in cash. Due to the stage of development of the licensed technology and the risk associated with technology developed in Cuba, the amounts payable to CIMAB and YM BioSciences prior to product commercialization will be charged to research and development expense.

The agreements terminate upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreements or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreements. CIMAB may terminate the agreements if we have not used reasonable commercial efforts to file an investigational new drug, or IND, submission to the United States Food and Drug Administration, or FDA, for the leading product candidate by July 12, 2006, or if the first regulatory approval for marketing this product candidate within our territory is not obtained by July 12, 2016, provided that CIMAB has timely complied with all of its obligations under the agreements, or if CIMAB does not receive timely payment of the initial technology access and transfer fees. In addition, if CIMAB does not receive payments under the agreements due to changes in United States law, actions by the United States government or by order of any United States 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 United States and Canada. We may terminate the agreement for any reason following 180 days written notice to CIMAB.

Through December 31, 2004, we have recognized an aggregate of $4.3 million of research and development expenses under the agreements, of which $2.8 million represents amounts paid to CIMAB and YM BioSciences for technology access and transfer fees and the remaining $1.5 million represents technology access fees, payable to CIMAB in future periods, where payment is committed and not subject to future performance.

SemaCo, Inc.

On March 10, 2004, we signed an agreement with SemaCo, Inc. whereby we obtained an exclusive, worldwide sublicense to develop and commercialize novel technology utilizing T-oligonucleotides for the potential treatment or prevention of cancer. In exchange, during 2004 we paid to SemaCo $0.5 million for the acquisition of the technology rights and $0.3 million for the reimbursement of certain patent costs.

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Additionally, we will make research support payments totaling $1.2 million over the three-year period commencing on the effective date of the agreement, of which we have paid $0.4 million through December 31, 2004. We are also obligated to make future milestone payments upon meeting certain regulatory and clinical objectives and royalties on sales of commercial products, if any. The agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreement or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreement. We may terminate the agreement for any reason following 60 days written notice to SemaCo. Due to the early stage of development of the sublicensed technology and since no alternative uses were sublicensed at the time of acquisition, the amounts paid and payable to SemaCo under the sublicense agreement are charged to research and development expenses when due and payable.

Other Licensing and Research and Development Agreements

We have entered into licensing and research and development agreements with various universities, research organizations and other third parties under which we have received licenses to certain intellectual property, scientific know-how and technology. In consideration for the licenses received, we are required to pay license and research support fees, milestone payments upon the achievement of certain success-based objectives and/or royalties on future sales of commercialized products, if any. We may also be required to pay minimum annual royalties and the costs associated with the prosecution and maintenance of the patents covering the licensed technology. If all potential product candidates under these agreements were successfully developed and commercialized, the aggregate amount of milestone payments we would be required to pay is at least approximately $56 million over the terms of the related agreements as well as royalties on net sales of each commercialized product.

As of December 31, 2004, annual future minimum payments under our licensing and research and development agreements, including our agreements with CIMAB, YMB and SemaCo, are as follows at December 31, 2004 (in thousands):

2005	$ 2,980
2006	855
2007	255
2008	55
2009	55
Thereafter	400
	$ 4,600

7. Stockholders Equity

Preferred Stock

Since our inception, we have issued shares of our preferred stock, including Series A, Series B and Series C redeemable convertible preferred stock and Series A, Acquisition and Junior convertible preferred stock, to various investors and related parties in exchange for cash and technology rights and in the Cell-Matrix acquisition. Upon completion of our initial public offering on November 4, 2003, all outstanding shares of our preferred stock automatically converted into an aggregate of 20.1 million shares of common stock.

We were accruing the dividends due on our Series A and Series B redeemable convertible preferred stock and accreting up the difference between the carrying value and redemption value of the Series A and

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Series B redeemable convertible preferred stock through the first redemption date of December 15, 2005. Upon the conversion of the redeemable convertible preferred stock, we ceased accruing dividends and accreting the redemption value. The accrued dividends and the accretion increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share and decreased total stockholders equity.

In August 2003, we sold 20.6 million shares of Series C redeemable convertible preferred stock at a purchase price of $2.01 per share for proceeds of $41.2 million, net of offering costs. The conversion price of the Series C redeemable convertible preferred stock was $8.84 per share. Because this conversion price was less than the fair value of the common stock into which the Series C redeemable convertible preferred stock is convertible into, the Series C redeemable convertible preferred stock was considered to have been issued with a beneficial conversion feature. Accordingly, pursuant to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features*, we recorded a non-cash deemed dividend on the Series C redeemable convertible preferred stock of $14.8 million, which is equal to the number of shares of Series C redeemable convertible preferred stock multiplied by the difference between the initial public offering price and the Series C redeemable convertible preferred stock conversion price per share. The deemed dividend increased the net loss applicable to common stockholders in the calculation of basic and diluted net loss per common share but did not have any effect on total stockholders equity.

Warrants

In February 2003, we issued a warrant to purchase 150,000 shares of preferred stock with an exercise price of $2.45 per share in connection with the signing of a consulting agreement with a research company. The cash exercise of the warrant will result in the issuance of approximately 34,000 shares of our common stock and no issuance of preferred stock. The warrant is fully exercisable and will expire on the seventh anniversary of the date of issuance. The warrant provides the holder with the option to exercise the warrant with a (i) cash payment; (ii) cancellation of our indebtedness to the holder; or (iii) net issuance exercise based on the fair market value of our common stock on the date of exercise. We determined that the fair value of the warrant was $0.2 million using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 70%, risk-free interest rate of 3.45% and expected life of 7 years. The value of the warrant is being recognized as research and development expense over the term of the related consulting agreement.

In September 2002, we issued a warrant to purchase 151,685 shares of preferred stock with an exercise price of $2.67 per share in connection with a secured loan. The cash exercise of the warrant will result in the issuance of approximately 34,000 shares of our common stock and no issuance of preferred stock. The warrant is fully exercisable and will expire on June 30, 2013. The warrant provides the holder with the option to exercise the warrant with a (i) cash payment; (ii) cancellation of our indebtedness to the holder; or (iii) net issuance exercise based on the fair market value of our common stock on the date of exercise. We determined that the fair value of the warrant was $0.2 million using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 70%, risk-free interest rate of 2.42% and expected life of 10 years. The value of the warrant was being recognized as interest expense over the term of the related loan. In December 2004, this loan was repaid in full and accordingly we charged the remaining warrant value to interest expense in 2004.

In February 2002, we issued a warrant to purchase 75,000 shares of preferred stock with an exercise price of $2.45 per share in connection with the signing of the lease related to our corporate headquarters and research and development facility. The cash exercise of the warrant will result in the issuance of approximately 17,000 shares of our common stock and no issuance of preferred stock. The warrant is fully exercisable and will expire on November 4, 2006. The warrant provides the holder with the option to exercise the warrant with a (i) cash payment; (ii) cancellation of our indebtedness to the holder; or

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(iii) net issuance exercise based on the fair market value of our common stock on the date of exercise. We determined that the fair value of the warrant was $0.1 million using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 70%, risk-free interest rate of 4.71% and expected life of 7 years. The value of the warrant is being recognized as rent expense over the term of the related lease.

In 2001, we issued warrants to purchase an aggregate of 65,306 shares of preferred stock with an exercise price of $2.45 per share in connection with a secured equipment financing. The warrants were exercised in full in November 2003 resulting in the issuance of 2,086 shares of common stock. We determined that the fair value of the warrants was $0.1 million using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%, expected volatility of 70%, risk-free interest rate of 4.84% and expected life of 7 years. The value of the warrants is being recognized as interest expense over the term of the related loan.

Equity Compensation Plans

On June 10, 2004, our stockholders approved the Amended and Restated 2003 Equity Incentive Award Plan, or 2003 Plan, which effectively terminates the Third Amended and Restated 2000 Stock Incentive Plan, or the 2000 Plan. The 2003 Plan authorizes the grant of equity awards to purchase the number of shares of our common stock equal to the sum of (i) 2.5 million shares, (ii) the number of shares of common stock remaining available for grant under the 2000 Plan as of June 10, 2004, and (iii) the number of shares of common stock underlying any options granted under the 2000 Plan on or before June 10, 2004 that expire or are canceled without having been exercised in full or that are repurchased by us. Additionally, on June 10 of each year during the term of the 2003 Plan commencing June 10, 2004, the number of shares authorized for the grant of equity awards under the 2003 Plan will increase by an amount equal to the lesser of (i) 5% of our outstanding common shares on such date, (ii) 2.5 million shares, or (iii) a lesser amount determined by our board of directors. Potential types of equity awards that may be granted under the 2003 Plan include stock options, restricted stock, stock appreciation rights, performance-based awards, dividend equivalents, stock payments and deferred stock. The terms and conditions of specific awards are set at the discretion of our board of directors although generally awards vest over four years, expire no later than ten years from the date of grant and do not have exercise prices less than the fair market value of the underlying common stock. Additionally, under certain circumstances, all or a portion of outstanding awards under the 2003 Plan may become immediately vested and exercisable in full upon a change of control, as defined in the 2003 Plan. To date, only stock options have been granted under the 2003 Plan. At December 31, 2004, equity awards to purchase 2.5 million shares of our common stock remain available for grant under the 2003 Plan.

Prior to its termination, the 2000 Plan, which was approved by our stockholders, allowed for the grant of incentive and nonstatutory stock options to purchase shares of our common stock to employees, directors, and third parties. Options granted under the 2000 Plan generally expire no later than ten years from the date of grant and vest over a period of four years. The 2000 Plan allowed for certain options to be exercised prior to the time such options are vested and all unvested shares of common stock are subject to repurchase at the exercise price paid for such shares. At December 31, 2004, 2003 and 2002, 24,506, 91,403 and 149,544 shares, respectively, of common stock were subject to repurchase.

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A summary of stock option activity under the 2000 Plan and the 2003 Plan is as follows (shares in thousands):

	Number of Options	Weighted Average Exercise Price
Outstanding at December 31, 2001	738	$ 1.25
Granted:		
Exercise prices below fair value	377	3.30
Exercise prices equal to fair value	118	2.95
Exercised	(146)	1.37
Cancelled	(29)	2.50
Outstanding at December 31, 2002	1,058	2.12
Granted:		
Exercise prices below fair value	895	3.45
Exercise prices equal to fair value	301	10.76
Exercised	(131)	2.00
Cancelled	(91)	2.44
Outstanding at December 31, 2003	2,032	3.98
Granted (all equal to fair value)	1,371	10.96
Exercised	(42)	2.66
Cancelled	(179)	8.39
Outstanding at December 31, 2004	3,182	$ 6.76

The following table summarizes information about stock options outstanding under the 2000 Plan and 2003 Plan at December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding (thousands)	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable (thousands)	Weighted Average Exercise Price
$1.08-2.16	463	6.13	$ 1.25	458	$ 1.25
3.30	1,160	8.04	3.30	1,088	3.30
6.60-8.62	179	9.46	7.52	31	6.75
8.95-9.75	204	9.18	9.45	108	9.45
10.00-11.55	465	9.30	10.92	3	10.45

11.98-12.87	711	9.10		12.28	112	12.18
$1.08-12.87	3,182	8.34	$	6.76	1,800	$ 3.77

At December 31, 2004, 2003 and 2002, options to purchase 1.8 million, 1.5 million and 0.9 million shares, respectively, were exercisable at weighted average exercise prices of $3.77, $3.06 and $2.06 per share, respectively.

We also have an Employee Stock Purchase Plan, or ESPP, which was approved by our stockholders in 2003. The ESPP initially allowed for the issuance of up to 300,000 shares of our common stock, increasing annually on December 31 by the lesser of (i) 30,000 shares, (ii) 1% of the outstanding shares of our common stock on such date, or (iii) a lesser amount determined by our board of directors. Under

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the terms of the ESPP, employees can elect to have up to 20% of their annual compensation withheld to purchase shares of our common stock. The purchase price of the common stock is equal to 85% of the lower of the fair market value per share of our common stock on the commencement date of the applicable offering period or the purchase date. In 2004, 31,785 shares were purchased under the ESPP and 328,215 shares remain available for issuance under the ESPP as of December 31, 2004.

Stockholder Rights Plan

On November 3, 2004, we adopted a Stockholder Rights Plan, or the Rights Plan. Pursuant to the Rights Plan, our board of directors declared a dividend distribution of one preferred share purchase right, or Right, on each outstanding share of our common stock. Subject to limited exceptions, the Rights will be exercisable if a person or group acquires 15% or more of our common stock or announces a tender offer for 15% or more of our common stock. If we are acquired in a merger or other business combination transaction that has not been approved by our board of directors, each Right will entitle its holder to purchase, at the Right s then-current exercise price, a number of the acquiring company s common shares having a market value at the time of twice the Right s exercise price. Under certain circumstances, each Right will entitle the common stockholders to buy one one-thousandth of a share of our newly created Series A Junior Participating Preferred Stock at an exercise price of $95.00 per share. Our board of directors will be entitled to redeem the Rights at $0.01 per right at any time before a person or group has acquired 15% or more of our outstanding common stock. The Rights Plan will expire in 2014.

Common Shares Reserved For Future Issuance

At December 31, 2004, we have 6.0 million common shares reserved for issuance under our equity compensation plans and 0.1 million common shares reserved for issuance upon the exercise of outstanding stock warrants.

8. Income Taxes

There was no income tax benefit attributable to net losses for 2004, 2003 and 2002. The difference between taxes computed by applying the U.S. federal corporate tax rate of 35% and the actual income tax provision in 2004, 2003 and 2002 is primarily the result of establishing a valuation allowance on our deferred tax assets.

The tax effects of temporary differences and tax loss and credit carryforwards that give rise to significant portions of deferred tax assets and liabilities are comprised of the following (in thousands):

	December 31,	
	2004	**2003**
Deferred tax assets:		
Net operating loss carryforwards	$ 32,713	$ 27,579
Orphan drug and research and development credit carryforwards	37,791	24,822
Property and equipment and intangibles	2,787	884
Deferred revenues	10,078	
Accrued liabilities and deferred rent	1,485	1,057
Other, net	1,304	851
Total net deferred tax assets	86,158	55,193
Valuation allowance for deferred tax assets	(86,158)	(55,193)
Net deferred taxes	$	$

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The increase in the valuation allowance for deferred tax assets in 2004 and 2003 of $31.0 million and $21.3 million, respectively, was due primarily to the inability to utilize net operating loss, orphan drug and research and development credits.

At December 31, 2004, we had net operating loss carryforwards for federal and state income tax purposes of approximately $75.5 million and $109.7 million, respectively, which expire beginning in 2018 and 2010, respectively, unless previously utilized. We also had orphan drug credit carryforwards and research and development credit carryforwards for federal income tax purposes of approximately $34.9 million and $0.3 million, respectively, which expire beginning in 2019 unless previously utilized. In addition, we had research and development credit carryforwards for state income tax purposes of approximately $4.0 million, which are not expected to expire.

As previously discussed in Note 2, we acquired Cell-Matrix in January 2002. As of the acquisition date, Cell-Matrix had approximately $1.8 million of net deferred tax assets consisting principally of federal and state net operating loss carryforwards, federal and state research and development credit carryforwards and tax basis in depreciable and amortizable assets. Due to the uncertainty over the realization of these assets, a valuation allowance has been recorded against the net deferred tax assets acquired. Subsequent tax benefits resulting from realization of these deferred tax assets will be applied to reduce the valuation allowance and goodwill related to the Cell-Matrix acquisition. As a result of the change in control for Cell-Matrix, the utilization of the acquired net operating loss and tax credit carryforwards will be subject to annual limitations in accordance with Internal Revenue Code, or IRC, Sections 382 and 383.

Pursuant to IRC Sections 382 and 383, use of our net operating loss and tax credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period.

9. Quarterly Financial Data (unaudited)

The following quarterly financial data, in the opinion of management, reflects all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of results for the periods presented (in thousands, except per share amounts):

	Year Ended December 31, 2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	$	$	$	$ 1,526
Total operating expenses	12,890	12,851	15,768	15,767
Net loss	(12,831)	(12,754)	(15,656)	(14,345)
Net loss applicable to common stockholders	(12,831)	(12,754)	(15,656)	(14,345)
Basic and diluted net loss per common share	(0.48)	(0.48)	(0.59)	(0.53)

	Year Ended December 31, 2003			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total operating expenses	$ 7,698	$ 8,451	$ 9,907	$ 11,138
Net loss	(7,816)	(8,602)	(10,013)	(11,142)
Net loss applicable to common stockholders(1)	(9,966)	(10,752)	(27,357)	(12,140)
Basic and diluted net loss per common share	(27.72)	(24.83)	(57.14)	(0.73)

(1) Included in net loss applicable to common stockholders for the third quarter of 2003 is a $14.8 million non-cash, deemed dividend resulting from the beneficial conversion feature on our Series C redeemable convertible preferred stock issued in August 2003 (Note 7).