CANCERVAX CORP
Form 10-K
March 29, 2004

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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, 2003

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 o No þ

As of March 10, 2004, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $207.9 million, based on the closing price of the registrant s common stock on the Nasdaq National Market on March 10, 2004 of $11.98 per share. The registrant s common stock was not publicly traded as of the last business day of its most recently completed second quarter.

The number of outstanding shares of the registrant s common stock, par value $0.00004 per share, as of March 10, 2004 was 26,737,555.

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, 2003 are incorporated by reference into Part III of this report.

CANCERVAX CORPORATION

FORM 10-K ANNUAL REPORT

For the Year Ended December 31, 2003

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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, would. Among the factors that could 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 Cell-Matrix, Inc., a wholly owned subsidiary of CancerVax Corporation, 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. Our lead product candidate, Canvaxin, is one of a new class of products being developed in the area of specific active immunotherapy, also known as therapeutic cancer vaccines. Canvaxin is currently being studied in two Phase 3 clinical trials at 80 sites worldwide for the treatment of advanced-stage melanoma, the deadliest form of skin cancer.

In retrospective analyses of 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 for Stage III melanoma versus 739 historical control patients with Stage III melanoma who were treated at JWCI 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 for Stage IV melanoma versus 107 historical control patients with Stage IV melanoma who were treated at JWCI but did not receive Canvaxin. These results were published in the December 2002 issue of the *Journal of Clinical Oncology*; and

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a favorable safety and side effect profile when compared to existing therapies.

Based on the positive results of the Phase 1 and Phase 2 clinical trials, two Phase 3 randomized, double-blind, placebo-controlled clinical trials were initiated for the treatment of patients with advanced-stage melanoma following the surgical removal of their tumors and any clinically detectable metastases. Canvaxin has received fast track designation from the FDA for the treatment of advanced-stage melanoma and orphan drug designation from the FDA for the treatment of invasive melanoma. In February 2004, the independent Data and Safety Monitoring Board, or DSMB, with oversight responsibility for the Phase 3 clinical trials on Canvaxin completed its planned, second interim analysis of our clinical trial of Canvaxin in Stage III melanoma. The DSMB recommended that we continue the trial as planned. We anticipate that in 2004 we will complete enrollment in our Phase 3 clinical trial in Stage III melanoma and complete the second interim analysis of data from our Phase 3 clinical trial in Stage IV melanoma. If the FDA and foreign regulatory authorities accept a positive result in a single Phase 3 clinical trial as sufficient for approval, and if we obtain approval, we anticipate launching Canvaxin as a five-year course of therapy in the United States and Europe in 2006.

Canvaxin is based on our proprietary specific active immunotherapy technology platform that uses human tumor cell lines that express a broad array of tumor-related antigens. Canvaxin has been studied in a Phase 1/2 clinical trial for advanced-stage colorectal cancer, and we are finalizing the design of a Phase 2 clinical trial for patients with Stage III colon cancer.

We are targeting large disease markets with significant unmet medical needs. Melanoma is the sixth most common cancer in the United States, and colorectal cancer is one of the four most common cancers worldwide. In both indications, existing therapeutic alternatives are not highly effective and involve serious toxicity. We have retained worldwide commercialization rights to Canvaxin and intend to market it through our own sales force or co-promote it in the United States and establish strategic collaborations abroad. We manufacture Canvaxin at our biologics manufacturing facility. In 2004 and 2005, we plan to expand our production capabilities in this facility, which we believe, following the planned expansion, will have the capacity to satisfy commercial demand for several years after the initial launch.

In addition to Canvaxin, we plan to identify and develop new product candidates based on our proprietary specific active immunotherapy, anti-angiogenesis and T-oligonucleotide, or telomere homolog oligonucleotide, technology platforms, as well as on our human monoclonal antibody technology.

Industry Background

Cancer

The World Health Organization estimates that in the year 2000 more than 10 million people were diagnosed with cancer worldwide and that this number will increase to 15 million by 2020. In addition, the World Health Organization estimates that 6 million people died from the disease in 2000. The American Cancer Society estimates that over 1.3 million people in the United States will be diagnosed with cancer in 2004 and over 500,000 people will die from the disease. Because cancer is a progressive disease, the total number of people living with cancer significantly exceeds the number of patients diagnosed with cancer in a given year.

Corresponding with an expected growth in cancer incidence, 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, a 11% compounded annual growth rate.

Melanoma

According to the American Cancer Society, melanoma is the deadliest type of skin cancer and is the sixth most commonly diagnosed cancer in the United States. As reported by the World Health Organization, the worldwide incidence, or number of newly diagnosed cases, of melanoma in 2000 was 132,600, with 37,000 people dying of the disease. The American Cancer Society estimates that in the

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United States, approximately 55,000 people will be diagnosed with melanoma and 7,900 will die as a result of the disease in 2004. 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. In 2000, over 510,000 patients in the United States were alive who had been diagnosed with melanoma.

Melanoma is classified into four stages, which are based on well-defined criteria, including characteristics of the primary tumors, regional lymph nodes and 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. For example, 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 improved 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. 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.

Colorectal Cancer

According to the World Health Organization, colorectal cancer is the third most commonly diagnosed cancer worldwide, with approximately 945,000 new cases recorded worldwide in 2000 and an estimated 492,000 deaths in the same year. The American Cancer Society estimates that in 2004, approximately 147,000 people in the United States would be initially diagnosed with colorectal cancer and approximately 57,000 people will die as a result of the disease. According to the National Cancer Institute, in 2000, there were approximately 940,000 patients in the United States who were alive with colorectal cancer. The American Cancer Society also estimates that colon cancer represents approximately 73% of the total number of cases of colorectal cancer in the United States.

Colorectal cancer is classified into four stages, which are based on well-defined criteria, including characteristics of the primary tumor, regional lymph nodes and metastases. If detected early, patients with colorectal cancer have a relatively high rate of survival, with the National Cancer Institute reporting five-year survival approaching 90%. However, for patients with advanced-stage colorectal cancer, the prognosis is much worse. Five-year survival rates in Stage IV colorectal cancer are as low as 9%, as reported by the National Cancer Institute. According to the National Cancer Institute, approximately 40% of patients with colorectal cancer are initially diagnosed with Stage III disease.

The most widely-prescribed therapies for treatment of patients with advanced-stage colorectal cancer include surgery and the combination of two chemotherapeutic agents. These agents have been associated with substantial toxicity, including treatment-related deaths. In 2002, the FDA approved an additional chemotherapeutic agent, which has similar side effects to other chemotherapeutic agents. In February 2004, the FDA approved Imclone Systems, Inc. s Erbitux™, a monoclonal antibody directed at the epidermal growth factor receptor, for use in combination with Pfizer, Inc. s Camptosar® (irinotecan) for the treatment of colorectal cancer. In the same month, the FDA also approved Genentech Inc. s Avastin™, a therapeutic antibody designed to inhibit vascular endothelial growth factor, for use in combination with the IFL chemotherapy regimen (5-FU/Leucovorin/ irinotecan) for the treatment of colorectal cancer.

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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 subsets of these 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.

Since the first use of the smallpox vaccine in the late 1700s, products have been developed to activate the immune system to prevent various infectious diseases. Recently, there has been a significant increase in research focused on the activation of the immune system in the treatment of cancer. 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.

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 triggers immune responses 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. Because this type of therapy is not targeted exclusively at cancer cells, it frequently generates significant side effects. Non-specific active immunotherapy also includes other stimulatory agents such as bacillus Calmette-Guérin, known as BCG.

Specific active immunotherapy, such as Canvaxin, generates targeted cell-mediated and antibody immune responses focused on specific antigens expressed by cancer 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 oncolytic viruses.

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. The onset of angiogenesis is caused mainly by tumor cell production of growth factors that activate the cells that line the blood vessels. These activated cells begin to divide and form new blood vessels. During this process of tumor cell growth and activation of blood vessel cells, the extracellular matrix, which is a dense protein network that provides support and growth signals for blood vessels and tumors, is remodeled. In addition, these activated cells migrate on the remodeled extracellular matrix and form new blood vessels to support the growth of an existing tumor. Newly-formed blood vessels create a potential conduit for the tumor to metastasize. By

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inhibiting the angiogenesis process, it may be possible to restrict blood supply to a tumor, limiting its ability to grow and metastasize.

T-Oligonucleotides for the Treatment of Cancer

Genetic information communicated through DNA is organized into strands called chromosomes, which are capped with a looped nucleotide chain called a telomere. In normal cells, disruption of the telomere loop caused by cell division or DNA damage exposes a region of the DNA that triggers DNA repair responses and normal cell growth, maturation and cell death. In cancer cells, this normal control of cell growth and maturation is lost and the cells continue to proliferate and grow.

Telomere homolog oligonucleotides, or T-oligonucleotides, are short chains of two or more nucleotides that resemble the telomere. Research has demonstrated that T-oligonucleotide treatment of cells from multiple tumor types, including breast, ovarian, pancreatic, fibrosarcoma and melanoma, mimics the effect of telomere disruption in normal cells and causes arrest of cell growth and death through apoptosis, or programmed cell death. Administration of T-oligonucleotides has also been shown to inhibit tumor growth in several *in vivo* tumor models by enabling innate growth regulation and repair mechanisms in cancerous cells, leading to the cessation of cancer cell growth and death through normal mechanisms. 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.

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
	Stage IV melanoma	Phase 3	CancerVax
	Stage III colon cancer	Planned Phase 2	CancerVax
Canvaxin with GM-CSF	Stages II, III and IV melanoma	Phase 1/2	CancerVax
Lung cancer candidate	Lung cancer	Research	CancerVax
Anti-Angiogenesis			
Humanized monoclonal antibodies	Solid tumors	Preclinical	CancerVax
	Ophthalmic diseases	Preclinical	Eyetech Pharmaceuticals
Various peptides	Solid tumors, ophthalmic diseases	Research	CancerVax
Human Monoclonal Antibodies			
Three human antibodies	Solid tumors	Preclinical	CancerVax
T-oligonucleotides	Cancer	Research	CancerVax

Canvaxin and Other Specific Active Immunotherapy Programs

Canvaxin, initially developed by our founder, Donald L. Morton, M.D., 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 melanoma patients. Since 1984, over 2,600 patients have been treated with Canvaxin in various Phase 1 and Phase 2 clinical trials primarily supported by the National Institutes of Health through peer-reviewed grants. Results from these clinical trials demonstrate that Canvaxin has a favorable safety and side effect profile relative to existing therapies for the treatment of patients with advanced-stage melanoma.

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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 more effective than other immunotherapeutic approaches because of the following characteristics:

Use of Whole Cells. This technology uses whole cells, which may stimulate a stronger immune response than other immunotherapy approaches that use cell fragments, peptides or antigens alone. These whole cancer cells are irradiated during the manufacturing process to prevent replication when administered to patients, but they continue to produce antigens and stimulate the immune system for a period of days to weeks after they have been injected into a patient. In contrast, we believe that cell fragments, peptides and antigens are more likely to rapidly degrade in the body, which minimizes their ability to stimulate the immune system.

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. For example, 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, 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-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. We believe there are numerous 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 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. The Phase 3 clinical trials are randomized, double-blind, placebo-controlled studies designed to detect an increase in median overall survival in patients treated with Canvaxin plus BCG, an adjuvant, compared to those treated with a placebo plus BCG. An 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, we administer Canvaxin 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 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

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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 to further enrollment 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 enrollment in 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 or that it is not sufficiently efficacious to continue the trials.

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. As of March 15, 2004, we had enrolled 891 out of a planned total of 1,118 patients in the Stage III melanoma clinical trial and 354 out of a planned total of 670 patients in the Stage IV melanoma clinical trial. We anticipate that in 2004 we will complete enrollment in our Phase 3 clinical trial in Stage III melanoma, and that the DSMB will complete the second interim analysis of data from our Phase 3 clinical trial in Stage IV melanoma. If the FDA and foreign regulatory authorities accept a positive result in a single Phase 3 clinical trial as sufficient for approval, and if we obtain approval, we anticipate launching Canvaxin for the treatment of patients with advanced-stage melanoma in the United States and Europe in 2006.

Phase 2 Results

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. *(p-value = 0.0001)*	48.8% vs. 36.8%
	Non-Canvaxin	739	according to key		
	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. 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. 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. 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.

(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 1998. The 214 patients that were matched according to key prognostic factors are a subset of the 263 total patient population.

Results from these clinical trials demonstrate that Canvaxin has 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.

Despite these results, retrospective analyses are not generally deemed sufficient by the FDA and most foreign regulatory authorities as a basis for approval to market a product because they may be subject to potential selection biases that may be minimized in prospective, randomized, double-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 those patients 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 patients 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.

The survival benefit conferred by 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 patients who did not receive Canvaxin. Patients were matched

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according to the following key prognostic factors: the number and degree of palpability of lymph node metastases, patient 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 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 patients 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 patients 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 patients 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. 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 who did not receive Canvaxin had a 56% increased risk of death compared to patients that 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 those patients 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.

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 patients from the JWCI database who did not receive Canvaxin indicated that those patients who received Canvaxin experienced an approximate

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doubling in median overall survival when compared to similar patients 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 patient group 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 group 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 metastases are clearly visible on the skin. 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. Based on the consistency of our results in Phase 2 clinical trials, a multicenter, 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 received high-dose interferon 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. Prior to the

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change in the protocol, 43 patients were enrolled at six clinical trial sites, and we continue to collect data on these patients. 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 Stage III melanoma, described above.

Canvaxin with GM-CSF. In association with JWCI, we are studying the clinical effect of administering GM-CSF to patients who receive Canvaxin and BCG in a Phase 1/2 clinical trial for patients with Stage II, III or IV melanoma who are not eligible for our ongoing Phase 3 clinical trials. In this clinical trial, patients were randomized to receive either Canvaxin and BCG or Canvaxin, BCG and GM-CSF. BCG is administered to all patients during the first two doses of therapy. GM-CSF, a stimulatory protein, is administered in addition to Canvaxin and BCG during the first four months to patients randomized to that arm of the study.

The purpose of this clinical trial is to determine whether administering GM-CSF with Canvaxin and BCG will stimulate an enhanced immune response relative to patients who receive only Canvaxin plus BCG. We have completed the treatment of all 120 patients enrolled in this clinical trial. This clinical trial is being supported in part by a grant to JWCI from the National Cancer Institute. We plan to initiate studies to evaluate Canvaxin in conjunction with other adjuvants and co-stimulatory molecules to determine whether these approaches may further enhance the efficacy of Canvaxin.

Stage II Melanoma. At the 2003 meeting of the American Society of Clinical Oncologists, Dr. Morton presented data from a retrospective matched-pair analysis of 153 patients with Stage II melanoma who received Canvaxin following surgical removal of their tumors compared to those who did not. In a preliminary analysis of this data, overall survival was higher in patients who received Canvaxin. At the time the presentation was given, the median overall survival could not yet be calculated.

Non-Resectable Stage IV Melanoma. At the same 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. Even in this challenging patient population, median overall survival was significantly higher in patients who received Canvaxin compared to those who did not receive Canvaxin. The median overall survival rates for the Canvaxin-treated population was 11 months versus 7 months for the 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 Colon Cancer

Proposed Phase 2 Clinical Trial for Stage III Colon Cancer

We are developing the final design for a Phase 2 clinical trial with Canvaxin in patients with Stage III colon cancer who have had surgical resection of their primary tumors and lymph node metastases.

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 to evaluate immune responses to Canvaxin in patients with Stage IV 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

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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 colon cancer.

Additional Programs Using Our Specific Active Immunotherapy Platform

Lung Cancer Product Candidate

We have identified many cross-reactive antigens between Canvaxin and lung cancer and are currently screening lung cancer cell lines for additional immunogenic antigens. Our intent is to identify one or more cell lines that contain a large number of lung cancer-associated antigens to create a specific active immunotherapy product for the treatment of this disease. We plan to select one or more lung cancer cell lines to add to Canvaxin, complete preclinical studies and submit an Investigational New Drug, or IND, application to begin a Phase 1/2 study in lung cancer.

Other Indications

In addition to our current research, preclinical and clinical development programs for melanoma, colon cancer and lung cancer, we plan to assess the efficacy of product candidates developed with our proprietary specific active immunotherapy development platform in other cancers that express antigens that are expressed by the cells in Canvaxin. We also have established a research program to screen, test and incorporate additional tumor cell lines into our specific active immunotherapy development platform, as we develop new product candidates for other solid tumor cancers that share fewer antigens with the cell lines used for Canvaxin. Potential indications for products developed from our platform include renal, prostate, breast, pancreatic and brain cancers.

EGF Product Candidates for Lung Cancer

We have signed non-binding letters of intent with CIMAB, S.A., a Cuban company, and YM Biosciences, Inc., a Canadian company, relating to the license of a specific active immunotherapeutic agent that targets epidermal growth factor, or EGF, receptors and, in particular, the HER-1 receptor. These letters of intent also cover the license of two molecules that bind to this receptor, including the EGF molecule and the tumor growth factor alpha, or TGF- , molecule. Any definitive agreements for the license of this technology are subject to United States governmental approval. We have submitted a license application seeking approval to enter into such agreements to the United States Department of Treasury s Office of Foreign Assets Control. Our license application is currently being reviewed, however, there can be no assurance that such a license will be granted.

EGF is one of several molecules that bind to EGF receptors and may be responsible for activating a series of intracellular processes that impact cell growth and cell death. While many cells in the human body express EGF receptors, a number of solid tumor cancer cells express EGF receptors in excessive quantities. In addition, a number of solid tumor cancers are also associated with increased production of EGF and TGF- molecules. Non-small-cell lung cancer is one of the solid tumor cancers that over-express EGF receptors and is also associated with increased production of TGF- . Other solid tumors that are associated with over-expression of EGF receptors and/or increased production of TGF- include: brain, breast, colorectal, esophageal, head and neck, ovarian, pancreatic and prostate cancers.

The EGF specific active immunotherapeutic product candidate has been studied in Phase 1 and Phase 2 clinical trials conducted in Canada, the United Kingdom and Cuba. An article in the *Annals of Oncology* (Volume 14, 2003) described pooled results of two clinical trials involving 40 patients with advance-stage non-small cell lung cancer who were treated with this EGF specific active immunotherapeutic. Of these 40 patients, 19 patients, or 47.5%, were determined to be high responders to the EGF specific active immunotherapeutic, while 21 patients, or 52.5%, were determined to be low responders. The high responders, in aggregate, had a median survival of 9.1 months, versus 4.5 months for the low responders, with a p-value of less than 0.05.

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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 this platform of complementary technologies, which have a mechanism of action that is distinct from anti-angiogenesis products currently in development by other companies, will provide us with an opportunity to develop products that target various solid tumors.

Advantages of Our Anti-Angiogenesis Platform

Our antibodies and peptides bind to new sites exposed on proteins, such as collagen, during the remodeling of the extracellular matrix. Because our antibodies bind preferentially to collagen that has been remodeled rather than to normal collagen, we believe our monoclonal antibodies may be more specific and cause fewer side effects than other therapies that interact with targets that have broad biologic activity. Additionally, collagen may provide a better long-term target than binding sites found directly on tumor cells because it is a stable structure that may be less likely to mutate than tumor cells.

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. Two of our humanized monoclonal antibodies have demonstrated the ability to inhibit angiogenesis and tumor growth in animal models of melanoma and breast cancer. Specifically, our humanized antibody QH2B was injected into two groups of immune-suppressed mice, one implanted with breast cancer tumor cells and the other implanted with melanoma cells. In the breast cancer study, mice that received the QH2B antibody experienced 61% less tumor growth than the mice that did not receive the antibody. Similarly, the QH2B antibody inhibited melanoma tumor growth in mice by 54%. A second anti-angiogenesis humanized antibody, 2D4, has been shown to inhibit melanoma tumor growth in a mouse model by 71%. We also have several peptides that are directed at various binding sites on the extracellular matrix. We have sublicensed our rights to ophthalmic indications for our lead monoclonal antibodies and the underlying technology to Eyetech Pharmaceuticals, Inc.

Human Monoclonal Antibodies

In October 2002, we licensed the exclusive worldwide commercialization rights from M-Tech Therapeutics, Inc. to three human monoclonal antibodies. These monoclonal antibodies have been tested in preclinical models and appear to target tumor-associated antigens that are expressed in a variety of solid tumor cancers. We are conducting further preclinical evaluations of these human monoclonal antibodies.

T-Oligonucleotide Technology

In March 2004, we sublicensed the exclusive worldwide commercialization rights from SemaCo, Inc., to certain T-oligonucleotide technology to develop product candidates for the prevention, treatment, control, prognosis and diagnosis of cancer. An article in the March 1, 2004 issue of the *Proceedings of the National Academy of Sciences*, described preclinical studies in murine models of several types of cancers that suggest that these T-oligonucleotides may activate defense mechanisms used by healthy cells to stop tumor cell growth and replication, and cause cancer cell death.

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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 to complete our Phase 3 clinical trials for the treatment of patients with advanced-stage melanoma and launch Canvaxin as promptly as practicable. We plan to file a biologics license application, or BLA, with the FDA at the conclusion of one or both of our Phase 3 clinical trials. If the FDA and foreign regulatory authorities accept a positive result in a single Phase 3 clinical trial as sufficient for approval, and if we obtain approval, we anticipate launching Canvaxin for advanced-stage melanoma in the United States and Europe in 2006.

Directly Market or Co-Promote Canvaxin in the United States and Establish Strategic Collaborations to Market Canvaxin Abroad. We plan to build a focused sales force to market Canvaxin to the relatively concentrated group of oncologists in the United States who specialize in the treatment of patients with advanced-stage melanoma. We intend to establish strategic collaborations to market Canvaxin in Europe, Australia and elsewhere, and we may enter into an agreement to co-promote Canvaxin in the United States.

Expand the Indications for Canvaxin. We are currently developing the final design of our Phase 2 clinical trial for the treatment of patients with Stage III colon cancer. We also are planning to evaluate whether Canvaxin can be used to treat other solid tumor cancers, either alone or in combination with additional therapeutic products.

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. In addition, we intend to leverage the experience that we have gained from developing the manufacturing process for Canvaxin to our additional biological product candidates.

Create Additional Product Candidates Using Our Proprietary Specific Active Immunotherapy Technology Platform. We are currently conducting research on lung cancer cell lines and anticipate completing preclinical studies and filing an IND to begin a Phase 1/2 study in lung cancer. We plan to evaluate the applicability of our proprietary specific active immunotherapy technology platform to a number of other solid tumor cancers, such as renal, prostate, breast, pancreatic and brain cancers.

Advance the Development of Our Preclinical Product Candidates. We plan to continue to advance our preclinical antibodies, peptides and T-oligonucleotide technology into preclinical studies and clinical trials for the treatment of various solid tumor cancers.

Identify Additional Product Candidates Based on Our Anti-Angiogenesis Technology Platform. We plan to leverage our research and preclinical experience in angiogenesis to identify additional product candidates that will interact with sites exposed during the 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. For example, we acquired Cell-Matrix in January 2002 to acquire the rights to our anti-angiogenesis platform technology, and entered into a license agreement with New York University in June 2003 to further expand our anti-angiogenesis technology. In March 2004, we sublicensed rights from SemaCo to certain

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T-oligonucleotide technology that has potential in the prevention, treatment, control, prognosis and diagnosis of cancer.

Marketing

We intend to market and sell Canvaxin and future products directly or with a co-promotion partner in the United States. The three 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 of approximately 75 to 100 sales representatives to launch Canvaxin for advanced-stage melanoma.

Outside of the United States, we plan to establish strategic collaborations for the marketing and development of Canvaxin. 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. In 2004 and 2005, we plan to expand our production capabilities. The capital expenditures associated with this expansion are anticipated to be approximately $16 million, a significant portion of which we intend to fund through new leasehold and equipment financing.

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. 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 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.

Collaborations

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

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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 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, including the ongoing Phase 1/2 clinical trial testing of Canvaxin with GM-CSF.

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, 2003, we have paid JWCI installments totaling $875,000, and we are obligated to pay three additional installments to JWCI of $125,000 each in 2004, 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 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 antibodies, we paid AME a fixed fee of $500,000 for each of the two antibodies. In addition, AME is entitled to certain milestone payments, up to a maximum of $3,250,000 per therapeutic product developed using these antibodies and $1,250,000 per diagnostic product developed using these antibodies. AME is also entitled to royalties on net sales of products, if any, developed using these antibodies. To date $750,000 per antibody has been paid to AME for milestones

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achieved. In the aggregate, a total of $2,500,000 has been paid to AME including both the fixed fee costs and milestone payments. From January 2002, the date we acquired Cell-Matrix and assumed this agreement, through December 31, 2003, we have not recognized any expenses under the agreement. 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 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 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 antibodies that are the subject of the agreement and the products that incorporate or are derived from one or more of the 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.

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, we paid USC up-front license fees of $500,000 for the September 1999 license agreement and $250,000 for the May 2000 license agreement and we are obligated to pay USC 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, 2003, we have recognized a total of $25,000 in expenses under the license agreements. 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.

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, we paid up-front license fees of $50,000 to Scripps, and we are obligated to pay Scripps 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, we are obligated to pay Scripps milestone payments, up to a maximum of $1,225,000 per therapeutic product and $385,000 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, 2003, we have not recognized any expenses under the license agreement. 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

In March 2001, we sublicensed to Eyetech Pharmaceuticals, Inc. several antibodies and related technology for ophthalmic indications. Eyetech Pharmaceuticals paid us a signing fee of $2,400,000 and is obligated to pay us milestone payments, up to a maximum of $20,000,000 per therapeutic product and $2,400,000 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. From January 2002, the date

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we acquired Cell-Matrix and assumed this agreement, through December 31, 2003, we have not recognized any revenues under the agreement. Eyetech Pharmaceuticals is also responsible for research and development costs in the ophthalmic area. 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 10 years after the date of the first commercial sale of the last product licensed or developed under the agreement. Either party may terminate this agreement for any reason following 90 days written notice to the other party. Eyetech Pharmaceuticals is a public biotechnology company whose focus is on the treatment of diseases related to the back of the eye, such as age-related macular degeneration and diabetic retinopathy.

M-Tech Therapeutics

In October 2002, we acquired the exclusive worldwide commercialization rights from M-Tech Therapeutics to three human monoclonal antibodies that appear to target tumor-associated antigens that are expressed in a variety of solid tumor cancers. Pursuant to our licensing arrangement, we paid M-Tech Therapeutics upfront payments and are obligated to pay future annual license fees of $10,000 for each of the three licensed cell lines. We are also obligated to pay milestone payments, up to a maximum of $1,050,000 for each product developed under this agreement, based on meeting certain regulatory and clinical milestones and royalties. From inception through December 31, 2003, we have recognized a total of $280,000 in expenses under the agreement, $160,000 of which was licensing fees and $120,000 of which was an upfront payment. 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. M-Tech Therapeutics may terminate, on an individual basis, the licenses granted under the agreement to the three human monoclonal antibodies 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 we determine not to file an IND application for a licensed product by a specified date because of negative preclinical results. In either event, we would be subject to specified termination fees.

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, we paid New York University an upfront payment of $66,666 and are obligated to pay an additional $66,667 on the first anniversary of the date of the agreement and $66,667 on the second anniversary. In addition, we are obligated to pay future anniversary payments of $15,000 representing license maintenance fees. We are also obligated to pay milestone payments, up to a maximum of $750,000 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. From inception through December 31, 2003, we have recognized a total of $67,000 in expenses under the agreement, all of which were licensing fees. 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.

Synteract

In January 2002, we contracted 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. From inception through December 31, 2003, we have recognized a total of $4,300,000 in expenses under this agreement. This agreement requires Synteract to provide these services to us through December 31, 2005. However, this agreement is subject to early termination by

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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.

SemaCo

In March 2004, we acquired the exclusive worldwide commercialization rights from SemaCo to novel technology using T-oligonucleotides for the potential treatment or prevention of cancer. In 2003 and 2004, we paid SemaCo a total of $350,000 in option payments. Pursuant to our licensing arrangement, in 2004 we paid SemaCo $450,000 in upfront payments and $256,000 for reimbursement of certain patent costs. We are also obligated to pay research support totaling $1.2 million over three years, milestone payments of up to a maximum of $9.2 million for each product developed under this agreement, based on meeting certain regulatory and other milestones, and royalties. 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 this agreement for any reason following 60 days written notice to SemaCo.

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. As of December 31, 2003 we had exclusive rights to develop for commercial purposes specified therapeutic cancer vaccines under four issued patents in the United States and additional patents in Europe and Australia. In addition, a patent application has been published in Japan and another is pending in Canada. The patents include composition of matter claims as well as process 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 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 on procedural grounds, our patents may be the subject of other challenges by our competitors in Europe, the United States and elsewhere.

We are party to several license agreements that give us rights to use technologies in our research and development. We have licensed intellectual property for technology related to Canvaxin from Cancer Diagnostics Laboratories, Inc. and JWCI, to our angiogenesis technology from USC, Scripps and NYU, to

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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 and patent applications directed to Cell-Matrix s angiogenesis 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. 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.

Competition

We are aware of a number of competitive products currently available in the marketplace or under development that are used 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 melanoma. In addition, Corixa Corporation s Melacine® has been approved in Canada for the treatment of melanoma, however, Corixa recently announced that it is discontinuing the U.S. development of Melacine for melanoma. A number of other competitors are developing immunotherapeutics and other approaches for the treatment of melanoma, including Progenics Pharmaceuticals, Inc. s GMK™, Antigenics, Inc. s Oncophage™, Maxim Pharmaceutical, Inc. s Ceplene™, Celgene Corporation s Revimid™ and Genta, Inc. s Genasense™, which are all in Phase 3 clinical trials. In November 2003, Maxim announced that it has filed for European approval to market Ceplene, in combination with interleukin-2 for the treatment of advanced malignant melanoma in patients with liver metastases, and in February 2004, Genta announced that the FDA had accepted for priority review a new drug application for Genasense, for use in combination with dacarbazine for the treatment of patients with advanced malignant melanoma. Oncophage, Ceplene, Revimid and Genasense are all being studied in patients with metastatic melanoma, but none of these clinical trials require that patients undergo surgical resection to remove all clinically detectable disease prior to initiating their treatment. This is contrasted with patients who are being studied in Canvaxin s Phase 3 clinical trials, who have their tumors and all clinically detectable metastases resected. If we receive approval to market and sell Canvaxin, we may compete with these companies and their products as well as other products in various stages of development.

Various companies are currently marketing or developing biopharmaceutical products that may compete with our product candidates that target colon cancer. Canvaxin and other product candidates we may develop are subject to competition in the treatment of colon cancer from a number of products already approved and on the market, including the following chemotherapy products: AstraZeneca PLC s Tomudex®, Hoffmann-LaRoche, Inc. s Xeloda® (capecitabine), Immunex Corporation s Leucovorin® calcium, Pfizer, Inc. s Camptosar® (irinotecan) and Aduracil® (5-FU) and Sanofi-Synthelabo Groupe s Eloxatin™ (oxaliplatin). In February 2004, the FDA approved a BLA for Imclone Systems, Inc. s Erbitux™, a monoclonal antibody directed at the epidermal growth factor receptor, for use in combination with Camptosar® for the treatment of colorectal cancer. In the same month, the FDA also approved a BLA for Genentech, Inc. s Avastin™, a therapeutic antibody designed to inhibit vascular endothelial growth factor, for use in combination with the IFL chemotherapy regimen (5-FU/ Leucovorin/ irinotecan) for the treatment of colorectal cancer. Other product candidates currently in late stages of development for the treatment of colorectal cancer include Antigenics, Inc. s Oncophage™, Aphton Corporation s G-17™, AVI BioPharma, Inc. s Avicine™, GlaxoSmithKline s Eniluracil™, Intracel Corporation s Oncovax™ and Titan Pharmaceuticals, Inc. s CeaVac™. We also face competition from a number of companies working in the fields of anti-angiogenesis and specific active immunotherapy for the treatment of other solid tumor cancers, and working to develop technologies similar to the T-oligonucleotide technology that use internal

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cellular mechanisms to regulate cell responses as a treatment for cancer. We expect that competition among specific active immunotherapy and anti-angiogenesis products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent position.

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.

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.

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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 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 Institutional Review Board, or IRB, 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

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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.

The Modernization Act specifies that the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor s request. 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 subject approval of an application for certain fast track products to post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and prior review of all promotional materials. In addition, the FDA may withdraw its approval of a fast track designation 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. However, the time periods specified under the Prescription Drug User Fee Act concerning timing goals to which the FDA has committed in reviewing an application do not begin until the sponsor submits the entire application.

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 a rare disease or certain 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 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, seizure of product, or voluntary recall 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

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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.

Employees

As of December 31, 2003, we employed 151 full-time employees, of whom approximately 62 were engaged in research, development and regulatory affairs, 62 in manufacturing and quality assurance, and 27 in administration, finance, management information systems, corporate development 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 allergic reactions, may also be associated with bacillus Calmette-Guérin, or BCG, which is the adjuvant we administer to patients with the first two doses of Canvaxin. Furthermore, the availability of alternative treatments and the cost effectiveness of Canvaxin will affect our ability to commercialize Canvaxin. If we fail to commercialize this lead product candidate, our business, financial condition and results of operations will be materially and adversely affected.

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

The preclinical development, clinical trials, manufacturing and marketing of our product candidates are all subject to extensive regulation by United States and foreign governmental authorities. It takes many years and significant expense to obtain the required regulatory approvals for biological products. Satisfaction of regulatory requirements depends upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. In particular, the specific active immunotherapy technology on which Canvaxin is based is a relatively new form of cancer therapy that presents novel issues for regulatory authorities to consider and, therefore, may be subject to heightened scrutiny in the regulatory process. For example, in 2002, the FDA sent a letter requesting additional information from all holders of Investigational New Drug, or IND, applications for products involving somatic cell or gene therapies, including Canvaxin. We cannot be certain that any of our product candidates will be shown to be safe and effective or that we will ultimately receive approval from the FDA or foreign regulatory authorities to market these products. In addition, even if granted, product approvals and designations such as fast-track and orphan drug may be withdrawn or limited at a later time.

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

In addition, manufacturers of biological products, including specific active immunotherapies, must comply with the FDA s current good manufacturing practice regulations. These regulations apply to our biologics manufacturing facility, located in the Los Angeles, California area, where we currently manufacture Canvaxin. These regulations include quality control, quality assurance and the maintenance of records and documentation. Our manufacturing facility also is subject to the licensing requirements of the California Department of Health Services and may be inspected by the FDA and the California Department of Health Services at any time. We and our present or future suppliers may be unable to comply with the applicable good manufacturing practice regulations and with other FDA, state and foreign regulatory requirements. Failure to maintain a license from the California Department of Health Services or to meet the inspection criteria of the FDA and the California Department of Health Services would disrupt our manufacturing processes and would delay our clinical trials. If an inspection by the FDA, California Department of Health Services or a foreign regulatory authority indicates that there are deficiencies, we could be required to take remedial actions, we could be prohibited from supplying product for our ongoing clinical trials and for commercial sale, or our facility could be closed.

If clinical trials of Canvaxin or any other product candidates that we may develop do not produce successful results, we will be unable to commercialize these product candidates.

In order to receive regulatory approval for the commercial sale of our product candidate Canvaxin or any other product candidates that we may develop, we must conduct, primarily at our own expense, extensive clinical trials to demonstrate safety and efficacy. Clinical testing is expensive, can take many years and has an uncertain outcome. For example, while difficult to predict, we estimate that we will incur at least an additional $100 million in costs, including internal costs, prior to commercialization of Canvaxin. Failure can occur at any phase of the clinical testing. While Canvaxin is currently being studied in two Phase 3 clinical trials for advanced-stage melanoma, these trials may not produce positive results and may, under some circumstances, be terminated early. Both Phase 3 clinical trials for Canvaxin in advanced-stage melanoma were designed with three interim analyses prior to the planned completion of the clinical trials. At each interim analysis, an independent data and safety monitoring board will review unblinded data from the clinical trials primarily to evaluate the safety of Canvaxin. It is possible that in connection with any of the interim analyses or at any other stage of the trials, the monitoring board may

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determine that there are safety risks associated with Canvaxin or that it is not sufficiently effective to continue the trials, and may, as a result, recommend the discontinuation of these clinical trials.

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 in 2004 we will complete the planned, second interim analysis of our Phase 3 clinical trial of Canvaxin in Stage IV melanoma.

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. We may be subject to additional clinical holds imposed by the FDA or other regulatory authorities in the future.

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

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting the ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. In April 2002, the FDA inspected our clinical trial operations and three of our clinical trial sites. As a result of the FDA s inspections, we received a report of observations from the FDA. The deficiencies noted in this report included inadequate documentation of the review and approval of clinical site investigators and a contract clinical trial monitoring firm; delays in obtaining formal internal approvals of some of our standard operating procedures; and lack of timeliness in preparing and filing certain reports associated with the clinical trials and in obtaining compliance with corrective action plans by several clinical trial sites. We responded to the FDA s report of observations 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. The deficiencies noted in these warning letters included the use of an incorrect version of patient informed consent forms, delayed reporting of serious adverse events and failures to rigorously follow the investigational plan. Both sites

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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 reinspect our clinical operations for a variety of reasons, including to confirm that we and our clinical trial sites continue to observe the corrective actions taken in response to the initial FDA inquiry. Moreover, if the FDA determines that the deficiencies noted at any of the sites are of sufficient concern, it could require that data from such sites be excluded from our clinical trial results and additional patients be enrolled as part of the protocol, that the Phase 3 studies be redone, or that additional Phase 3 clinical trials be conducted.

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

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

Of the approximately 2,600 patients who have been administered Canvaxin in Phase 1 and Phase 2 clinical trials, fewer than 50 of those patients received Canvaxin at locations other than JWCI and UCLA. As of December 31, 2003, Dr. Morton beneficially owned approximately 19.4% 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. 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 results of Phase 1 and Phase 2 clinical trials of Canvaxin may not be predictive of the future results of our ongoing Phase 3 clinical trials. Data from these Phase 1 and Phase 2 clinical trials were evaluated using retrospective survival analyses that may be subject to potential selection biases.

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

In addition to analyses of survival data from all patients with advanced-stage melanoma in the JWCI database who met certain criteria, matched-pair analyses were performed. These matched-pair analyses were conducted by using prognostic factors to match patients who received Canvaxin with similar patients in the database who did not receive Canvaxin. Median overall survival and five-year survival rates were compared between patients treated with Canvaxin and the matched-pair patient control groups who were not treated with Canvaxin. All clinical data reported regarding the patients in the Phase 1 and Phase 2

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clinical trials were obtained from JWCI s database and we have not independently performed any audit or other reconciliation against actual patient medical records. In addition, retrospective analyses of matched-pair data are not generally deemed sufficient by the FDA and most foreign regulatory authorities as a basis for approval to market a product because they may be subject to potential selection biases that may be minimized in prospective, randomized, double-blind, placebo-controlled clinical trials.

Due to the differences in patient populations and study methodologies, it may be difficult to compare results from the retrospective analyses in our Phase 1 and Phase 2 clinical trials for Canvaxin to any other analyses by other groups. Differences in survival rates between studies in patients with Stage III 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 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 our Phase 3 clinical trials, we plan to enroll 1,118 patients with Stage III melanoma, and 670 patients with Stage IV melanoma, and we rely on clinical investigators and medical institutions to enroll these patients. As of March 15, 2004, 891 patients had been enrolled in our Phase 3 clinical trial in Stage III melanoma and 354 patients had been enrolled in our Phase 3 clinical trial in Stage IV melanoma. From June 1, 2003, through the end of February 2004, the rate of patient enrollment in these trials has been between 18 and 31 patients per month for the clinical trial in Stage III melanoma, and between 4 and 11 patients per month for the clinical trial in Stage IV melanoma. We anticipate that the rate of enrollment will increase as the new clinical trials sites we have added begin to enroll patients, and as we add additional clinical trial sites to our program, but we cannot be sure that we will be able to accelerate clinical trial enrollment or enroll an adequate number of patients to complete the Phase 3 clinical trials. In addition, we may not be able to control the amount and timing of resources that the medical institutions that conduct the clinical testing may devote to these Phase 3 clinical trials. If these clinical investigators and medical institutions fail to enroll a sufficient number of patients in our clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for Canvaxin. In addition, the interim and final analyses of the data from these clinical trials may not be performed until a specified number of patients in each of these clinical trials has expired, so a delay in enrollment will adversely impact the timely completion of these clinical trials. A total of 392 patients participating in the Phase 3 clinical trial in Stage III melanoma, and a total of 390 patients participating in the Phase 3 clinical trial in Stage IV melanoma, respectively, must have died before we can perform the final analyses on these clinical trials. Eighty clinical trial sites are currently participating in our two Phase 3 clinical trials. In the event that we are unable to maintain our relationship with any of these clinical trial sites, or elect to terminate the participation of any of these clinical trial sites, we may experience the loss of follow-up information on patients enrolled in the Phase 3 clinical trials unless we are able to transfer the care of those patients to another clinical trial site. Any delays could significantly slow the pace of our patient enrollment activities and the ultimate development of Canvaxin.

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

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

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

We have limited experience in manufacturing and testing biological products and may encounter problems or delays that could result in delayed development 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.

We have experienced significant delays in connection with our commercial-scale manufacturing processes and may encounter delays in the future. For example, as a result of a sterility concern caused by a third party testing process related to one lot of Canvaxin used in our Phase 3 clinical trials, we initiated a product retrieval from 35 clinical trial sites in June 2003. While we do not believe this voluntary product retrieval was due to our manufacturing process, we may experience other delays in our development programs and commercialization efforts stemming from our manufacturing and testing processes, including testing and other services performed by third parties. 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.

In 2004 and 2005, we plan to expand our production capabilities. If we are unable to manufacture sufficient quantities of Canvaxin using our commercial-scale process in accordance with FDA and foreign regulatory authority regulations, the lack of supply could delay our clinical trials, thereby delaying submission of Canvaxin for regulatory approval and its commercial launch. Similarly, if we are unable to complete the development and validation of the specialized assays required to ensure the consistency of

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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. 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.

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

We rely on the availability and condition of our sole biologics manufacturing facility, located in 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 terms for an additional five years. After that time, we may not be able to negotiate a new lease for our facility. Our facility is located in a seismic zone, and there is the possibility of an earthquake which could be disruptive to our operations and result in a lack of supply of Canvaxin. Any lack of supply could, in turn, delay our clinical trials and any potential commercial sales. In addition, if the facility or the equipment in the facility is significantly damaged or destroyed for any reason, we may not be able to replace our manufacturing capacity, and our business, financial condition and results of operations will be materially and adversely affected.

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

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

- regulatory authorities may withdraw their approvals;
- 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 are in a very early stage and, therefore, these efforts are subject to a high risk of failure.

Our strategy is to discover, develop and commercialize new products for the treatment of cancer. The process of successfully developing product candidates is very time-consuming, expensive and unpredictable. We have only recently begun to direct significant effort toward the expansion of our scientific staff and research capabilities to identify and develop product candidates in addition to Canvaxin. We do not know whether our planned preclinical development or clinical trials for these other product candidates will begin on time or be completed on schedule, if at all. In addition, we do not know whether these clinical trials will result in marketable products. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials. We do not anticipate that any of our product candidates will reach the market for at least several years.

We may not identify, develop or commercialize any additional new product candidates from our proprietary specific active immunotherapy, anti-angiogenesis, or T-oligonucleotide technology platforms or

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other technologies. Our ability to develop successfully any of these product candidates depends on our ability to demonstrate safety and efficacy in humans through extensive preclinical testing and clinical trials and to obtain regulatory approval from the FDA and other regulatory authorities. Our development programs for product candidates will also depend upon our ability to fund our research and development operations.

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

Our strategy includes substantial reliance on strategic collaborations for marketing and commercialization of Canvaxin, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other product candidates. To date, we have not entered into any strategic collaborations with third parties capable of providing these services. In addition, we have not yet marketed or sold any of our product candidates in the United States or elsewhere and 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. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators 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

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technical resources and development, production and marketing capabilities than we do. In addition, many of these companies and other institutions have more experience than we do in preclinical testing, human clinical trials and manufacturing of new or improved biological therapeutics, as well as in obtaining FDA and foreign regulatory approvals.

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

We are aware of a number of competitive products currently available in the marketplace or under development for the prevention and treatment of the diseases we have targeted for product development. Products marketed in the United States and elsewhere for melanoma include Chiron Corporation s Proleukin® (IL-2), Schering-Plough Corporation s IntronA® (interferon alpha) and Bayer AG s chemotherapeutic agent dacarbazine. Despite the side effects associated with these chemotherapy and biotherapy products, these products are currently being used in the treatment of patients with melanoma. In addition, Corixa Corporation s Melacine® has been approved in Canada for the treatment of melanoma, however, Corixa recently announced that it is discontinuing the 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 melanoma, including Progenics Pharmaceuticals, Inc. s GMK™, Antigenics, Inc. s Oncophage®, Maxim Pharmaceutical, Inc. s Ceplene™, Celgene, Inc. s Revimid™ and Genta, Inc. s Genasense™, which are all in Phase 3 clinical trials. In November 2003, Maxim announced that it has filed for European approval to market Ceplene, in combination with interleukin-2 for the treatment of advanced malignant melanoma in patients with liver metastases, and in February 2004, Genta announced that the FDA had accepted for priority review a new drug application for Genasense, for use in combination with dacarbazine for the treatment of patients with advanced malignant melanoma. Oncophage, Ceplene, Revimid and Genasense are all being studied in patients with metastatic melanoma, but none of these clinical trials require that patients undergo surgical resection to remove all clinically detectable disease prior to the initiation of their treatment. This is contrasted with patients who are being studied in Canvaxin s Phase 3 clinical trials, who have their tumors and all clinically detectable metastases resected. If we receive approval to market and sell Canvaxin, we may compete with these companies and their products as well as other products in varying stages of development. In addition, researchers are continually learning more about the treatment of melanoma and other forms of cancer, and new discoveries may lead to new technologies for treatment. As a result, Canvaxin, or any other product candidates that we may develop, may be rendered obsolete and noncompetitive.

Various companies are currently marketing or developing biopharmaceutical products that may compete with our product candidates that target colon cancer. Canvaxin and other product candidates we may develop are subject to competition in the treatment of colon cancer from a number of products already approved and on the market, including the following chemotherapy products: AstraZeneca PLC s Tomudex®, Hoffmann-LaRoche Inc. s Xeloda® (capecitabine), Immunex Corporation s Leucovorin® calcium, Pfizer, Inc. s Camptosar® (irinotecan) and Aduracil® (5-FU) and Sanofi-Synthelabo Groupe s Eloxatin™ (oxaliplatin). In February 2004, the FDA approved a BLA for Imclone Systems, Inc. s Erbitux™, a monoclonal antibody directed at the epidermal growth factor receptor, for use in combination with Camptosar® for the treatment of colorectal cancer. In the same month, the FDA also approved a BLA for Genentech, Inc. s Avastin™, a therapeutic antibody designed to inhibit vascular endothelial growth factor, for use in combination with the IFL chemotherapy regimen (5-FU/ Leucovorin/ irinotecan) for the treatment of colorectal cancer. Other product candidates currently in late stages of development for the treatment of colorectal cancer include Antigenics, Inc. s Oncophage™, Aphton Corporation s G-17™, AVI BioPharma, Inc. s Avicine™, GlaxoSmithKline s Eniluracil™, Intracel Corporation s Oncovax™ and Titan Pharmaceuticals Inc. s CeaVac™. We also face competition from a number of companies working in the fields of anti-angiogenesis and specific active immunotherapy for the treatment of other solid tumor cancers, and working to develop technologies similar to the T-oligonucleotides that use internal cellular

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

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

our ability to generate revenues and achieve profitability;

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

the availability of capital.

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

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

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

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

our ability to provide acceptable evidence of safety and efficacy;

convenience and ease of administration;

prevalence and severity of adverse side effects;

availability of alternative treatments;

cost effectiveness;

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

publicity concerning our products or competitive products; and

our ability to obtain third-party coverage or reimbursement.

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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 allergic reactions, 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 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. Developing an effective sales and marketing force will require a significant amount of our financial resources and time. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating demand for Canvaxin or our other product candidates. Although we intend to establish strategic collaborations to market our products outside the United States, if we are unable to establish such collaborations, we may be required to market our product candidates outside of the United States directly. In that event, we may need to build a corresponding international sales and marketing capability with technical expertise and with supporting distribution capabilities.

We currently plan to distribute Canvaxin from our manufacturing facility in pressurized liquid nitrogen storage containers which will require any distribution service we retain to comply with exacting standards and precise specifications in order to preserve Canvaxin in the appropriate form for administration to patients. Although there are several distributors that could potentially meet our requirements for the handling, storage and distribution of 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 strain of BCG that we administer to patients with the first two doses of Canvaxin. Our supply agreement with Organon Teknika had an initial term of one year beginning in April 1998, with automatic renewals for successive one year terms. Under some circumstances, Organon Teknika can terminate the agreement if we fail to purchase BCG for specified periods of time. However, we have purchased BCG recently, which should preserve our agreement with Oganon Teknika for the foreseeable future. The FDA may require that if the manufacturing source of BCG is changed, comparability be demonstrated before patients may be administered BCG from the 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

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

Organon Teknika is also subject to FDA rules and regulations. Therefore, our ability to continue to purchase BCG from Organon Teknika could be significantly delayed or halted completely if Organon Teknika failed to comply with applicable regulatory requirements or if the FDA or another regulatory agency instituted a hold on the manufacture of BCG. In addition, Organon Teknika may supply BCG to a number of significant purchasers and may in the future experience capacity constraints that would cause it to limit the quantity of BCG that we can purchase. Organon Teknika manufactures BCG at a single location. Any interruption or unavailability of this critical adjuvant used with the first two doses of Canvaxin would delay or prevent us from completing our clinical trials and commercializing Canvaxin.

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

We will need to expand and effectively manage our organization, operations and facilities in order to successfully pursue our research, development and commercialization efforts and secure collaborations to market and distribute our products. We increased the number of our full-time employees from 22 as of December 31, 2000 to 151 as of December 31, 2003, and we expect the number of employees to continue to grow to meet our strategic objectives. If we continue to grow, it is possible that our management and scientific personnel, systems and facilities currently in place may not be adequate. Our need to effectively manage our operations, growth and various projects requires that we continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

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

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

exposure to unknown liabilities;

disruption of our business and diversion of our management s time and attention to developing acquired technologies;

increased amortization expenses;

higher than expected acquisition and integration costs;

difficulty and cost in combining the operations and personnel of acquired businesses with our operations and personnel;

impairment of relationships with key suppliers or customers of acquired businesses due to changes in management and ownership;

inability to retain key employees of acquired businesses; and

incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions.

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

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

We have a consulting agreement with our founder, Donald L. Morton, M.D. This agreement expires in December 2004, and Dr. Morton will thereafter be able to develop products that compete with

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

The loss of the services of any principal member of our management and scientific staff, including David F. Hale, our President and Chief Executive Officer, and John Petricciani, M.D., our Senior Vice President, Medical and Regulatory Affairs, could significantly delay or prevent the achievement of our scientific and business objectives. Mr. Hale s employment agreement expires in October 2005, and Dr. Petricciani s employment agreement expires in January 2005. Competition among biotechnology companies for qualified employees is intense, and the ability to retain and attract qualified individuals is critical to our success. For example, it took more than six months to fill executive positions in our research, quality and manufacturing areas. We may be unable to attract and retain key personnel on acceptable terms, if at all. We do not maintain key person life insurance on any of our officers, employees or consultants, including Mr. Hale or Drs. Morton and Petricciani.

We have relationships with scientific advisors at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research, development or clinical strategy. These scientific advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these scientific advisors and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our programs could harm our business. In addition, these advisors may have arrangements with other companies to assist those companies in developing technologies that may compete with our products.

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. 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 an allergic reaction to Canvaxin. Side effects may also be associated with BCG, which we administer to patients with the first two doses of Canvaxin. BCG is also used to prevent tuberculosis and some patients treated with BCG have developed

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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 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 $94.8 million in net losses from our inception through December 31, 2003. To date, we have recognized no revenues and we do not anticipate generating significant revenues for at least several years. We expect to increase our operating expenses over the next several years as we expand the clinical trials for Canvaxin, advance other product candidates into clinical trials, expand our research and development activities, acquire or license new technologies and product candidates and scale up our manufacturing and quality operations. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

If we fail to obtain the capital necessary to fund our operations, we will be unable to develop or commercialize Canvaxin or other product candidates.

We will need to raise additional capital in order to expand the clinical trials for Canvaxin, advance other product candidates into clinical trials and expand our research and development activities. Our ability to scale up our manufacturing and quality operations and respond to competitive pressures could be significantly limited if we are unable to obtain the necessary capital. We do not know whether additional financing will be available when needed, or whether it will be available on favorable terms or at all. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

the expansion of clinical testing for Canvaxin;

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

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

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

the scope, prioritization and number of programs we pursue;

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

the costs of expanding our manufacturing capabilities;

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

our acquisition and development of technologies and product candidates; and

competing technological and market developments.

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

We currently have no source of revenue and may never become profitable.

Our ability to generate revenue depends on a number of factors, including our ability to successfully complete our ongoing Phase 3 clinical trials for Canvaxin and obtain regulatory approvals to commercialize this product candidate. To date, Canvaxin has not generated any revenue, and we do not know when or if any of our product candidates will generate revenue. Even if Canvaxin receives regulatory approvals, we will need to establish and maintain sales, marketing and distribution capabilities. We plan to rely on strategic collaborators to help generate revenues in markets outside of the United States, and, potentially, to co-promote our products in the United States, and we cannot be sure that our collaborations, if any, will be successful. Even if we are able to commercialize Canvaxin, we may not achieve profitability for at least several years after generating material revenue. If we are unable to generate revenue, we may not become profitable, and we may be unable to continue our operations.

Our quarterly operating results and stock price may fluctuate significantly.

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

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

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

whether or not we achieve specified research or commercialization milestones under any agreement that we enter into with collaborators and the timely payment by commercial collaborators of any amounts payable to us;

the addition or termination of research programs or funding support;

the timing of milestone and other payments that we may be required to make to others; and

variations in the level of expenses related to our product candidates or potential product candidates during any given period.

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

Risks Related to Our Intellectual Property and Litigation

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

The patent protection of our product candidates and technology is generally very uncertain and involves complex legal and factual questions. We cannot be certain that any of the patents or patent applications related to our products and technology will provide adequate protection from competing products. Our success will depend, in part, on whether we can:

obtain and maintain patents to protect our product candidates;

obtain and maintain licenses to use certain technologies of third parties, which may be protected by patents;

protect our trade secrets and know-how; and

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

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

In addition, we hold rights to commercialize our anti-angiogenesis product candidates and our rights to additional cell lines for the development of cancer vaccines under agreements that require, among other things, royalty payments on future sales, if any, and our achievement of certain development milestones. We hold rights to three human monoclonal antibodies under a license from M-Tech Therapeutics, which can be terminated if we determine not to file and obtain approval of an IND application for a licensed product by a specified date and conduct clinical trials for such product, or if we determine not to file and obtain approval of an IND application for a licensed product by a specified date because of negative pre-clinical results. We 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.

We are party to a collaboration agreement with Applied Molecular Evolution, Inc., or AME, under which AME utilized their technology to humanize two of our antibodies. AME, which recently completed a merger with Eli Lilly and Company, may terminate the agreement if we fail to make milestone or royalty payments to AME or if we fail to file an IND application for one or more products that incorporate or are derived from one or more of the antibodies that are the subject of the agreement or fail to meet certain other specified commercial development obligations. In the event of such termination, we will be required to grant to AME an exclusive license under all of our patent rights relating to the antibodies that are the subject of this agreement and the products that incorporate or are derived from one or more of the antibodies that are the subject of the agreement. If we were to materially breach any of the agreements discussed above or any of our other license and collaboration agreements, we could lose our ability to commercialize the related technologies, and our business could be materially and adversely affected.

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

we might not have been the first to make the inventions covered by each of our pending patent applications;

we might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that none of our pending patent applications will result in issued patents;

any patents under which we hold rights may not provide us with a basis for commercially-viable products, may not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or unenforceable under United States or foreign laws;

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

we may not develop additional proprietary technologies that are patentable.

Proprietary trade secrets and unpatented know-how are also very important to our research, development and manufacturing activities. However, we cannot be certain that others will not develop the same or similar technologies on their own. Although we have taken steps, including entering into confidentiality and intellectual property disclosure agreements with all of our employees to protect our trade secrets and unpatented know-how and keep them secret, third parties may still obtain this information. In particular, before we obtained commercial development rights to Canvaxin and related technology, development of some of the related technology was carried out at UCLA Medical Center and JWCI over a period of 15 years. While we have agreements with these parties designed to protect our trade secrets and know-how, these agreements may not be sufficient to prevent all parties who have had access to this proprietary information over the years from using this information to compete with us.

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

We know that others have filed patent applications in various countries that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. The pending patent applications may also result in patents being issued. In addition, since patent applications are secret until patents are issued in the United States, or corresponding applications are published in foreign countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that Dr. Morton, from whom we have acquired the patent rights for Canvaxin, was the first to make his inventions or to file patent applications for those inventions. Issued patents are entitled to a rebuttable presumption of validity under the laws of the United States and certain other countries. These issued patents may therefore limit our ability to develop commercial products. If we need licenses to such patents to permit us to develop or market our product candidates, we may be required to pay significant fees or royalties and we cannot be certain that we would be able to obtain such licenses at all.

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

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

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

While we prevailed in the opposition proceeding and the appeal by Boehringer Ingelheim was rejected on procedural grounds, our patents 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 or challenged and declared narrow in scope, invalid or unenforceable.

Legal standards relating to the scope of claims and the validity of patents in the biotechnology field are still evolving, and no assurance can be given as to the degree of protection any patents issued to or licensed to us would provide. The defense and prosecution of intellectual property suits and related legal and administrative proceedings can be both costly and time consuming. Litigation and interference proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. Further, the outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of

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the adverse party. This is especially true in biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. An adverse determination in an interference proceeding or litigation, particularly with respect to Canvaxin, to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. If required, the necessary licenses may not be available on acceptable terms or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from commercializing our product candidates, which could have a material and adverse effect on our business, financial condition and results of operations.

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

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

Our current stockholders hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. A significant portion of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, the holders of approximately 14,481,602 shares of common stock, including shares issued upon the exercise of warrants, will 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 registered all 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. In addition, directors, officers and all persons known to us to hold of record 5% or more of our outstanding shares of common stock prior to our initial public offering have agreed under lock-up agreements, subject to specified exceptions, not to, directly or indirectly, offer, sell or otherwise dispose of any shares of our common stock without the prior written consent of Lehman Brothers Inc. for a period of 180 days from October 29, 2003. 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, in part because our shares have only recently become publicly traded. In addition, the market price of our common stock 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, significant contracts, new technologies, acquisitions, commercial relationships, joint ventures or capital commitments;

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

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.

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We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules proposed by the Securities and Exchange Commission and by the Nasdaq Stock Market, could result in increased costs to us. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

If our officers and directors choose to act together, they may be able to control our management and operations, acting in their best interests and not in the best interests of other stockholders.

As of December 31, 2003, our officers and directors beneficially owned approximately 38.0% of our common stock. As a result, these stockholders, acting together, can significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions include:

dividing our board of directors into three classes serving staggered three-year terms;

prohibiting our stockholders from calling a special meeting of stockholders;

permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;

prohibiting our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and

requiring advance notice for raising matters of business or making nominations at stockholders meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder s acquisition of our stock was approved in advance by our board of directors.

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

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financial results or the way we conduct our business. For example, any changes requiring that we record compensation expense in the statement of operations for employee stock options using the fair value method or changes in existing taxation rules related to stock options could have a significant negative effect on our reported results. Several agencies and entities are considering, and the Financial Accounting Standards Board has announced, proposals to change generally accepted accounting principles in the United States, that, if implemented, would require us to record charges to earnings for employee stock option grants. This pending requirement would negatively impact our earnings. For example, if we accounted for employee stock options under the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation, our net loss would have increased by $1.1 million and $0.5 million for 2003 and 2002, respectively.

Item 2. Properties

We entered into a ten-year lease, which commenced in July 2002, for our corporate headquarters and research and development facility of approximately 60,000 square feet located in Carlsbad, California. 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 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. In 2004 and 2005, we plan to expand our production capabilities in this facility. The capital expenditures associated with this expansion are anticipated to be approximately $16 million, a significant portion of which we intend to fund through new leasehold and equipment financing. We believe that, following the planned expansion, this facility will have sufficient capacity to satisfy potential commercial demand for several years after we launch Canvaxin.

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

On October 9, 2003, our stockholders acted by written consent to approve the following:

a 1-for-4.4 reverse split of our common stock;

our restated certificate of incorporation which, among other things, provided for authorized capital stock of 75,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock;

our amended and restated bylaws;

the classification of our board of directors and the election of our directors to their respective classes;

indemnification agreements to be entered into between us and our directors and executive officers;

our 2003 equity incentive award plan and the reservation of 2,500,000 shares of common stock to be issued upon the exercise of awards granted thereunder; and

our employee stock purchase plan and the reservation of 300,000 shares of common stock to initially be issued thereunder.

Stockholders holding an aggregate of 18,762,365 shares approved each of the above matters and stockholders holding approximately 1,913,009 shares did not vote with respect to such matters.

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PART II

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

Market Information

Our common stock has been traded on the Nasdaq National Market since October 30, 2003 under the symbol CNVX. Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices for our common stock as reported on the Nasdaq National Market for the periods indicated.

	High	Low
Year Ended December 31, 2003		
Fourth Quarter (beginning October 30, 2003)	$13.24	$8.82

As of March 10, 2004, there were approximately 299 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.

Recent Sales of Unregistered Securities

During the year ended December 31, 2003, we issued and sold the following unregistered securities:

In February 2003, we issued a warrant to purchase 150,000 shares of our Vendor preferred stock, Series 1 with an exercise price of $2.45 per share. Upon completion of our initial public offering on November 4, 2003, this warrant became exercisable for 34,091 shares of our common stock with an exercise price of $10.78 per share. The warrant was issued to a collaborator as partial consideration for the collaboration services from this party. This warrant had a fair value of $199,000, using the Black Scholes valuation model. The offer, sale, and issuance of the warrant was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act in that the issuance of the warrant did not involve a public offering. The recipient of the warrant represented its intention to acquire the warrant 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 warrant issued in such transaction. The recipient of the warrant was an accredited person and had adequate access, through employment, business or other relationships, to information about us;

In August 2003, we issued and sold an aggregate of 20,572,789 shares of Series C preferred stock to institutional and accredited investors at a per share price of $2.01 for aggregate consideration of $41.2 million. Upon completion of our initial public offering on November 4, 2003, these shares of Series C preferred stock were converted into 4,675,634 shares of common stock at a conversion price of $8.84 per share. The offer, sale, and issuance of the Series C preferred stock were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The purchasers of securities in such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates issued in such transaction. Each of the recipients of securities in the sale of Series C preferred stock were accredited investors under Rule 501 of Regulation D; and

Between January 1, 2003 and October 29, 2003, we granted options to purchase 919,324 shares of common stock to employees, directors and consultants under our stock incentive plan at exercise prices ranging from $3.30 to $6.60 per share. During such time, 128,037 shares of common stock were purchased pursuant to exercises of stock options and no shares were repurchased and returned

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to the stock incentive plan option pool. The offers, sales, and issuances of the options and common stock were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under such rule. The recipients of such options and common stock were our employees, directors or bona fide consultants and received the securities under our stock incentive plan. Appropriate legends were affixed to the share certificates issued in such transactions. Each of these recipients had adequate access, through employment or other relationships, to information about us.

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 to the underwriters underwriting discounts and commissions 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.

We have used approximately $5.6 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 our specific active immunotherapy product candidate, Canvaxin, and to scale up our manufacturing operations and quality systems. To a lesser extent, we anticipate using the net proceeds from the offering to:

expand our research and development programs;

advance our preclinical anti-angiogenesis, T-oligonucleotide and human monoclonal antibody product candidates into clinical development;

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

fund other working capital and general corporate purposes.

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

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

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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 the consolidated financial statements and related notes appearing elsewhere in this Form 10-K. The Selected Consolidated Quarterly Financial Data presented below has been derived from our unaudited consolidated interim financial statements which, in our opinion, have been prepared on substantially the same basis as the audited consolidated financial statements contained herein and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited quarterly results should be read in conjunction with our audited consolidated financial statements and related notes appearing elsewhere in this Form 10-K. The operating results in any quarter are not necessarily indicative of the results that may be expected for any future period. Amounts are in thousands, except per share amounts.

	Years Ended December 31,				
	2003	2002	2001	2000	1999
Consolidated Statement of Operations Data:					
Operating expenses:					
Research and development	$ 27,725	$ 24,517	$ 13,910	$ 3,495	$ 329
General and administrative	6,826	6,514	5,441	765	
Amortization of employee stock-based compensation(1)	2,643	1,412			
Purchased in-process research and development		2,840			
Total operating expenses	37,194	35,283	19,351	4,260	329
Other income (expense):					
Option fee income				1,000	
Interest income	553	691	909	147	
Interest expense	(932)	(621)	(140)		
Total other income (expense)	(379)	70	769	1,147	
Net loss	(37,573)	(35,213)	(18,582)	(3,113)	(329)
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	$(60,215)	$(42,848)	$(22,687)	$(3,113)	$ (329)
Basic and diluted net loss per share(2)(3)	$ (13.30)	$(153.85)	$(266.02)	$ (0.58)	$ (0.06)
Weighted average shares used to compute basic and diluted net loss per share(2)(3)	4,527	279	85	5,361	5,405

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(1) Amortization of employee stock-based compensation is allocated among operating expense categories as follows for the years ended December 31, 2003 and 2002:

	2003	2002
Research and development	$ 838	$ 379
General and administrative	1,805	1,033
	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 years ended December 31, 2003, 2002 and 2001. 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. Please reference Note 7 to our consolidated financial statements included elsewhere in this Form 10-K for further discussion.

	As of December 31,				
	2003	2002	2001	2000	1999
Consolidated Balance Sheet Data:					
Cash, cash equivalents and securities available-for-sale	$ 107,092	$ 36,201	$ 10,103	$29,194	$ 10
Total assets	127,007	55,187	20,795	32,854	10
Long-term debt, net of current portion	1,811	7,379	3,353	625	
Redeemable convertible preferred stock		96,582	32,455		
Accumulated deficit	(129,192)	(68,977)	(26,129)	(3,442)	(329)
Total stockholders equity (deficit)	112,773	(55,878)	(20,663)	30,651	(319)

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

	Year Ended December 31, 2002			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total operating expenses	$ 10,489	$ 8,316	$ 8,182	$ 8,296
Net loss	(10,525)	(8,204)	(8,113)	(8,371)
Net loss attributable to common stockholders	(11,710)	(10,355)	(10,262)	(10,521)

Basic and diluted net loss per common share	(72.24)	(34.89)	(32.46)	(31.25)

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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. Canvaxin is currently in two Phase 3 clinical trials at 80 sites worldwide for the treatment of advanced-stage melanoma. Canvaxin is based on our proprietary specific active immunotherapy development platform that uses human tumor cell lines that express a broad array of tumor related antigens. Canvaxin has also been studied in a Phase 1/2 clinical trial for advanced-stage colorectal cancer, and we are finalizing the design of a Phase 2 clinical trial for patients with Stage III colon cancer.

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

We were incorporated in Delaware in June 1998 and have incurred net losses since inception. As of December 31, 2003, our accumulated deficit was approximately $129.2 million. We expect to incur substantial and increasing losses for the next several years as we:

- continue the development and prepare for the commercialization of our specific active immunotherapy product candidate, Canvaxin;
- advance our preclinical anti-angiogenesis, human monoclonal antibody and T-oligonucleotide product candidates into clinical development;
- scale up our manufacturing operations and quality systems;
- expand our research and development programs; and
- in-license technology and acquire or invest in businesses, products or technologies that are complementary to our own.

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

We have retained worldwide commercialization rights to Canvaxin and intend to market it through our own sales force or with a co-promotion partner in the United States and through strategic collaborations outside of the United States. Agreements with potential collaborators may include joint marketing or promotion arrangements. Alternatively, we may grant exclusive marketing rights to potential collaborators in exchange for up-front fees, milestones and royalties on future sales, if any. We manufacture Canvaxin at our biologics manufacturing facility located in the Los Angeles, California area. We plan to expand the production capabilities at our biologics manufacturing facility and anticipate capital expenditures of approximately $16 million in 2004 and 2005 associated with this expansion. We intend to fund a significant portion of these capital expenditures through new leasehold and equipment financing. Upon completion of this expansion, we believe our biologics manufacturing facility will have the capacity to satisfy commercial demand for Canvaxin for several years after the initial launch.

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

In January 2002, we completed the acquisition of Cell-Matrix, Inc., a private company focused on developing products and technologies in the field of angiogenesis, in a transaction accounted for as a purchase. In connection with the acquisition of Cell-Matrix, we paid cash of $0.1 million, assumed $2.5 million of notes payable and issued 2.1 million shares of our acquisition preferred stock valued at approximately $5.7 million, which converted into approximately 0.5 million shares of our common stock upon completion of our initial public offering on November 4, 2003. The operating results of Cell-Matrix are included in our results of operations commencing as of the date of acquisition. Upon completing the acquisition, we recorded goodwill of $5.4 million and a charge for purchased in-process research and development of $2.8 million.

Research and Development

Our research and development expenses consist primarily of costs associated with the clinical trials of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, amortization of purchased technology and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on clinical trials of Canvaxin for advanced-stage melanoma, the development of additional indications for Canvaxin and the development of product candidates based on our proprietary specific active immunotherapy, anti-angiogenesis and T-oligonucleotide technology platforms. We are also developing several human monoclonal antibodies that target various solid tumor cancers.

From our inception through December 31, 2003, we incurred costs of approximately $68.0 million associated with the research and development of Canvaxin, representing over 97% of our research and development expenses for all program areas. Included in the costs associated with the research and development of Canvaxin are certain external costs of our Phase 3 clinical trials for Canvaxin, including payments made to clinical sites participating in the trials and payments to third parties for data collection, management and analysis services and clinical trial monitoring services, all of which are recognized as research and development expenses. In 2003, we recognized $4.6 million of these external costs associated with the Canvaxin Phase 3 clinical trials. While difficult to predict, we estimate that we will incur at least an additional $100 million in costs, including internal costs, prior to the commercialization of Canvaxin.

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

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

Product candidate completion dates and completion costs vary significantly for each product candidate and are difficult to estimate. The 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. If we obtain the requisite regulatory approval of Canvaxin, we anticipate launching the product candidate in the United States and Europe in 2006. Our projected launch date for Canvaxin in the United States in 2006 is dependent upon the FDA s acceptance of a positive result in one of our two

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ongoing Phase 3 clinical trials as sufficient for marketing approval. Although the FDA typically requires successful results in two Phase 3 clinical trials to support marketing approval, the FDA has, on several occasions, approved products based on a single Phase 3 clinical trial that demonstrates a high level of statistical significance where there is an unmet need for a life-threatening condition. In the event that the FDA requires the results of a second Phase 3 clinical trial before accepting a marketing application or before granting approval of Canvaxin, the launch of Canvaxin would be delayed. We cannot be certain when any net cash inflows from Canvaxin or any of our other development projects will commence.

We anticipate that the rate of enrollment in our Phase 3 clinical trials for Canvaxin will increase as we add additional clinical trial sites to our program, but we cannot be sure that we will be able to accelerate clinical trial enrollment or enroll an adequate number of patients to complete the Phase 3 clinical trials. In addition, we may not be able to control the amount and timing of resources that the medical institutions that conduct the clinical testing may devote to these Phase 3 clinical trials. If these clinical investigators and medical institutions fail to enroll a sufficient number of patients in our clinical trials, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for Canvaxin. In addition, the interim and final analyses of the data from these clinical trials may not be performed until a specified number of patients in each of these clinical trials has expired, so a delay in enrollment will adversely impact the timely completion of these clinical trials.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis, including those related to valuation of goodwill, intangibles and other long-lived assets. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis 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. We have identified the following as the most critical accounting policies and estimates used in the preparation of our consolidated financial statements.

Goodwill

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

Our goodwill has a carrying value of $5.4 million at December 31, 2003 and resulted from our acquisition of Cell-Matrix in January 2002. We have assigned the goodwill to our Cell-Matrix reporting unit. In October 2003, we performed our annual goodwill impairment test in accordance with

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

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property and equipment and intangible assets subject to amortization, are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the market price of an asset or asset group, a significant adverse change in the extent or manner in which an asset or asset group is being used, a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset or asset group, or the presence of other indicators that would indicate that the carrying amount of an asset or asset group is not recoverable. Determination of recoverability is based on the undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. The determination of the undiscounted cash flows requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete in-process projects, projecting regulatory approvals and estimating future cash inflows from product sales and other sources. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated fair value. There have been no indicators of impairment with respect to our long-lived assets through December 31, 2003.

Results of Operations

The comparisons which follow 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, 2003 and 2002

Research and Development Expenses. Research and development expenses were $27.7 million for the year ended December 31, 2003, compared with $24.5 million for the year ended December 31, 2002. Research and development expenses are associated with our three main research and development programs, our specific active immunotherapy platform, including Canvaxin, our anti-angiogenesis platform and our human monoclonal antibody program. The costs related to the continuing development of Canvaxin constituted the majority of our research and development expenses for the years ended December 31, 2003 and 2002.

The $3.2 million increase in our research and development expenses reflects several factors, including additional investment in personnel in the manufacturing, clinical affairs, 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

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research, analytical and clinical development capabilities. Excluded from research and development expenses for the years ended December 31, 2003 and 2002, was $0.8 million and $0.4 million, respectively, of non-cash employee stock-based compensation which is 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 with $6.5 million for the year ended December 31, 2002. General and administrative expenses consist primarily of salaries and benefits for administrative, finance, business development, human resources, legal and internal systems support personnel. In addition, general and administrative expenses include insurance costs, professional services and facilities costs. The $0.3 million increase was primarily due to a general increase in compensation costs. Excluded from general and administrative expenses for the years ended December 31, 2003 and 2002 was $1.8 million and $1.0 million, respectively, of non-cash employee stock-based compensation which is reported under a separate caption.

Amortization of Employee Stock-based Compensation. In connection with the grant of stock options to employees and directors, we recorded deferred employee stock-based compensation of $5.0 million and $2.7 million for the years ended December 31, 2003 and 2002, respectively, representing the difference between the exercise price and the estimated fair value of the underlying common stock on the option grant date. We recorded the $5.0 million and the $2.7 million as a component of stockholders equity (deficit) and will amortize the amounts, on an accelerated basis, as a non-cash charge to operations 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. The $1.2 million increase is due to the grant of stock options to employees and directors in May through October 2003 that contained exercise prices that were below our revised estimated fair value of our common stock. As of December 31, 2003, we had $3.4 million of deferred employee stock-based compensation. We anticipate recognizing amortization of deferred employee stock-based compensation of approximately $2.0 million, $1.0 million, $0.3 million and $0.1 million in 2004, 2005, 2006 and 2007, respectively.

Purchased In-Process Research and Development. In the first quarter of 2002, we recorded an expense of $2.8 million representing the write-off of the fair value of acquired in-process research and development related to the Cell-Matrix acquisition. The amount expensed represents the estimated fair value of purchased 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 the process of being developed. 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, 2003, 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.

Interest Income. Interest income for the year ended December 31, 2003 was $0.6 million, compared with $0.7 million for the year ended December 31, 2002. The $0.1 million decrease was primarily attributable to lower prevailing interest rates during 2003 as compared to the previous year, partially offset by the effect of an increase in average invested balances 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 with $0.6 million for the year ended December 31, 2002. The $0.3 million increase was primarily due to our increased debt balances that were incurred during the second half of 2002 related to the financing of equipment and leasehold improvements.

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Comparison of the Years Ended December 31, 2002 and 2001

Research and Development Expenses. Research and development expenses were $24.5 million for the year ended December 31, 2002, compared with $13.9 million for the year ended December 31, 2001. Research and development expenses are associated with our three main research and development programs, our specific active immunotherapy platform, including Canvaxin, our anti-angiogenesis platform and our human monoclonal antibody program. The costs related to the continuing development of Canvaxin constituted the majority of our research and development expenses for the years ended December 31, 2002 and 2001.

The $10.6 million increase in our research and development expenses reflects several factors, including higher Canvaxin Phase 3 clinical trial data management costs, new hires in the clinical affairs and research departments, a decline in the amount of grant reimbursement funds and 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. Excluded from research and development expenses for the year ended December 31, 2002 was $0.4 million of non-cash employee stock-based compensation which is reported under a separate caption. There was no employee stock-based compensation recognized in the year ended December 31, 2001.

General and Administrative Expenses. General and administrative expenses were $6.5 million for the year ended December 31, 2002, compared with $5.4 million for the year ended December 31, 2001. The $1.1 million increase in general and administrative expenses primarily reflects $0.4 million of increased legal and accounting fees associated with a discontinued financing and $0.7 million of increased salaries and employee benefit costs resulting from newly hired personnel in our administrative functions to support organizational growth. Excluded from general and administrative expenses for the year ended December 31, 2002 was $1.0 million of employee stock-based compensation which is reported under a separate caption. There was no employee stock-based compensation recognized in the year ended December 31, 2001.

Amortization of Employee Stock-Based Compensation. In connection with the grant of stock options to employees and directors, we recorded deferred employee stock-based compensation of $2.7 million for the year ended December 31, 2002 representing the difference between the exercise price and the estimated fair value of the underlying common stock on the option grant date. The deferred employee stock-based compensation will be amortized, on an accelerated basis, over the vesting period of the options. For the year ended December 31, 2002, amortization of deferred employee stock-based compensation totaled $1.4 million. There was no employee stock-based compensation recognized in the year ended December 31, 2001.

Purchased In-Process Research and Development. In the first quarter of 2002, we recorded an expense of $2.8 million representing the write-off of the fair value of acquired in-process research and development related to the Cell-Matrix acquisition. The amount expensed represents the estimated fair value of purchased 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 the process of being developed. 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.

Interest Income. Interest income was $0.7 million for the year ended December 31, 2002, compared with $0.9 million for the year ended December 31, 2001. The $0.2 million decrease in interest income was primarily attributable to lower prevailing interest rates associated with cash investments.

Interest Expense. Interest expense was $0.6 million for the year ended December 31, 2002, compared with $0.1 million for the year ended December 31, 2001. The $0.5 million increase was primarily due to our increased debt balances that were incurred during the second half of 2002 related to the purchase of equipment and leasehold improvements.

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Liquidity and Capital Resources

As of December 31, 2003, we had $107.1 million in cash, cash equivalents and securities available-for-sale as compared to $36.2 million as of December 31, 2002, an increase of $70.9 million. This increase resulted from the $41.2 million in net proceeds from the sale of our Series C preferred stock in August 2003 and $65.1 million in net proceeds from our initial public offering of common stock on November 4, 2003.

Net cash used in operating activities was $30.9 million in 2003, compared with $28.8 million in 2002. The increase in net cash used in operating activities was primarily due to the increase in our operating expenses as we expanded our research and development activities.

Net cash provided by investing activities was $2.3 million in 2003, compared with cash used in investing activities of $14.4 million in 2002. Significant components of cash flows from investing activities in 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. Significant components of cash flows from investing activities in 2002 included a $10.1 million net increase in our securities available-for-sale portfolio, $4.4 million of purchases of property and equipment and a $0.6 million decrease in restricted cash.

Net cash provided by financing activities was $104.1 million in 2003, compared with $59.1 million in 2002. Significant components of cash flows from financing activities in 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. Significant components of cash flows from financing activities in 2002 included $55.6 million in net proceeds from the sale of our Series B preferred stock in March 2002 and net proceeds from long-term debt of $3.4 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 activities;

the number and scope of our research programs;

the progress of our preclinical development activities;

our ability to establish and maintain strategic collaborations;

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

the costs and timing of regulatory approvals;

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

the success of the commercialization of Canvaxin; and

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

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for the next 18 months.

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, 2003, we had received aggregate net proceeds of approximately $196.6 million from the sale of equity securities. In addition, through December 31, 2003, we had financed through capital leases and loans the purchase of equipment and leasehold improvements totaling approximately $9.3 million, of which $4.8 million remained outstanding under the loans as of December 31, 2003. These obligations are secured by the purchased equipment and leasehold improvements, bear interest at rates ranging from approximately 9.3% to 14.0%

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and are due in monthly installments through June 2006. As of December 31, 2003, no further draws may be made under our credit facilities.

We plan to expand the production capabilities at our biologics manufacturing facility located in the Los Angeles, California area and anticipate capital expenditures of approximately $16 million in 2004 and 2005 associated with this expansion. We intend to fund a significant portion of these capital expenditures through new leasehold and equipment financing.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of offerings of our equity securities and from equipment and leasehold improvement financing. In addition, we may finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements. In addition, we cannot be sure that our existing cash and marketable securities resources will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Contractual Obligations

The following summarizes our long-term contractual obligations as of December 31, 2003 (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	$21,165	$2,309	$4,796	$5,103	$8,957
Contractual license payments	1,277	274	353	150	500
Equipment and tenant improvement notes payable	4,802	3,241	1,395	166	
Notes payable to related parties	2,725	2,725			
Installment obligation due to JWCI	375	125	250		
	$30,344	$8,674	$6,794	$5,419	$9,457

We have two irrevocable standby letters of credit associated with the operating leases for our corporate headquarters and research and development facility and our manufacturing facility. The amount of the letter of credit related to the operating lease for our corporate headquarters and research and development facility is $1.4 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. At December 31, 2003 and 2002, the amounts of the letters of credit totaled $2.0 million and $1.6 million, respectively. To secure the letters of credit, we pledged twelve-month certificates of deposit for similar amounts as of December 31, 2003 and 2002 which have been classified as restricted cash on our consolidated balance sheets. Subsequent to December 31, 2003, the amount of the letter of credit related to the operating lease for our corporate headquarters and research and development facility decreased from $1.4 million to $0.4 million based on our cash position as of December 31, 2003.

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Additionally, we have entered into various licensing and research and development arrangements under which we may be obligated to make future milestone payments upon the achievement of certain success-based objectives and royalties on sales of commercialized products, if any.

Related Party Transactions

For a description of our related party transactions, see Note 4 to our consolidated financial statements.

Off-Balance Sheet Arrangements

Through December 31, 2003, 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.

Recent Accounting Pronouncements

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

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148, which was effective January 1, 2003, is an amendment to SFAS No. 123 providing alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and also provides additional disclosures about the method of accounting for stock-based employee compensation. We have chosen not to adopt the voluntary change to the fair value based method of accounting for stock-based employee compensation. If we were required to adopt such a method, its implementation pursuant to SFAS No. 148 would have a material effect on our consolidated results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

At December 31, 2003 and 2002, 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.

Our long-term debt bears interest at fixed rates and therefore we do not have significant market risk exposure with respect to our debt obligations.

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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

Not applicable.

Item 9A. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the 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 at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

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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, 2003, 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. The following financial statements of CancerVax Corporation and Report of Ernst & Young LLP, independent auditors, are included in this report:

Report of Ernst & Young LLP, Independent Auditors

Consolidated balance sheets as of December 31, 2003 and 2002

Consolidated statements of operations for the years ended December 31, 2003, 2002 and 2001

Consolidated statements of stockholders equity (deficit) for the years ended December 31, 2003, 2002 and 2001

Consolidated statements of cash flows for the years ended December 31, 2003, 2002 and 2001

Notes to consolidated financial statements

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of exhibits required by Item 601 of Regulation S-K. See part (c) below.

(b) *Reports on Form 8-K.* There were no current reports filed on Form 8-K for the quarter ended December 31, 2003.

(c) *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
4.01(1)	Form of Specimen Common Stock Certificate
4.02(1)	Second Amended and Restated Investors Rights Agreement, made as of August 13, 2003, among CancerVax Corporation and the investors listed on Schedule A thereto
4.03(1)	Form of Warrant to Purchase Vendor Preferred Stock, Series 1
4.04(1)	Warrant to Purchase Vendor Preferred Stock, Series 2, dated September 6, 2002, issued to Venture Lending & Leasing III, LLC
4.05(1)	Form of Incidental Registration Rights Agreement
10.01(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(1)#	Third Amended and Restated 2000 Stock Incentive Plan
10.07(1)#	2003 Employee Stock Purchase Plan

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Exhibit Number	Description
10.08#	Employment Agreement, effective as of November 18, 2003, between CancerVax Corporation and Steven J. Ruhl
10.09(1)#	Form of Indemnification Agreement entered into by CancerVax Corporation with its directors and executive officers
10.10(1)#	Employment Agreement, dated October 23, 2000, between CancerVax Corporation and David F. Hale
10.11(1)#	First Amendment to Employment Agreement, dated April 29, 2003, between CancerVax Corporation and David F. Hale
10.12(1)#	Amended and Restated Employment Agreement, dated January 1, 2001, between CancerVax Corporation and Guy Gammon
10.13(1)#	Amended and Restated Employment Agreement, dated January 5, 2001, between CancerVax Corporation and John Petricciani, M.D.
10.14(1)#	Amended and Restated Employment Agreement, entered into as of January 15, 2001, between CancerVax Corporation and Robert L. Jones
10.15(1)#	Amended and Restated Employment Agreement, entered into as of February 9, 2001, between CancerVax Corporation and Hazel M. Aker
10.16(1)#	Amended and Restated Employment Agreement, entered into as of April 2, 2001, between CancerVax Corporation and William R. LaRue
10.17(1)#	Amended and Restated Employment Agreement, entered into as of November 26, 2001, between CancerVax Corporation and Dennis Van Epps
10.18(1)#	Amended and Restated Employment Agreement, entered into as of February 1, 2002, between CancerVax Corporation and Debra J. Arnold
10.19(1)#	Employment Agreement, effective as of May 15, 2003, between CancerVax Corporation and Martin A. Mattingly
10.20(1)#	Consulting Agreement, effective as of December 15, 2000, by and between Dr. Donald L. Morton and CancerVax Corporation
10.21(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
10.22(1)	Cross-License Agreement, dated as of July 24, 1998, by and between CancerVax, Inc. and the John Wayne Cancer Institute
10.23(1)	Agreement, dated as July 31, 2000, by and between Cancer Diagnostic Laboratories, Inc. and CancerVax Corporation
10.24(1)	Amendment No. 1 to CDL Agreement, dated as of December 15, 2000, by and between Cancer Diagnostic Laboratories, Inc. and CancerVax Corporation
10.25(1)	Second Amendment to CDL Agreement, dated as of May 1, 2002, between Cancer Diagnostic Laboratories, Inc. and CancerVax Corporation
10.26(1)	Contribution of Technology and Exchange Agreement, dated as of December 15, 2000, by and between Donald L. Morton, M.D. and CancerVax Corporation
10.27(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
10.28(1)	Fetal Antigen License Agreement, dated as of December 15, 2000, by and between Donald L. Morton, M.D. and CancerVax Corporation
10.29(1)	License Agreement, dated May 23, 2000, by and between the University of Southern California and Bio-Management, Inc.
10.30(1)	License Agreement, dated September 19, 1999, by and between the University of Southern California and Bio-Management, Inc.
10.31(1)	Development and Sublicensing Agreement, effective as of March 5, 2001, by and among EyeTech Pharmaceuticals, Inc. and Cell-Matrix, Inc.

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Exhibit Number	Description
10.32(1)	License Agreement, dated October 26, 2001, by and between The Scripps Research Institute and Cell-Matrix, Inc.
10.33(1)	Collaboration Agreement, dated as of November 29, 1999, between Ixsys, Inc. and Bio-Management, Inc.
10.34(1)	Amendment to Collaboration Agreement, effective as of June 5, 2000, between Cell Matrix, Inc., f/k/a Bio-Management, Inc. and Applied Molecular Evolution, Inc., f/k/a Ixsys, Inc.
10.35(1)	Amendment to Collaboration Agreement, effective as of July 3, 2000, between Cell Matrix, Inc., f/k/a Bio-Management, Inc. and Applied Molecular Evolution, Inc., f/k/a Ixsys, Inc.
10.36(1)	License Agreement, effective as of June 2, 2003, between New York University and Cell-Matrix, Inc.
10.37(1)	License Agreement, entered into as of October 4, 2002, between M-Tech Therapeutics, Inc. and CancerVax Corporation
10.38(1)	Assignment of Supply Agreement, entered into as of July 31, 2000, between 3DLM, Inc., f/k/a CancerVax, Inc., and CancerVax Corporation
10.39(1)	Supply Agreement, entered into as of April 15, 1998, between CancerVax, Inc. and Organon Teknika Corporation
10.40(1)	Loan and Security Agreement (Equipment), dated as of September 6, 2002, between CancerVax Corporation and Venture Lending & Leasing III, Inc.
10.41(1)	Third Amended and Restated Stockholders Agreement, dated as of August 13, 2003, by and among CancerVax Corporation, The Donald L. Morton Family Trust created under trust dated June 2, 1989, the Donald L. Morton, M.D., Grantor Retained Annuity Trust dated September 6, 2002, OncoVac, Inc., the investors listed on Exhibit A thereto and John Wayne Cancer Institute
10.42(1)	Master Services Agreement, entered into as of January 22, 2002, among CancerVax Corporation, the John Wayne Cancer Institute and Synteract, Inc.
10.43(1)	Letter Agreement, entered into as of January 22, 2002, between the John Wayne Cancer Institute and CancerVax Corporation
10.44(1)#	2003 Equity Incentive Award Plan
10.45(3)+	Sublicense Agreement, dated as of March 10, 2004, by and among SemaCo, Inc., Barbara Gilchrest, M.D. and CancerVax Corporation
21.01	List of Subsidiaries
23.01	Consent of Ernst & Young LLP, Independent Auditors
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 March 15, 2004.

# Indicates management contract or compensatory plan.

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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 29, 2004

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 29, 2004
/s/ WILLIAM R. LARUE William R. LaRue	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 29, 2004
/s/ IVOR ROYSTON Ivor Royston	Director *(Chairman of the Board of Directors)*	March 29, 2004
/s/ MICHAEL G. CARTER Michael G. Carter	Director	March 29, 2004
/s/ CAM L. GARNER Cam L. Garner	Director	March 29, 2004
/s/ CLAYBURN LA FORCE, JR. Clayburn La Force, Jr.	Director	March 29, 2004
/s/ DONALD L. MORTON Donald L. Morton	Director	March 29, 2004
/s/ BARCLAY A. PHILLIPS Barclay A. Phillips	Director	March 29, 2004
/s/ PHILLIP M. SCHNEIDER	Director	March 29, 2004

Phillip M. Schneider		
/s/ GAIL S. SCHOETTLER	Director	March 29, 2004
Gail S. Schoettler		

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CANCERVAX CORPORATION

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

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, 2003 and 2002 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, 2003. 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 auditing standards generally accepted in the 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, 2003 and 2002 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

San Diego, California
February 13, 2004
except for Note 10 as to which the date is
March 15, 2004

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CANCERVAX CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except par value amounts)

	December 31,	
	2003	**2002**
Assets		
Current assets:		
Cash and cash equivalents	$ 101,681	$ 26,083
Securities available-for-sale	5,411	10,118
Restricted cash	1,000	
Other current assets	917	133
Total current assets	109,009	36,334
Property and equipment, net	10,529	10,845
Goodwill	5,381	5,381
Intangibles, net	519	588
Restricted cash	1,000	1,550
Other assets	569	489
Total assets	$ 127,007	$ 55,187
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable and accrued liabilities	$ 5,650	$ 3,908
Current portion of long-term debt	6,091	2,960
Total current liabilities	11,741	6,868
Long-term debt, net of current portion	1,811	7,379
Deferred rent	682	236
Commitments		
Redeemable convertible preferred stock, $.00004 par value; no shares authorized at December 31, 2003; no shares and 35,155 shares issued and outstanding at December 31, 2003 and 2002, respectively		96,582
Stockholders equity (deficit):		
Convertible preferred stock, $.00004 par value; no shares authorized at December 31, 2003; no shares and 27,189 shares issued and outstanding at December 31, 2003 and 2002, respectively		1
Common stock, $.00004 par value; 75,000 shares authorized at December 31, 2003; 26,736 and 496 shares issued and outstanding at December 31, 2003 and 2002, respectively	1	
Additional paid-in capital	245,314	14,409
Accumulated other comprehensive income (loss)	3	(43)
Deferred compensation	(3,353)	(1,268)
Accumulated deficit	(129,192)	(68,977)
Total stockholders equity (deficit)	112,773	(55,878)
Total liabilities and stockholders equity (deficit)	$ 127,007	$ 55,187

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,		
	2003	2002	2001
Operating expenses:			
Research and development	$ 27,725	$ 24,517	$ 13,910
General and administrative	6,826	6,514	5,441
Amortization of employee stock-based compensation	2,643	1,412	
Purchased in-process research and development		2,840	
Total operating expenses	37,194	35,283	19,351
Other income (expense):			
Interest income	553	691	909
Interest expense	(932)	(621)	(140)
Total other income (expense)	(379)	70	769
Net loss	(37,573)	(35,213)	(18,582)
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	$(60,215)	$(42,848)	$(22,687)
Basic and diluted net loss per share(1)	$ (13.30)	$(153.85)	$(266.02)
Weighted averaged shares used to compute basic and diluted net loss per share(1)	4,527	279	85
The allocation of employee stock-based compensation is as follows:			
Research and development	$ 838	$ 379	$
General and administrative	1,805	1,033	
	$ 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, 2000	26,690	$ 1		$	$ 5,009	$	$	$ (3,442)	$ 1,568
Exercise of stock options			358		401				401
Conversion of Series A convertible preferred stock to Series A redeemable convertible preferred stock	(1,644)				(1)				(1)
Compensation expense from issuance of stock options to consultants					47				47
Issuance of warrants in conjunction with debt					10				10
Accretion to redemption value of redeemable convertible preferred stock								(4,105)	(4,105)
Net loss and comprehensive loss								(18,582)	(18,582)
Balance at December 31, 2001	25,046	1	358		5,466			(26,129)	(20,662)
Exercise of stock options			146		199				199
Deferred employee stock-based compensation					2,740		(2,740)		
Unamortized deferred compensation on cancelled stock options					(60)		60		
Amortization of deferred employee stock-based compensation							1,412		1,412
Repurchase of stock			(8)		(17)				(17)
Compensation expense from issuance of stock options to consultants					41				41
Issuance of warrants in conjunction with debt and facility lease					319				319
Issuance of 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)
Exercise of stock options and warrants			133		263				263
Deferred employee stock-based compensation					4,999		(4,999)		

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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					
Unamortized deferred compensation on cancelled stock options					(271)		271		
Amortization of deferred employee stock-based compensation							2,643		2,643
Compensation expense from 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)	
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

See accompanying notes to consolidated financial statements.

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CANCERVAX CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,		
	2003	**2002**	**2001**
Cash flows from operating activities:			
Net loss	$ (37,573)	$ (35,213)	$ (18,582)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred employee stock-based compensation	2,643	1,412	
Stock compensation from the issuance of stock options and warrants to third parties	177	41	47
Non-cash interest expense from warrants issued with debt	93	46	10
Amortization of premium on securities available-for-sale	170	56	
Interest receivable on securities available-for-sale	46	(150)	
Depreciation	1,891	1,443	651
Amortization of intangibles	252	209	187
Purchased in-process research and development		2,840	
Deferred rent	446	80	64
Changes in operating assets and liabilities:			
Other assets	(759)	(51)	(188)
Accounts payable and accrued liabilities	1,742	500	2,047
Net cash used in operating activities	(30,872)	(28,787)	(15,764)
Cash flows from investing activities:			
Cash paid in Cell-Matrix acquisition		(222)	
Purchases of property and equipment	(1,575)	(4,421)	(5,956)
Purchases of securities available-for-sale	(2,942)	(10,567)	
Maturities of securities available-for-sale	1,998		
Sale of securities available-for-sale	5,481	500	
Increase in intangibles	(183)	(234)	
(Increase) decrease in restricted cash	(450)	578	(1,778)
Stockholder note receivable			166
Net cash provided by (used in) investing activities	2,329	(14,366)	(7,568)
Cash flows from financing activities:			
Proceeds from long-term debt	462	4,901	4,000
Payments on long-term debt	(2,900)	(1,541)	(326)
Proceeds from exercise of stock options, net	263	182	401
Proceeds from stock subscription receivable			166
Proceeds from issuance of common stock, net	65,139		
Proceeds from issuance of preferred stock, net	41,177	55,591	
Net cash provided by financing activities	104,141	59,133	4,241
Increase (decrease) in cash and cash equivalents	75,598	15,980	(19,091)
Cash and cash equivalents at beginning of year	26,083	10,103	29,194
Cash and cash equivalents at end of year	$ 101,681	$ 26,083	$ 10,103

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	Years Ended December 31,		
	2003	2002	2001
Supplemental cash flow information:			
Cash paid during the year for interest	$ 750	$ 416	$ 102
Supplemental schedule of non-cash investing and financing activities:			
Series A redeemable convertible preferred stock issuable	$	$ 900	$
Acquisitions (cancellations) of equipment purchased through capital leases	$	$ (60)	$ 116
Value of stock issued in Cell-Matrix acquisition	$	$5,721	$
Unrealized gain (loss) on available-for-sale securities	$ 46	$ (43)	$
Issuance of warrants in connection with debt, facility lease and research consulting agreement	$ 245	$ 296	$
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	$	$
Conversion of preferred stock into common stock	$145,624	$	$

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 are focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. We had no operations in 1998.

Our lead product candidate, Canvaxin, is in two worldwide Phase 3 clinical trials for the treatment of advanced-stage melanoma. In addition, we are developing a pipeline of products based upon our proprietary specific active immunotherapy, anti-angiogenesis and T-oligonucleotide technology platforms as well as monoclonal human antibodies. Our biologics manufacturing facility produces Canvaxin for use in clinical trials and, if Canvaxin is approved, the facility will be used to produce commercial quantities of Canvaxin. We also have research collaborations with both private and academic institutions.

Principles of Consolidation

The accompanying consolidated financial statements include our accounts and those of our wholly owned subsidiary, Cell-Matrix, Inc. 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 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 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, 2003 and 2002 totaled $101.5 million and $25.8 million, respectively, and consist of money market accounts.

Securities Available-for-Sale

We consider investments with an original maturity of more than three months 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 (deficit). The cost of available-for-sale securities sold is 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 accounts payable and accrued liabilities are considered to be representative of their respective fair values due to their short-term nature. Based on the borrowing rates currently available to us for loans with similar terms, we believe the fair value of the long-term debt approximates its carrying value.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Concentration of Credit 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 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.

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.

Goodwill

We have goodwill with a carrying value of $5.4 million at December 31, 2003 and 2002, respectively, which resulted from our acquisition of Cell-Matrix in January 2002. We have assigned the goodwill to our Cell-Matrix reporting unit. In accordance with Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, we do not amortize goodwill. Instead, we review goodwill for impairment at least annually and 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 October 2003, we performed our annual goodwill impairment test in accordance with SFAS No. 142 and determined that goodwill was not impaired.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets to be held and used, including property and equipment and intangible assets subject to amortization, are reviewed for impairment at least annually and 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. There have been no indicators of impairment with respect to our long-lived assets through December 31, 2003.

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, amortization of purchased technology and depreciation. Expenditures relating to research and development are expensed as incurred.

Stock-Based Compensation

We account for our employee stock option grants under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Accordingly, stock-

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. The deferred stock-based compensation is recognized and amortized on an accelerated basis in accordance with FASB Interpretation 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 2003 and 2002, we recognized stock-based compensation expense related to employee stock option grants of $2.6 million and $1.4 million, respectively.

The following table illustrates the effect on net loss and loss per share for the years ended December 31, 2003, 2002 and 2001 if we had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-based Compensation*, as amended, to stock-based employee compensation. For purposes of the pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period of the related options using the accelerated method.

	Years Ended December 31,		
	2003	2002	2001
	(In thousands, except per share amounts)		
Net loss applicable to common stockholders, as reported	$(60,215)	$(42,848)	$(22,687)
Add: Stock-based employee compensation expense included in net loss applicable to common stockholders, as reported	2,643	1,412	
Deduct: Stock-based employee compensation expense determined under the fair value based method for all awards	(3,763)	(1,939)	(278)
Pro forma net loss applicable to common stockholders	$(61,335)	$(43,375)	$(22,965)
Loss per share:			
Basic and diluted net loss per share, as reported	$ (13.30)	$(153.85)	$(266.02)
Pro forma basic and diluted net loss per share	$ (13.55)	$(155.74)	$(269.28)

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:

	Years Ended December 31,		
	2003	2002	2001
Dividend yield	0%	0%	0%
Expected volatility	70%	70%	70%
Risk-free interest rate	2.63%	3.81%	4.55%
Expected life in years	4.85	4.97	4.95
Per share grant date fair value:			
Exercise prices below fair value	$7.14	$8.58	
Exercise prices equal to fair value	$6.29	$1.77	$0.91

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net loss are estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 options.

In addition to employee stock option grants, we have granted options to non-employees which we account for in accordance with SFAS No. 123 and Emerging Issues Task Force, or 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, stock options granted to non-employees are periodically revalued as the options vest and are recognized to expense over the related service period. In 2003, 2002 and 2001, we granted stock options to purchase 5,341, 1,136 and 12,386 shares, respectively, of our common stock to non-employees and recognized related expense of $130,557, $40,685 and $46,845, respectively. The fair value of the options granted to non-employees was determined using the following weighted-average assumptions:

	Years Ended December 31,		
	2003	**2002**	**2001**
Dividend yield	0%	0%	0%
Expected volatility	70%	70%	70%
Risk-free interest rate	3.69%	4.50%	5.01%
Expected life in years	8.05	8.76	9.51

Net Loss Per Share

We calculate net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share is calculated by dividing net loss by the weighted average number of common shares outstanding for the period, reduced by the weighted average unvested common shares subject to repurchase, without consideration for common stock equivalents. Diluted earnings per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, reduced by the weighted average unvested common shares subject to repurchase and increased to include the potential dilutive effect of our common stock equivalents, if any, determined using the treasury-stock method.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The actual net loss per share amounts for the year ended December 31, 2003 were computed based on the shares of common stock outstanding during the year, including 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, 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 included. The shares used to compute unaudited pro forma basic and diluted net loss per share represent the weighted average common shares outstanding for the period, reduced by the weighted average unvested common shares subject to repurchase, and including the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as-if converted method as of the beginning of each year presented or the date of issuance, if later.

	Years Ended December 31,		
	2003	2002	2001
	(In thousands, except per share amounts)		
Actual:			
Numerator:			
Net loss, as reported	$(37,573)	$(35,213)	$(18,582)
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, as reported	$(60,215)	$(42,848)	$(22,687)
Denominator:			
Weighted average common shares outstanding	4,643	469	227
Weighted average unvested common shares subject to repurchase	(116)	(190)	(142)
Weighted average common shares used to calculate basic and diluted loss per share	4,527	279	85
Basic and diluted net loss per share	$ (13.30)	$(153.85)	$(266.02)

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Years Ended December 31,		
	2003	2002	2001
	(In thousands, except per share amounts)		
Pro forma:			
Numerator:			
Net loss, as reported	$(37,573)	$(35,213)	$(18,582)
Deemed dividend resulting from beneficial conversion feature on Series C preferred stock	(14,775)		
Pro forma net loss applicable to common stockholders	$(52,348)	$(35,213)	$(18,582)
Denominator:			
Weighted average common shares used to calculate basic and diluted loss per share	4,527	279	85
Pro forma adjustments to reflect weighted average effect of assumed conversion of preferred stock	14,098	13,132	8,849
Weighted average shares used to compute pro forma basic and diluted net loss per share	18,625	13,411	8,934
Pro forma basic and diluted net loss per share	$ (2.81)	$ (2.63)	$ (2.08)

The following securities, representing the historical amounts and not the common stock equivalent amounts, were excluded from the calculation of diluted loss per share as their effect would be antidilutive (in thousands):

	Years Ended December 31,		
	2003	2002	2001
Preferred stock		62,344	38,935
Common stock subject to repurchase	91	150	207
Options to purchase common stock	2,032	1,058	738
Warrants to purchase preferred stock	377	292	65
	2,500	63,844	39,945

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.

Reclassifications

Certain prior year expenses have been reclassified to conform to the current year presentation.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Effect of New Accounting Standards

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

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. SFAS No. 148, which was effective January 1, 2003, is an amendment to SFAS No. 123 providing alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and also provides additional disclosures about the method of accounting for stock-based employee compensation. We have chosen not to adopt the voluntary change to the fair value based method of accounting for stock-based employee compensation. If we were required to adopt such a method, its implementation pursuant to SFAS No. 148 would have a material effect on our consolidated results of operations.

2. Cell-Matrix Acquisition

On January 17, 2002, we acquired all of the outstanding common shares of Cell-Matrix 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):

Issuance of 2,142,853 shares of Acquisition preferred stock	$5,721
Cash paid at acquisition	118
Acquisition related costs	104
Assumed contractual obligations due to related parties	2,500
	$8,443

The 2,142,853 shares of Acquisition preferred stock issued to acquire Cell-Matrix converted into approximately 487,000 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.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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, 2003, 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 from the acquisition is not expected to be deductible for tax purposes.

The accompanying consolidated statements of operations for 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

All available-for-sale debt securities have contractual maturities of 12 months or less as of December 31, 2003. Securities available-for-sale consists of the following (in thousands):

	December 31, 2003				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government securities	$5,011	$101	$ 2	$	$5,114
Corporate debt securities	293	3	1		297
	$5,304	$104	$ 3	$	$5,411

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	December 31, 2002				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government securities	$ 7,153	$109	$	$(33)	$ 7,229
Corporate debt securities	2,858	41		(10)	2,889
	$10,011	$150	$	$(43)	$10,118

Property and Equipment

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

	December 31,	
	2003	2002
Leasehold improvements	$ 6,450	$ 6,383
Manufacturing and lab equipment	5,265	4,365
Office equipment and furniture	1,519	1,375
Computer equipment	1,053	817
Construction in progress	226	
	14,513	12,940
Less accumulated depreciation and amortization	(3,984)	(2,095)
	$10,529	$10,845

Intangibles

Intangibles consists of the following (in thousands):

	December 31, 2003		December 31, 2002	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Cell lines and licensed technology rights (Note 4)	$ 750	$563	$750	$375
Patents and patent applications	417	85	234	21
	$1,167	$648	$984	$396

We are amortizing our acquired cell lines and licenses to patent rights and related technology intangible asset on a straight-line basis over four years. We are capitalizing the costs associated with the preparation, filing and maintenance of the patents and patent applications related to our specific active immunotherapy platform technology and amortize these costs on a straight-line basis over 14 years, which represents the expected life of the patents and patent applications. Our intangible assets are reviewed for impairment in accordance with our policy regarding impairment of long-lived assets.

Restricted Cash

Restricted cash relates to two irrevocable standby letters of credit we entered into in connection with the operating leases for our corporate headquarters and research and development facility and our manufacturing facility. The amount of the letter of credit related to the operating lease for our corporate headquarters and research and development facility is $1.4 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for our manufacturing facility is $0.6 million, decreasing through the end of the lease term. At December 31, 2003 and 2002, the amounts of the letters of credit totaled $2.0 million and $1.6 million, respectively. To secure the letters of credit, we pledged twelve-month certificates of deposit for similar amounts as of December 31, 2003 and 2002 which have been classified as restricted cash. Subsequent to December 31, 2003, the amount of the letter of credit related to the operating lease for our corporate headquarters and research and development facility decreased from $1.4 million to $0.4 million based on our cash position as of December 31, 2003.

Accounts Payable and Accrued Liabilities

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

	December 31,	
	2003	2002
Accounts payable	$2,445	$2,238
Accrued employee benefits	1,844	961
Accrued clinical trial patient costs	591	194
Other accrued liabilities	770	515
	$5,650	$3,908

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.

In July 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, $375,000 remains unpaid as of December 31, 2003 (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. In accordance with Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 48, *Transfer of Nonmonetary Assets by Promoters or Shareholders,* JWCI, Dr. Morton and entities owned by Dr. Morton are considered to be founders or promoters and therefore no value has been ascribed to the technology acquired by us upon our formation in 1998, the assignment of the cross-license agreement to us during 2000 or the 284,090 shares issued to JWCI as the carrying value of the assets acquired was zero. Additionally, the $1,250,000 due to JWCI was recorded as research and development expense in 2000 as ultimate commercialization of Canvaxin was uncertain and the technology had no alternative uses.

In July 2000, we entered into three agreements with OncoVac, whereby we issued 408,163 shares of Series A preferred stock in December 2000, for the assignment of the cross license agreement with JWCI, the assignment of a supply agreement with Organon Teknika Corporation and a trademark assignment. In

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

accordance with SAB No. 48, no value was assigned to the assets acquired or the shares of Series A preferred stock issued because the carrying value of the assets acquired was zero.

In July 2000, we entered into an agreement with Cancer Diagnostics Laboratories, Inc., or CDL, which is also controlled by Dr. Morton, under which we obtained 20 cell lines and licenses to patent rights and related technology in exchange for $750,000. We capitalized the acquired cell lines, patents and technology as an intangible asset because we intend to use this acquired technology in research and development related to new biological product candidates for the treatment of cancer (Note 3). We also assumed CDL s obligation to the party from whom CDL originally acquired the cell lines to pay a royalty of up to 2% of net sales of any products that include the cell lines that we acquired.

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

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

In July 2001, we entered into a clinical trial services agreement with JWCI, under which we agreed to reimburse JWCI for all approved payments to clinical trial study sites which were not covered by National Cancer Institute, or NCI, 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 NCI grants and $50,000 per year thereafter, or such greater amounts incurred by JWCI in connection with the Phase 3 clinical trials. In July 2002, the service agreement was amended, pursuant to which we became obligated to directly reimburse the clinical trial study sites, instead of reimbursing JWCI, for all approved payments which are not covered by NCI grants. JWCI remains obligated to reimburse the clinical trial study sites for all approved payments for which NCI grants are available. We are responsible for compliance with the payment terms of the agreements with the various clinical trial study sites regardless of the amount of NCI grant funds available. Reimbursements to JWCI by us under the service agreement amounted to $0.1 million, $0.2 million and $0.4 million for the years ended December 31, 2003, 2002 and 2001, respectively. Reimbursements to the clinical trial study sites by JWCI under the service agreement amounted to $0.2 million, $0.5 million and $1.6 million for the years ended December 31, 2003, 2002 and 2001, respectively. Included in accounts payable and accrued liabilities as of December 31, 2003 is $0.1 million for current approved payments owed to the clinical trial study sites of which $19,000 will be reimbursed by JWCI.

For the years ended December 31, 2003, 2002 and 2001, we also paid to JWCI $0.4 million, $0.3 million and $0.6 million, respectively, as reimbursement for rent, assays, employee salaries and equipment purchases as well as payments on our installation obligation to JWCI and recorded such amounts as operating expenses, property and equipment, or as a reduction of our installment obligation, as appropriate. Included in accounts payable and accrued liabilities as of December 31, 2003, 2002 and 2001

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

is $21,000, $0.1 million and $0.2 million, respectively, representing amounts owed to JWCI for reimbursements.

5. Debt

Debt consists of the following (in thousands):

	December 31,	
	2003	**2002**
Equipment and tenant improvement notes payable	$ 4,802	$ 7,216
Notes payable to related parties (Note 2)	2,725	2,616
Installment obligations due to JWCI (Note 4)	375	500
Capital lease obligations		7
	7,902	10,339
Current portion of debt	(6,091)	(2,960)
Long-term debt, less current portion	$ 1,811	$ 7,379

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 make 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 more fully in Note 7.

During 2002, we entered into a $6.0 million loan and security agreement with a financing institution to finance eligible equipment and tenant improvements. As of December 31, 2003 and 2002, outstanding borrowings under the credit facility were $5.1 million and $4.9 million, respectively. As the credit facility was utilized, separate promissory notes were executed. Each promissory note has payments ranging from 30 to 38 months with the interest rate being fixed at the funding date of each promissory note (13.69% to 14.04%). Each promissory note is collateralized by the related equipment or tenant improvements. As of September 30, 2003, no further draws may be made under the credit facility. We issued warrants in connection with this loan as discussed more fully in Note 7.

As of December 31, 2003, annual principal payments due on our equipment and tenant improvement notes payable are $3.2 million in 2004, $1.4 million in 2005 and $0.2 million in 2006.

6. Commitments

Leases

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. For financial reporting 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 in accompanying consolidated balance sheets. Rent expense was $3.0 million, $2.1 million and $1.0 million for the years ended December 31, 2003, 2002 and 2001, respectively. We issued warrants in connection with the lease agreement for our corporate headquarters and research and development facility as

discussed more fully in Note 7.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Licensing and Research Agreements

We have license agreements with the University of Southern California, or USC, and with The Scripps Research Institute for certain anti-angiogenesis technology which we assumed in the Cell-Matrix acquisition. In consideration for the technology licenses granted under these agreements, up-front license fees were paid to USC and Scripps by Cell-Matrix and we are obligated to pay USC and Scripps royalties on future net sales of products relating to these licenses, subject to a minimum annual royalty payment commencing on the third anniversary of the agreements. In addition, we are obligated to pay Scripps milestone payments based on meeting certain regulatory and clinical milestones. Since we assumed these agreements through December 31, 2003, we have incurred a total of $25,000 under the USC agreements, which has been recorded as research and development expense, and no amounts under the Scripps agreement. The USC 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. The Scripps 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.

In October 2002, we acquired the exclusive worldwide commercialization rights from M-Tech Therapeutics to three human monoclonal antibodies that appear to target tumor-associated antigens that are expressed in a variety of solid tumor cancers. Pursuant to the licensing arrangement, we paid M-Tech upfront payments and are obligated to pay future license fees, milestone payments based on meeting certain regulatory and clinical milestones and royalties. Through December 31, 2003, we have incurred a total of $0.3 million under the agreement, which has been recognized as research and development expense. 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. M-Tech may terminate, on an individual basis, the licenses granted under the agreement to the three human monoclonal antibodies if we determine not to file and obtain approval of an Investigational New Drug, or IND, application for a licensed product by a specified date and conduct clinical trials for such product, or if we determine not to file an IND application for a licensed product by a specified date because of negative preclinical results. In either event, we would be subject to specified termination fees.

In June 2003, we licensed from New York University, or NYU, the exclusive worldwide commercial rights to several peptides related to angiogenesis. Pursuant to the licensing arrangement, we made an upfront payment to NYU and are obligated to pay future anniversary payments, milestone payments 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, 2003, we have incurred a total of $0.1 million under the agreement, which has been recognized as research and development expense. 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.

Additionally, we have entered into various licensing and research and development arrangements under which we may be obligated to make future milestone payments upon the achievement of certain success-based objectives and royalties on sales of commercialized products, if any.

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In connection with our research and licensing agreements, we recognized research and development expenses of $0.2 million and $0.3 million, respectively, in 2003 and 2002. No amounts were recognized in 2001.

Annual future minimum payments under our commitments are as follows at December 31, 2003 (in thousands):

	Operating Leases	Licensing and Research Agreements
2004	$ 2,309	$ 274
2005	2,373	278
2006	2,423	75
2007	2,505	75
2008	2,598	75
Thereafter	8,957	500
	$21,165	$1,277

Guarantees

In November 2002, the FASB issued FASB Interpretation, or FIN, No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.* FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002.

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, 2003.

7. Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)

Reverse Stock Split

On October 9, 2003, our stockholders approved a 1-for-4.4 reverse stock split of the then-outstanding common stock, effective upon completion of our initial public offering. The accompanying consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

Initial Public Offering

On November 4, 2003, we completed an initial public offering, or IPO, of 6.0 million shares of common stock for proceeds of $65.1 million, net of underwriting discounts and offering expenses.

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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. The following lists the preferred shares issued since our inception. Upon completion of the IPO, all outstanding shares of our preferred stock automatically converted into an aggregate of 20.1 million shares of common stock.

In 2003, we issued 20.6 million shares of Series C redeemable convertible preferred stock as discussed further below.

In 2002, we issued 0.4 million shares of Series A redeemable convertible preferred stock and 20.9 million shares of Series B redeemable convertible preferred stock. Additionally, we issued 2.1 million shares of Acquisition preferred stock in the Cell-Matrix acquisition as previously discussed in Note 2.

In 2001, ownership in 1.6 million shares of the Series A convertible preferred stock previously held by Dr. Morton were transferred to third parties and accordingly we reclassified these shares to Series A redeemable convertible preferred stock.

In 2000, we effected a reorganization and our outstanding common stock was exchanged for 26.3 million shares of Junior preferred stock. Additionally, we issued and sold 12.2 million shares of Series A redeemable convertible preferred stock for cash. In connection with this financing, we issued 0.4 million shares of Series A convertible preferred stock to an entity controlled by Dr. Morton in exchange for technology. We also exchanged 3.7 million shares of Dr. Morton s Junior preferred stock for 3.7 million shares of Series A convertible preferred stock pursuant to the terms of a contribution of technology and exchange agreement.

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 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 (deficit). Because we did not close a public offering of our common stock prior to June 30, 2003 and as a result of the issuance of the Series C redeemable convertible preferred stock, the Series A and Series B redeemable convertible preferred stock per share conversion prices were automatically adjusted. In accordance with EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, the conversion price adjustments did not have an impact on the financial statements because the revised conversion price was not less than the estimated fair value of the underlying security on the date of issuance.

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, after giving effect to the 1-for-4.4 reverse stock split, is $8.84 per share. Because this conversion price is 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 is 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 on an if-converted basis multiplied by the difference between the initial public

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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 (deficit).

Warrants

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. Using the Black-Scholes option pricing model, we determined that the fair value of the warrants was $0.1 million which we are recording as interest expense over the term of the related notes payable.

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 (iii) net issuance exercise based on the fair market value of our common stock on the date of exercise. Using the Black-Scholes option pricing model, we determined that the fair value of the warrant was $0.1 million which we are recording as rent expense over the term of the lease.

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. Using the Black-Scholes option pricing model, we determined that the fair value of the warrant was $0.2 million which we are recording as interest expense over the term of the notes payable.

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. Using the Black-Scholes option pricing model, we determined that the fair value of the warrant was $0.2 million which we are recording as research and development expense over the term of the consulting agreement.

The fair value of the warrants was determined using the Black-Scholes option pricing model using the following assumptions:

	Years Ended December 31,		
	2003	2002	2001
Dividend yield	0%	0%	0%
Expected volatility	70%	70%	70%
Risk-free interest rate	3.45%	2.42-4.71%	4.55-5%
Expected life in years	7	7-10	7

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Equity Compensation Plans

We have three equity compensation plans for our employees, nonemployee directors and consultants: the 2000 Stock Incentive Plan, as amended, or the 2000 Amended Plan, the 2003 Equity Incentive Award Plan, or the 2003 Plan, and the Employee Stock Purchase Plan, or the Purchase Plan. All three equity compensation plans have been approved by our stockholders. The 2000 Amended Plan allows for the grant of incentive and nonstatutory stock options to purchase up to 2.5 million shares of our common stock to employees, directors, and third parties. Options granted under the 2000 Amended Plan generally expire no later than ten years from the date of grant and vest over a period of four years. The 2000 Amended Plan allows 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, 2003, 2002 and 2001, 91,403, 149,544 and 207,378 shares, respectively, of common stock were subject to repurchase. At December 31, 2003, options to purchase 7,995 shares of our common stock remain available for grant under the 2000 Amended Plan.

The 2003 Plan allows for the grant of equity awards to purchase up to 2.5 million shares of our common stock. Under the 2003 Plan, potential types of awards 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 the Board of Directors although generally awards 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. To date, only stock options have been granted under the 2003 Plan. At December 31, 2003, awards to purchase 2.3 million shares of our common stock remain available for grant under the 2003 Plan.

The Purchase Plan allows for the issuance of up to 0.3 million shares of our common stock. Under the terms of the Purchase Plan, employees can elect to have up to twenty percent of their annual compensation withheld to purchase shares of our common stock. The purchase price of the common stock is equal to 85 percent of the lower of the fair market value per share of the common stock on the enrollment date or the date on which the shares are purchased. No shares were purchased under the Purchase Plan in 2003.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Options Outstanding	Weighted Average Exercise Price
Outstanding at December 31, 2000	769	$ 1.08
Granted (all equal to fair value)	344	1.53
Exercised	(358)	1.12
Cancelled	(17)	1.67
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

The following table summarizes information about stock options outstanding under the 2000 Amended Plan and 2003 Plan at December 31, 2003 (shares in thousands):

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.08	397	6.99	$ 1.08	302	$1.08
2.16	90	7.82	2.16	78	2.16
3.30	1,227	9.05	3.30	1,085	3.30
6.60-9.19	122	9.83	8.30	53	8.05
9.60-10.50	34	9.88	9.89	22	9.60
12.00-12.87	162	9.83	12.81		
$1.08-12.87	2,032	8.71	$ 3.98	1,540	$3.06

At December 31, 2003, 2002 and 2001, options to purchase 1.5 million, 0.9 million and 0.6 million shares, respectively, were exercisable at weighted average exercise prices of $3.06, $2.06 and $1.19 per share, respectively.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shares Reserved For Future Issuance

At December 31, 2003, we have 4.6 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 preferred stock warrants.

8. Development and Sublicensing Agreement

We have a collaboration agreement with Eyetech Pharmaceuticals, Inc. pursuant to which certain antibodies and related technology was sublicensed to Eyetech for development in ophthalmic indications. We assumed this agreement in our acquisition of Cell-Matrix. Under the agreement, Eyetech paid Cell-Matrix a signing fee and is obligated to pay us milestone payments based upon meeting specified regulatory and clinical milestones and royalties on future net sales of 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 10 years after the date of the first commercial sale of the last product licensed or developed under the agreement. Either party may terminate this agreement for any reason following 90 days written notice to the other party.

9. Income Taxes

There was no income tax benefit attributable to net losses for 2003, 2002 and 2001. The difference between taxes computed by applying the U.S. federal corporate tax rate of 35% and the actual income tax provision in 2003, 2002 and 2001 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,	
	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 27,579	$ 16,410
Orphan drug and research and development credit carryforwards	24,822	15,722
Depreciation and amortization	884	974
Accrued liabilities and deferred rent	1,057	475
Other, net	851	329
Total net deferred tax assets	55,193	33,910
Valuation allowance for deferred tax assets	(55,193)	(33,910)
Net deferred taxes	$	$

The increase in the valuation allowance for deferred tax assets in 2003 and 2002 of $21.3 million and $20.7 million, respectively, was due primarily to the inability to utilize net operating loss, orphan drug and research and development credits.

At December 31, 2003, we had net operating loss carryforwards for federal and state income tax purposes of approximately $64.6 million and $86.8 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 $22.8 million and $0.2 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 $2.7 million, which are not expected to expire.

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CANCERVAX CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

10. Subsequent Event

On March 10, 2004, we signed an agreement with SemaCo, Inc. whereby we obtained an exclusive, worldwide sublicense from SemaCo to develop novel technology utilizing T-oligonucleotides for the potential treatment or prevention of cancer. In exchange, we made upfront payments totaling $0.5 million for the acquisition of the technology rights and a $0.3 million payment for the reimbursement of certain patent costs. Additionally, research support payments totaling $1.2 million will be payable over the three-year period commencing on the effective date of the agreement. We are also obligated to make future milestone payments upon meeting certain regulatory and clinical objectives and royalties on sales of commercial products, if any. The agreement terminates upon the later of the expiration of the last of any patent rights to licensed products that are developed under the agreement or 15 years after the date of the first commercial sale of the last product licensed or developed under the agreement. We may terminate the agreement for any reason following 60 days written notice to SemaCo.