

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the fiscal year ended December 31, 2002.

Or

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the transition period from to .

Commission file number: 0-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or
organization)

93-0948554
(IRS Employer Identification No.)

10390 Pacific Center Court
San Diego, California
(Address of registrant's principal executive offices)

92121-4340
(Zip Code)

Registrant's telephone number, including area code: **(858) 646-1100**

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.01 par value
(Title of Class)

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 No

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 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.

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the National Association of Securities Dealers Automated Quotation National Market System on June 28, 2002, was approximately \$94,046,000. Shares of Common Stock held by each officer and director and by each person who owns 10% or more of the outstanding Common Stock of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Common Stock outstanding as of March 19, 2003, was 20,091,344.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of our Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the solicitation of proxies for our 2003 Annual Meeting of Stockholders to be held on May 21, 2003, are hereby incorporated by reference in Part III of this report.

FORWARD-LOOKING STATEMENTS

The statements incorporated by reference or contained in this report discuss our future expectations, contain projections of our results of operations or financial condition and include other "forward-looking" information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Our actual results may differ significantly and materially from those expressed or implied in forward-looking statements made or incorporated by reference in this report. Forward-looking statements that express or imply our beliefs, plans, objectives or assumptions, or that describe future events or performance, may involve estimates, assumptions, risks and uncertainties. Therefore, our actual results and performance may differ significantly and materially from those expressed in the forward-looking statements. Forward-looking statements often, although not always, include words or phrases such as the following, or the negative of such words, or other comparable terminology:

- "will likely result,"

- “are expected to,”
- “will continue,”
- “is anticipated,”
- “estimate,”
- “believe,”
- “predict,”
- “potential,”
- “intends,”
- “plans,”
- “projection,” and
- “outlook.”

You should not unduly rely on forward-looking statements contained or incorporated by reference in this report. Actual results or outcomes may differ significantly and materially from those predicted in our forward-looking statements due to the risks and uncertainties inherent in our business, including risks and uncertainties related to:

- progress of our preclinical and clinical product development programs,
- clinical trial results,
- obtaining and maintaining regulatory approval,
- market acceptance of and continuing demand for our products,
- the attainment of patent protection for any of these products,
- the impact of competitive products, pricing and reimbursement policies,
- our ability to obtain additional financing to support our operations,
- the continuation of our corporate collaborations and licenses,
- our ability to enter into new corporate collaborations and licenses,
- changing market conditions, and
- other risks detailed below.

You should read and interpret any forward-looking statements together with:

- our Quarterly Reports on Form 10-Q,
- the risk factors contained in this report under the caption “Additional Business Risks,” and
- our other filings with the Securities and Exchange Commission.

Any forward-looking statement speaks only as of the date on which that statement is made. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

PART I

ITEM 1. BUSINESS

Overview

We were incorporated in Delaware in 1987. We research and develop biopharmaceutical products based on our patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. In addition, we have gained access to enhancing technologies through licensing and collaborative agreements. We believe the following areas of research offer the greatest potential for our product development efforts:

- Vaccines for use in high-risk populations for infectious disease targets for which there are significant U.S. needs,
- Vaccines for general pediatric or adult populations for infectious disease applications for which a challenge model or accepted surrogate marker are available, and
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise.

For opportunities outside these areas, we plan to continue leveraging our patented technology through licensing and collaborations. In addition, we plan to use our expertise, infrastructure, and financial strength to explore in-licensing or acquisition opportunities.

We have established relationships through licensing our technology to a number of commercial entities, including:

- Merck & Co., Inc.,
- Two divisions of Aventis S.A.:
 - Aventis Pasteur, and
 - Aventis Pharmaceuticals Inc.,
- Merial,
- Centocor, Inc., a wholly-owned subsidiary of Johnson & Johnson,
- Invitrogen Corporation,
- Human Genome Sciences, Inc., and

- Vascular Genetics Inc., which recently merged into Corautus Genetics Inc.

We have also licensed poloxamer technologies from CytRx Corporation.

Our Core Technology

The key discovery leading to our patented core technology was that muscle tissues can take up polynucleotide genetic material, such as DNA or RNA, directly, without the use of viral components or other delivery vehicles, and subsequently express the proteins encoded by the genetic material for periods ranging from weeks to more than a year. We often describe our approach as “DNA delivery technology” because it typically involves designing and constructing closed loops of DNA called plasmids. These plasmids contain a DNA segment encoding the protein of interest, as well as short segments of DNA that control protein expression. We are able to use uniform methods of fermentation and processing that are applicable to all plasmids. This could result in faster development times than technologies that require development of product-specific manufacturing processes.

Since the initial discovery of our DNA delivery technology, our researchers have improved the design of our plasmids to provide increases in efficiency of gene expression and immunogenicity. In addition, we are developing other formulation and delivery technologies, including the use of lipid molecules, synthetic polymers called poloxamers, and other approaches, to enhance DNA expression or increase the immune response in DNA vaccine applications. We own broad rights to certain non-viral

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polynucleotide delivery technologies through our series of core patents. Benefits of our DNA delivery technology may include the following which may enable us to offer novel treatment alternatives for diseases that are currently poorly addressed:

- *Broad Applicability.* Our DNA delivery technology may be useful in developing DNA vaccines for infectious diseases, in which the expressed protein induces an immune response; novel therapies for cancer, in which the expressed protein is an immune system stimulant or cancer-killing agent; and DNA therapeutic protein delivery, in which the expressed protein is a therapeutic agent;
- *Convenience.* Our DNA-based biopharmaceutical product candidates are intended to be administered on an outpatient basis;
- *Safety.* Our product candidates contain no viral components that may cause unwanted immune responses, infections, or malignant and permanent changes in the cell’s genetic makeup;
- *Repeat Administration.* Our product candidates contain no viral components that may preclude multiple dosing with a single product or use in multiple products;
- *Ease of Manufacturing.* Our product candidates are manufactured using straightforward fermentation and purification procedures; and
- *Cost-Effectiveness.* Our DNA delivery technology may be more cost-effective than other approaches. It may also cause fewer potential side effects, which itself may reduce per patient treatment costs.

Business Strategy

There are four basic elements to our business strategy:

Develop Products Independently

We currently focus our resources on the independent development of DNA vaccines for infectious diseases and cancer therapeutics. We intend to retain significant participation in the commercialization of our proprietary DNA vaccine and cancer products, although we may choose to enlist the support of marketing partners to accelerate market penetration.

Vaccines. Vaccines are perceived by government and medical communities as an efficient and cost-effective means of healthcare. According to the U.S. Centers for Disease Control and Prevention, or CDC, “Vaccines are among the very best protections we have against infectious diseases.” We believe our technology may lead to the development of novel preventive or therapeutic vaccines for infectious disease targets because:

- DNA vaccines may help combat diseases for which conventional vaccine methods have been unsuccessful;
- DNA vaccines may be safer than conventional vaccines; and
- DNA vaccines use straightforward manufacturing processes that may be simpler, more cost-efficient, and more generally applicable across a range of products than conventional vaccine production methods.

Cancer. In the cancer area, we have focused our resources on the development of Allovectin-7[®] as a potential treatment for metastatic melanoma, an aggressive form of skin cancer, to best apply the expertise and relationships we have established through prior development and testing in this area. We have no other potential cancer products currently under independent preclinical or clinical development.

Enhance and Expand Our Technologies

We are actively pursuing the refinement of our plasmids and formulations, the evaluation of potential enhancements to our core technologies and the exploration of additional DNA delivery technologies. We are developing future product candidates based on these technologies through preclinical and clinical testing to determine their safety and effectiveness. We also seek to develop

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additional applications for our technologies by testing new approaches to disease control or prevention. These efforts could lead to further independent product development or additional licensing opportunities. In addition, we continually evaluate compatible technologies or products that may be of potential interest for in-licensing or acquisition. We license intellectual property from companies holding complementary technologies in order to leverage the potential of our own DNA delivery technology and to further the discovery of innovative new therapies for internal development.

Expand the Applications of Our Technologies Through Strategic Collaborations

We collaborate with major pharmaceutical and biotechnology companies and government agencies, providing us access to complementary technologies or greater resources. These collaborations provide us with mutually beneficial opportunities to expand our product pipeline and serve significant unmet medical needs. We license our intellectual property to other companies in order to leverage our technologies for applications that may not be appropriate for our independent product development efforts.

Contract Manufacturing

In addition, we pursue contract manufacturing opportunities to leverage our infrastructure and expertise in plasmid manufacturing, and to provide revenues that contribute to our independent research and development efforts. We are currently engaged in contract manufacturing for the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institutes of Health, or NIH, and the International AIDS Vaccine Initiative, or IAVI.

Product Development

We are focused on the development of biopharmaceutical product candidates based on our patented DNA delivery technology. We, together with our licensees and collaborators, are currently developing a number of vaccine and therapeutic protein product candidates for the prevention or treatment of infectious diseases, cancer, and cardiovascular diseases. Our current independent development focus is on novel DNA vaccines for cytomegalovirus, or CMV, and anthrax, as well as our cancer immunotherapeutic, Allovectin-7[®]. The table below summarizes our independent, out-licensed and collaborative product development programs.

Product Development Programs

<u>Product Area</u>	<u>Project Target and Indication(s)</u>	<u>Development Status(1)</u>	<u>Development Rights</u>
<u>INFECTIOUS DISEASES</u>			
Infectious disease vaccines	<i>Plasmodium falciparum</i> (malaria)	Phase I/II	Vical
	Cytomegalovirus	Preclinical	Vical
	<i>Bacillus anthracis</i> (anthrax)	Preclinical	Vical
	HIV – preventive	Phase I	Merck
	HIV – therapeutic	Phase I	Merck
	Hepatitis B virus – preventive	Undisclosed	Merck
	Hepatitis B virus – therapeutic	Undisclosed	Merck
	Hepatitis C virus – preventive	Undisclosed	Merck
	Hepatitis C virus – therapeutic	Undisclosed	Merck
	Herpes simplex virus	Undisclosed	Merck
	Human papilloma virus – preventive	Undisclosed	Merck
	Human papilloma virus – therapeutic	Undisclosed	Merck
	Influenza virus	Undisclosed	Merck
<i>Mycobacterium tuberculosis</i>	Undisclosed	Merck	
<u>CANCER</u>			
Immunotherapeutic vaccine	High-dose Allovectin-7 [®] for metastatic melanoma	Phase II	Vical
Tumor-associated antigen therapeutic vaccines	Undisclosed	Preclinical/Phase I	Centocor
	Undisclosed	Undisclosed	Aventis Pasteur
<u>CARDIOVASCULAR</u>			
Angiogenic growth factors	VEGF-2	Phase II	Corautus Genetics
	Undisclosed	Phase II	Aventis Pharmaceuticals
<u>VETERINARY</u>			
Preventive vaccines	Various undisclosed	Research/Preclinical	Merial

(1) “Research” indicates laboratory studies to evaluate a potential product candidate in a nonclinical setting. “Preclinical” indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is undergoing toxicology testing in preparation for filing an Investigational New Drug application.

Clinical trials are used to determine whether new drugs or treatments are both safe and effective. Traditionally, clinical trials are done in three phases. Phase I clinical trials mark the first time a new drug or treatment is administered to humans and are normally conducted to determine the safety profile of a new drug. Phase II clinical trials are conducted in order to determine preliminary effectiveness, or efficacy, optimal dosage, and to confirm the safety profile. Phase III clinical trials are often large scale, multi-center studies conducted to compare a new treatment with a currently approved therapy. At times, a single trial may incorporate elements from different phases of development. An example might be a trial designed to determine both safety and initial efficacy. Such a trial may be referred to as a Phase I/II clinical trial.

DNA Vaccines for Infectious Diseases

DNA vaccines use portions of the genetic code of a pathogen to cause the host to produce specific features of the pathogen that may induce an immune response. This method potentially offers superior safety, ease and reliability of manufacturing, as well as convenient storage and handling characteristics, compared with conventional vaccines that use live, weakened, or dead pathogens to produce an immune response. DNA vaccines have the ability to induce potent T-cell responses against target pathogens as well as to trigger production of antibodies. Over the past decade, many scientific publications have documented the effectiveness of DNA vaccines in contributing to immune responses in dozens of species including fish, nonhuman primates and humans.

Vaccines are generally recognized as the most cost-effective approach for infectious disease healthcare. However, the technical limitations of conventional vaccine approaches have constrained the development of effective vaccines for many diseases. Development of vaccines based on conventional methods requires significant infrastructure in research and manufacturing. In addition, the safety risks associated with conventional vaccines may offset the potential benefits. We believe our potential vaccine products should be simpler to manufacture than vaccines made using chemical conjugation of polysaccharides and protein carriers or protein purification and

refolding techniques involving mammalian or avian cell, or egg-based, culture procedures and live viruses. In addition, our DNA delivery technology may accelerate certain aspects of vaccine product development such as nonclinical evaluation and manufacturing, and has demonstrated a favorable safety profile.

In the broader vaccine marketplace, it is important to note a changing dynamic. Traditionally, vaccines have been predominantly focused on the pediatric market, intended to protect children from diseases that could cause them serious harm. Today, there is a growing interest in vaccines against diseases that may affect adolescents and adults, which include both sexually transmitted diseases and infections that strike opportunistically, such as during pregnancy or in immunocompromised individuals, including the geriatric population. We believe our technology, because of its safety and development timeline advantages, could be ideally suited for the development of this new generation of vaccines.

The selection of targets for our infectious disease programs is driven by three key criteria: the complexity of the product development program, competition, and commercial opportunities.

Cytomegalovirus

In February 2003, we announced that a DNA-based immunotherapeutic vaccine against CMV will be our first independent development program focused on infectious diseases. Currently, there is no approved vaccine or even a late-stage vaccine development program for CMV. We intend to begin Phase I clinical testing of the vaccine by year-end 2003 for an initial indication in humans at high risk of serious complications from CMV infection—patients undergoing bone marrow or solid organ transplantation.

The Institute of Medicine, or IOM, of the National Academy of Sciences has estimated the cost of treating the consequences of CMV infection in the United States at more than \$4 billion per year and placed a CMV vaccine in its first priority category on the basis of cost-effectiveness. Our initial focus on the transplantation indication should allow proof-of-concept that could then lead to the opportunity to develop a CMV vaccine for other high-risk groups such as immunocompromised individuals and women of reproductive age, and eventually, to a universal vaccine for pediatric use. The unmet medical need in pregnant women at-risk for CMV infection and the need for controlling viral transmission in the general population may allow product expansion in the years ahead.

Our CMV immunotherapeutic vaccine program is based on:

- CMV genes that encode highly immunogenic proteins associated with protective antibody and cellular immune responses,
- Our DNA vaccine technologies that have the ability to induce potent cellular immune responses and trigger production of antibodies without the safety concerns that conventional attenuated vaccines have posed for immunocompromised patients, and

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- a focused clinical development plan designed to allow us to quickly establish proof of concept in transplant patients.

About CMV. CMV is a herpes virus, part of the family of viruses that cause genital herpes, cold sores or fever blisters, chicken pox and infectious mononucleosis. Although the body can never rid itself of CMV, a healthy immune system usually is able to keep the virus in check. As a result, CMV disease rarely occurs in healthy individuals, and reactivation typically occurs only when the immune system is compromised by other disease or drugs. People at greatest risk include bone marrow and solid organ transplant patients who take immunosuppressive drugs, AIDS patients and other immunocompromised individuals, and fetuses and newborns of mothers who become primarily infected during pregnancy.

CMV infection affects an estimated 30 to 60 percent of bone marrow transplant or organ transplant recipients, causing transplant rejection, serious illness and even death if untreated. Transplant patients who develop CMV disease use significantly more healthcare resources, including longer hospitalization, than asymptomatic or uninfected transplant patients. Expensive antiviral drug therapy is used to control the disease, but it does not prevent or eliminate the infection. As a result, many patients require long-term maintenance therapy, and reactivation of the disease often occurs if drug therapy is discontinued or if drug resistance develops. The treatment itself can be costly and, in some forms, inconvenient. Treatment is not effective for all patients and side effects may be severe, including damage to the bone marrow or kidneys.

The CDC estimates that, in the United States, CMV infects more than half of all adults by age 40, and as many as 85 percent of all adults at some point in their lives. An estimated 25,000 patients receive solid organ transplants in the United States annually, and another 4,000 receive bone marrow transplants, with similar numbers in the European market. Approximately one in a hundred infants in the United States is born with CMV infection, leading to severe consequences in about 3,600 infants and death in about 400 infants per year. Nearly 3,000 immunocompromised patients suffer from CMV infection in the United States each year, causing severe consequences in more than half of the cases and death in more than 150 cases.

Anthrax

In March 2003, we announced our second independent infectious disease DNA vaccine development program, an anthrax DNA vaccine which we intend to begin testing in humans by year-end 2003. We believe that we can develop a safe and effective DNA vaccine for anthrax that will validate the potential advantages of our proprietary vaccine technologies while addressing a pressing public need, because:

- The key anthrax immunogens have been identified, and we have verified in small animal studies that they can be delivered effectively by formulated DNA. Our technology allows us to readily combine two anthrax immunogens, Protective Antigen, or PA, and Lethal Factor, or LF, that together may provide broader protection than the currently licensed anthrax vaccine or proposed single recombinant protein vaccines;
- Our cationic lipid formulated DNA delivery technology, in which positively charged lipid molecules interact with the negatively charged DNA molecules, thus coating and protecting DNA, has established an excellent safety profile in previous clinical studies, and an important goal of this program is to extend that safety profile to vaccine applications;
- Another important goal of this program is to demonstrate that DNA vaccines can induce protective antibodies in humans and can do so with fewer injections than the currently licensed anthrax vaccine, offering a potentially shorter time to protection; and
- The potential stability of plasmid formulations may offer advantages in handling and storage, which would be important considerations for stockpiling.

Our anthrax vaccine team advanced this program from initial concept to evaluation of effectiveness in a stringent challenge model in less than ten months, and held a pre-IND meeting with the U.S. Food and Drug Administration, or FDA, in December 2002.

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Results with multiple formulations of the vaccine in mouse and rabbit challenge models have been encouraging and we intend to begin a safety and immunogenicity

study in human volunteers before year-end 2003.

We believe that the FDA would review this vaccine based on its Two-Animal Rule, which requires demonstration of effectiveness in two animal species in addition to safety in humans, and that development costs using this regulatory pathway should be moderate compared with conventional clinical trials.

Small Animal Testing. Our scientists developed formulated DNA vaccines encoding detoxified forms of two proteins produced by anthrax bacteria, PA and LF, that combine to form lethal toxin, or Letx, which contributes to the morbidity and mortality of anthrax. The vaccine formulations were tested in mice for their ability to produce anti-PA, anti-LF, and Letx-neutralizing antibodies.

In collaboration with The Ohio State University, or OSU, we then tested selected formulations in rabbits for immunogenicity. Groups of rabbits including vaccinated and control animals then were challenged by metered inhalation with aerosolized anthrax spores using established procedures and observed for lethal anthrax infection. Effectiveness data from this small animal testing were presented in March 2003 at the American Society for Microbiology meeting, "Future Directions for Biodefense Research: Development of Countermeasures."

Results from the rabbit study for cationic lipid formulated DNA vaccines indicated that:

- All PA DNA vaccine formulations stimulated anti-PA immune responses equal to or greater than the currently licensed anthrax vaccine;
- All rabbits immunized with PA DNA vaccine formulations, either alone or in combination with LF DNA vaccination, survived the inhalation challenge, indicating equivalent protection in rabbits to the currently licensed anthrax vaccine;
- All unvaccinated control rabbits died two to four days after challenge, validating the study procedures and confirming the severity of inhalation anthrax infection; and
- LF DNA vaccination stimulated anti-LF immune responses and, even when used alone, provided rabbits with partial protection against the inhalation challenge, suggesting a potential second means of protection and supporting its inclusion as a component of a bivalent anthrax vaccine candidate advancing into human testing.

This research has been supported, in part, by a one-year Small Business Technology Transfer Research, or STTR, grant from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, as announced in July 2002. In addition, we have submitted an application for a Phase II Small Business Innovation Research, or SBIR, grant to support, in part, the clinical development of our anthrax vaccine.

About Anthrax. Anthrax is a serious infectious disease most frequently occurring in hooved mammals, but also affecting humans exposed to the spore-forming *Bacillus anthracis*. Bacterial spores can survive for extended periods and become active upon gaining access to a host. Human infection with anthrax spores can occur after exposure through a cut or abrasion on the skin or through ingestion of contaminated meat, but the most serious risk is through inhalation.

Inhalation anthrax results in death for 90 percent to 100 percent of those exposed, if not treated promptly. Symptoms typically appear within a week of exposure, and may be misdiagnosed as a common cold or flu. Bacterial spores travel from the lungs to the lymph nodes, where they begin to grow. Eventually, they spread into the circulatory system and throughout the body, causing widespread internal bleeding and organ failure. People who work with animals or process animal products are at greatest risk of naturally acquired infection. The greatest potential threat for most people is the inhalation of anthrax spores used in biological warfare or in a bioterrorist attack.

The toxic effects of anthrax infection are the result of three proteins produced by the bacteria: PA, LF, and edema factor, or EF. PA couples with either EF or LF and allows these toxins to penetrate and kill host cells, releasing large numbers of bacteria into circulation.

In a review of the currently licensed anthrax vaccine, the IOM concluded, "the production, testing and licensure of a new vaccine requiring fewer doses and producing fewer local reactions is needed." Treatment for proven or suspected anthrax infection involves a long course of antibiotic therapy beginning as soon as possible after diagnosis or suspected exposure. Antibiotics used against anthrax work by killing the bacteria to prevent further production of the toxic proteins. They do not eliminate proteins that accumulate before treatment, and do not offer residual protection against infection after the treatment course has been completed.

Other Infectious Diseases

To supplement our independent vaccine development programs, we have licensed our technology to Merck & Co., Inc., or Merck, for the development of vaccines against seven infectious disease targets including HIV, hepatitis B and C, herpes simplex, tuberculosis, human papilloma and influenza. We have collaborated with the U.S. Navy toward the development of a vaccine against malaria. We also have provided contract manufacturing and contract regulatory support for VRC and IAVI. Details on these and other relationships can be found in "Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing," and "—Research Institutions," and "—Biodefense Efforts."

Cancer Therapies

Cancer is a disease of uncontrolled cell growth. When detected early and still confined to a single location, surgery or irradiation can often be curative. However, neither surgery nor irradiation is considered curative for cancer that has spread throughout the body. Chemotherapy can sometimes treat cancer that has spread throughout the body; however, a number of non-cancerous cells, such as bone marrow cells, are also highly susceptible to chemotherapy. As a result, chemotherapy often has fairly significant side effects. Finally, because each of these treatments only acts for a short period of time, it is common to see cancer return after apparently successful treatment.

Immunotherapy, using the patient's own immune system, may have advantages over surgery, irradiation, and chemotherapy in the treatment of cancer. It is generally believed that the immune system can recognize cancer cells and destroy them. Yet many cancers appear to have developed the ability to "hide" from the immune system. A treatment that can augment the immune response against tumor cells by making the cancer more "visible" to the immune system would likely represent a significant improvement in cancer therapy. Immune-enhancing proteins such as interleukin-2, or IL-2, and interferon-alpha, or IFN- α , have shown encouraging results. However, these agents often require frequent doses that regularly result in severe side effects.

We have researched delivery enhancements that may complement our core DNA delivery technology. Our current clinical-stage approach consists of injecting immune stimulating segments of DNA complexed with a cationic lipid-based delivery system, DMRIE/DOPE, directly into malignant tumors. Following injection, the lipid system also facilitates uptake of the DNA into tumor cells, where it directs the production of protein.

In addition, cancer therapies using non-viral DNA delivery may offer an added margin of safety compared to viral-based delivery, as no viral particles are contained in the formulation. The ease of manufacture, routine treatment administration performed in the clinic with minimal discomfort, and the excellent toxicity profile suggest that cancer therapies using non-viral DNA delivery may offer advantages over current modalities of therapy.

Preclinical studies in animals have demonstrated the safety and potential efficacy of this approach. Subsequently, in early human studies, a low incidence of

treatment-related adverse events has been observed. Our lead non-viral cancer immunotherapeutic under development is Allovectin-7[®], reviewed below.

Allovectin-7[®]

Allovectin-7[®] is a DNA/lipid complex containing the human DNA segments encoding HLA-B7 and β 2 microglobulin, which together form a Major Histocompatibility Complex, or MHC, Class I antigen. This type of antigen can trigger a potent immune response against foreign tissues, such as that seen in organ transplant rejections. Allovectin-7[®] is injected directly into tumors, and is designed to make malignant cells

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more visible to the immune system. The treatment may trigger an immune response against tumor cells, both locally and systemically, by enabling the immune system to recognize other features of tumor cells. We believe immunotherapeutics such as Allovectin-7[®] represent an attractive approach for patients with advanced melanoma.

Metastatic Melanoma. The American Cancer Society, estimates approximately 54,200 new diagnoses of, and 7,600 deaths from, melanoma in 2003 in the United States. Currently, there are no consistently effective therapies for advanced cases of malignant melanoma where the cancer has spread to other parts of the body, or metastasized. Treatment for these patients normally includes a combination of chemotherapy, radiation therapy, and surgery. In patients with metastatic melanoma, median survival typically ranges from six to eleven months. The toxicity associated with such licensed treatments as IL-2 or IFN- α is often significant, resulting in serious or life-threatening side effects in the majority of patients treated.

Low-Dose Allovectin-7[®]. In May 1998 we began two concurrent registration trials: a Phase II clinical trial and a Phase III clinical trial, with low-dose, 10 micrograms per injection, Allovectin-7[®] for patients with late-stage metastatic melanoma.

Our Phase II registration trial had endpoints of a 15 percent systemic clinical response rate, and a four-month median duration of response. Unadjudicated data from the investigation sites suggested that treatment with Allovectin-7[®] resulted in systemic clinical responses in 10.9 percent of the patients, with a median duration of response of 4.9 months. Adjudication refers to the process by which important efficacy results reported by trial investigators are reviewed to determine whether they meet protocol-specific endpoints. Estimated median survival in the Phase II registration trial was 14 months compared with published historical controls of 6 to 11 months. It was determined that these data alone likely would not support FDA approval, and therefore we decided not to pursue marketing approval based on these data.

In our randomized, controlled Phase III registration trial for the treatment of chemotherapy-naïve patients with metastatic melanoma, half the patients received dacarbazine, the only chemotherapeutic agent approved at that time by the FDA for metastatic melanoma. The other half received dacarbazine plus low-dose Allovectin-7[®]. We announced in September 2002 that an initial review of investigator-determined efficacy by an external consultant indicated that our Phase III registration trial would not meet statistical significance of objective response rate, time to disease progression, or survival. As a result, we avoided prematurely embarking on the time-consuming and costly process of Biologics License Application, or BLA, filing.

High-Dose Allovectin-7[®]. Based on preliminary data that injected melanoma tumors appear to respond more frequently than non-injected lesions, one strategy to increase the response rate to Allovectin-7[®] is to inject multiple tumors rather than single tumors as in prior studies. In addition, higher doses of Allovectin-7[®] may increase objective response rates. In February 2001, we initiated a Phase II clinical trial evaluating a higher dose of 2,000 micrograms, a 200-fold increase compared with the registration trials. The trial also allows for the distribution of that increased dose into as many as five tumor lesions. The higher dose, with or without multiple tumor injections, may provide a relevant increase in objective response rate.

We have four main reasons why we may continue to pursue development of our high-dose Allovectin-7[®] program in metastatic melanoma. First, the 10 microgram low-dose Allovectin-7[®] program was first developed over five years ago. Since then, we have learned from our experiences in human clinical trials of malaria vaccines with the U.S. Navy and from other DNA vaccine trials that immune responses in humans appear to be DNA dose-dependent. Second, our experience in prior trials has shown that while overall response rates of up to 15 percent have been observed, nearly 50 percent of the injected tumors shrank. As a result, injection of multiple tumors needs to be studied to determine its effect on increasing overall response rates. Third, because the safety record with Allovectin-7[®] is excellent, any significant benefit from Allovectin-7[®] would yield a highly favorable risk-to-benefit ratio when compared with conventional chemo- or biotherapies. Fourth, although survival was not an endpoint in the Phase II registration trial, the survival data from the trial suggested a beneficial trend—14 months median survival compared with published historical controls of 6 to 11 months.

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Even though the original study design of up to 80 patients was sufficient to evaluate the primary trial endpoint of overall response rate, the FDA allowed us to expand enrollment up to 124 patients at the highest dose to provide greater statistical confidence in conclusions that may be drawn from this non-registration trial.

We expect to release interim data from the high-dose trial by May 2003. Based on the interim results of the high-dose Phase II trial, we will determine whether to proceed with further development. If further development were supported by the data, at least one Phase III registration trial would likely be required with a sufficient number of patients to demonstrate statistically significant efficacy benefits with high-dose Allovectin-7[®]. The time and expense required for such a trial could exceed our available resources. Alternatively, we could seek a commercial partner to share or assume the costs of further development in exchange for potential future profits. If the data from the high-dose Phase II trial did not support further development, we would be unlikely either to proceed independently or to enlist the support of a development partner.

Head and Neck Cancer. Based on unadjudicated results from three sequential Phase I and Phase II clinical trials testing Allovectin-7[®] in patients with advanced squamous cell carcinoma of the head and neck, we initiated a multi-center Phase II clinical trial in February 2001 with Allovectin-7[®] in up to 25 patients scheduled for surgical treatment of early-stage cancer of the oral cavity and oropharynx. We announced in September 2002 our plan to close our Phase II trial with Allovectin-7[®] for early-stage head and neck cancer, in which recruitment of patients had been extraordinarily difficult.

Leuvectin[®]

Leuvectin[®] is a DNA/lipid complex containing a DNA segment encoding IL-2, a cytokine that plays a role in stimulating immune response. Systemic IL-2 protein therapy is currently approved by the FDA for treatment of certain cancers, but its administration is associated with serious toxicity in the majority of patients. Leuvectin[®], when injected into tumors, is designed to cause the malignant cells to produce IL-2. Local expression of IL-2 may then stimulate the patient's immune system to attack and destroy the tumor cells. Because Leuvectin[®] delivers IL-2 locally rather than throughout the body, it may provide efficacy comparable to the protein treatment with fewer side effects. Leuvectin[®] has been tested in clinical trials for patients with kidney cancer and prostate cancer.

Kidney Cancer. As announced in April 2001, we discontinued our Phase II clinical trial with Leuvectin[®] for patients with metastatic kidney cancer because the efficacy did not meet interim targets required to continue the trial. We have completed our investigation into this matter and have concluded that a change in the formulation likely resulted in reduced expression of IL-2. Following a thorough review of our options, we concluded in September 2002 that further independent development of Leuvectin[®] for kidney cancer is not justified in light of our other priorities.

Prostate Cancer. In prostate cancer, we conducted three trials of Leuvectin[®] in two distinct patient populations, with our decision to proceed driven by initial encouraging results based on a provisional surrogate marker, Prostate-Specific Antigen. We determined that further development for this indication would require far greater resources than we can devote independently, so we announced in September 2002 that we were bringing our two current prostate cancer trials to a close.

Out-licensing of Cancer Targets

Details for our collaborations regarding cancer targets with Centocor and Aventis Pasteur can be found in “Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing.”

Cardiovascular Programs

Our DNA delivery technology may allow the targeted delivery of certain proteins with potential therapeutic value in the emerging field of angiogenesis, the goal of which is inducing the growth of blood vessels to replace those blocked by disease. Angiogenesis has been shown to occur by the exogenous administration of angiogenic growth factors. We believe that the sustained delivery of these growth factors will be both safe and effective. Thus, although several attempts by others to intermittently deliver recombinant specific angiogenic growth factors directly have been unsuccessful, we believe our approach to deliver locally DNA segments that encode the desired growth factors is quite promising. Local delivery

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of angiogenic growth factor genes using our technology is in human trials. See “—Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing.”

Veterinary Applications

Prior to its development for human therapy, our DNA delivery technology was extensively tested in animals. Research scientists have published numerous papers detailing favorable results in many species and covering a broad range of disease indications. Animal health encompasses two distinct market segments: livestock, or animals bred and raised for food or other products; and companion animals, or pets. Serving the animal health markets requires highly efficient manufacturing and specialized distribution channels. Consequently, we have licensed our DNA delivery technology for development and commercialization to Merial. See “—Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing.”

Intellectual Property

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technology, inventions, and improvements to our inventions that we consider important to the development of our business. We believe that our patent portfolio is the most comprehensive of any company in the non-viral DNA delivery sector. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We have filed or participated as licensee in the filing of more than 40 patent applications in the United States and have made over 360 additional counterpart foreign filings in foreign countries relating to our technology. We and our exclusive licensors have received U.S. and foreign patents covering various aspects of our proprietary technology. Most of these patents are recently issued and have considerable patent life remaining.

Our patents and patent applications cover, for example, DNA delivery for immunization and delivery of therapeutic proteins, specific DNA constructs and formulations of gene-based product candidates, methods for producing pharmaceutical-grade DNA, and several families of lipid molecules and their uses in DNA delivery, as described more fully below:

- Core DNA Delivery Technology. We own rights to issued U.S. patents covering our core DNA delivery technology, including patents on methods of administering DNA sequences for the purposes of expressing therapeutic proteins or for inducing immune responses. Other issued patents specifically cover the administration of DNA sequences into blood vessels and the heart. In July 2002, we announced issuance of a broad patent covering methods for the non-viral, gene-based delivery of physiologically active polypeptides or proteins. Among the most advanced applications that would be covered by this patent are the clinical programs being run by our partners Aventis Pharmaceuticals and Corautus Genetics in the field of angiogenesis;
- Our core DNA delivery technology was covered by a patent issued in Europe in 1998, which was subsequently opposed by seven companies under European patent procedures. This patent was revoked on formal grounds in October 2001 under an initial ruling by the Opposition Division of the European Patent Office. The Opposition Division ruled that, as a result of amendments to the claims made during the process of obtaining the European patent and during the opposition process, the claims did not comply with European patent laws. In April 2002, we filed an appeal, which is still pending, seeking to overturn this initial ruling. We intend to vigorously defend our patent position in the European opposition proceedings. We may also use additional patent applications that are pending in Europe to secure patent protection for our core DNA delivery technology;
- Our core DNA delivery technology is also covered by patent applications filed in Canada. A Canadian patent was issued and then withdrawn from issuance and returned to the examiner for further consideration after protests against the issuance of the patent were filed on behalf of an undisclosed party or parties on August 10 and December 5, 2001. We have responded to the protests and are awaiting further action by the Canadian Patent Office;

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- Our core DNA delivery technology is also covered by patent applications filed in Japan. On January 2, 2002, Japanese Patent 3250802 was published, and simultaneously opened for third party opposition. We subsequently received an Office Action from the Japanese Patent Office, or JPO, notifying us that the patent had been revoked by the examining panel at the JPO. Both formal and substantive grounds for the revocation were given. We intend to file a rebuttal response on or before the due date of May 28, 2003;
- Core Lipid Technology. We have received issued U.S. patents covering numerous examples of cationic lipid compounds that are used to facilitate delivery of gene therapies to some tissues. These patented compounds include the lipids contained in some of our product candidates. Patent protection of these key lipids also has been obtained in Europe and Japan;
- Specific DNA Therapeutics. We have supplemented the broad patent coverage described above with patents covering specific product applications of our technology. To date, we have received patents issued in the United States covering Allovectin-7[®] and Leuvectin[®] and other patents related to gene delivery to the heart, including delivery of a vascular endothelial growth factor, or VEGF. We announced in June 2002 the issuance of a patent covering the gene-based delivery of IL-2 for the treatment of cancer;
- DNA Process Technology. As a result of our pioneering efforts to develop the use of pure DNA as a therapeutic agent, we have also developed manufacturing

processes for producing pharmaceutical-grade DNA. We have received issued U.S. patents covering various steps involved in the process of economically producing pure plasmids for pharmaceutical use; and

- **Licensed DNA Delivery Technology.** We have licensed from the University of Michigan rights to various U.S. and international patents related to injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7[®] and Leuvectin[®]. Included in this license is European Patent Number 0591385, which was granted, and simultaneously opened for opposition, on March 20, 2002. We have received notice from the European Patent Office that one company filed an opposition on December 19, 2002, alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible on February 13, 2003. We intend to file a rebuttal response on or before the due date of June 13, 2003, or, if we are granted a six-month extension, on or before the extended due date of December 13, 2003.

See “—Additional Business Risks—Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products,” and “—The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.”

Commercialization and Manufacturing

Because of the broad potential applications of our technology, we intend to develop and commercialize products both on our own and through corporate collaborators. We intend to develop and commercialize products to well-defined specialty markets, such as infectious diseases, oncology and other life-threatening diseases. Where appropriate, we intend to rely on strategic marketing and distribution alliances.

We believe our plasmids can be produced in commercial quantities through uniform methods of fermentation and processing that are applicable to all plasmids. In addition, our formulations consist of components that are synthesized chemically using traditional, readily scaleable organic synthesis procedures.

We produce and supply our own plasmids for all of our research needs and clinical trials and intend to produce sufficient supplies for all foreseeable clinical investigations. In January 2002, we signed a 15-year lease on a new facility that we believe will be sufficient for foreseeable commercial manufacturing requirements. Construction is in progress and is expected to be completed by mid-year 2003. We anticipate that the manufacturing capabilities of the new facility will be fully productive in the first half of 2004. We also engage in contract manufacturing of plasmid investigational products for selected

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clients. If we become capacity constrained, we may use outside organizations to manufacture our products.

Collaboration and Licensing Agreements

We have entered into various arrangements with corporate, academic, and government collaborators, licensors, licensees, and others. In addition to the agreements summarized below, we conduct ongoing discussions with potential collaborators, licensors and licensees.

Corporate Collaborators—Out-licensing

Invitrogen Corporation. In April 1991, we licensed the use of certain proprietary lipids for research products applications to Life Technologies, Inc., or Life Technologies, which was subsequently acquired by Invitrogen Corporation, or Invitrogen, in September 2000. Invitrogen manufactures and markets these lipid compounds, and pays royalties to us on the sales of the lipids. Through December 31, 2002, we had received approximately \$6.2 million in royalty revenues under the Invitrogen/Life Technologies agreement.

Merck & Co., Inc. In May 1991, we entered into a research collaboration and license agreement with Merck to develop and commercialize vaccines utilizing our DNA delivery technology to prevent infection and disease in humans. In connection with the 1991 agreement, we granted Merck a worldwide exclusive license to preventive vaccines using our technology against seven human infectious disease pathogens including: hepatitis B virus, or HBV; hepatitis C virus, or HCV; herpes simplex virus, or HSV; human immunodeficiency virus, or HIV; human papilloma virus, or HPV; influenza virus; and *Mycobacterium tuberculosis* bacteria. Merck has the right to terminate this agreement without cause on 90 days written notice.

In addition, Merck has rights to therapeutic uses of preventive vaccines developed under the 1991 agreement. In December 1995 and November 1997, Merck acquired additional rights to develop and commercialize therapeutic vaccines against HBV, HIV and HPV.

In November 2001, Merck made a payment to extend the term of Merck’s worldwide rights to use our DNA delivery technology to develop and commercialize therapeutic vaccines against both HIV and HBV. In connection with its agreements with us, Merck had paid us approximately \$25.1 million, including a \$5.0 million investment in our common stock, through December 31, 2002. Merck is obligated to pay additional fees if certain research milestones are achieved, and royalties on net sales if any covered products are developed and commercialized. For some indications, we may have an opportunity to co-promote product sales.

Merck is currently testing single-gene DNA vaccines for HIV in human trials. Human testing began in December 1999 in uninfected volunteers and, in May 2000, in volunteers already infected with HIV and receiving highly active anti-retroviral therapy.

Merck has provided data from the HIV vaccine program in scientific publications and presentations. These data indicate that DNA vaccination alone can provide sustained partial protection in monkeys against lethal challenge with the monkey equivalent of HIV; DNA vaccination alone induces a dose-related immune response; and a prime-boost regimen with formulated DNA vaccination followed by vaccination with an adenoviral vector vaccine can induce a potent immune response. Merck also has announced its intention to begin clinical testing in 2003 of a multivalent vaccine targeting three distinct HIV proteins.

Aventis. In December 2001 and December 2002, we restructured agreements with Aventis Pasteur, a division of Aventis S.A., granting Aventis Pasteur rights to use our patented DNA delivery technology for specific oncology applications. In exchange, Aventis Pasteur gave up rights to develop and commercialize infectious disease DNA vaccines against malaria, CMV, *Helicobacter pylori*, and respiratory syncytial virus, which we had licensed to Aventis Pasteur under a September 1994 agreement. Aventis Pasteur has the right to terminate this restructured agreement without cause on six months written notice.

In 1999, Aventis Pharmaceuticals Inc. began testing the DNA delivery of a gene encoding an angiogenic growth factor in patients with peripheral vascular disease, a severe condition caused by blockage of arteries feeding the foot and lower leg. Aventis Pharmaceuticals licensed the rights to our

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DNA delivery technology for cardiovascular applications using a specific angiogenic growth factor in June 2000. The angiogenic growth factor agreement, could generate milestone payments plus royalties if products advance through commercialization. Aventis Pharmaceuticals has the right to terminate this agreement without cause on 60 days written notice.

Through December 31, 2002, we had received approximately \$9.4 million under these two Aventis agreements. The restructured agreement provides for us to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

Merial. We entered into a corporate collaboration in March 1995 relating to DNA vaccines in the animal health area with Merial, a joint venture between Merck and Aventis S.A. Merial has options to take exclusive licenses to our DNA delivery technology to develop and commercialize DNA vaccines to prevent infectious diseases in domesticated animals. Through December 31, 2002, we had received \$7.0 million under this agreement. If Merial markets these vaccines, cash payments and royalties on sales would be due to us. Merial has the right to terminate this agreement without cause on 30 days written notice.

Human Genome Sciences, Inc. In February 2000, we signed a reciprocal, royalty-bearing license agreement with Human Genome Sciences, Inc., or HGS. Under the agreement, we have the option to exclusively license up to three genes from HGS for gene-based product development. HGS has the option to license our DNA delivery technology for use in up to three gene-based products. Each party has until September 30, 2004, to exercise its respective options. As of December 31, 2002, neither party had exercised any of its options.

Vascular Genetics Inc./Corautus Genetics Inc. In February 2000, we received shares of Series B Preferred Stock in Vascular Genetics Inc., or VGI, in exchange for granting VGI a license to our technology. These preferred shares had an estimated fair value of \$5.0 million on the date of investment and were convertible into common stock of VGI. VGI was a privately-held company developing gene-based delivery of the angiogenic growth factor VEGF-2 for cardiovascular applications. No cash was received or paid by either party to this transaction. In February 2003, GenStar Therapeutics, a public company listed on the American Stock Exchange, or AMEX, and VGI completed a merger that resulted in the creation of a new entity called Corautus Genetics Inc., or Corautus. The shares of Corautus are traded on AMEX.

Prior to the merger, VGI had conducted Phase I and Phase II clinical trials using DNA delivery of the VEGF-2 gene to promote the growth of blood vessels in patients with coronary artery disease or peripheral vascular disease. The FDA placed the VGI trials on a clinical hold in 2000 and lifted the hold in 2001. VGI subsequently announced that it was advancing toward new clinical trials.

Centocor, Inc. In February 1998, we entered into an exclusive license and option agreement allowing Centocor, Inc., a company subsequently acquired by Johnson & Johnson, Inc., to use our DNA delivery technology to develop and commercialize certain DNA vaccines for the potential treatment of some types of cancer. Through December 31, 2002, we had received \$3.7 million under this agreement. We may receive additional payments based upon achievement of milestones and royalty payments on product sales. Centocor has the right to terminate this agreement without cause on 180 days written notice.

Corporate Collaborators—In-licensing

Ichor Medical Systems, Inc. In October 2001, we entered into an exclusive agreement with Ichor Medical Systems, Inc., or Ichor, to develop products based on our DNA delivery technology and delivered using Ichor's proprietary electroporation systems. This agreement was concluded in December 2002.

CytRx Corporation. In December 2001, we entered into an exclusive agreement with CytRx Corporation which grants to us the rights to use or sublicense CytRx's poloxamer technology to enhance viral or non-viral delivery of polynucleotides in all preventive and therapeutic human and animal health applications. The agreement excludes applications for four infectious disease vaccine targets licensed to Merck and prostate-specific membrane antigen. In addition, the agreement permits our use of CytRx's technology to enhance the delivery of proteins in prime-boost vaccine applications that involve the use of polynucleotides. As part of the agreement, we made a \$3.8 million up-front payment and agreed to make

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potential future milestone and royalty payments. The license fee is being amortized over the estimated ten-year average useful life of the technology.

Payments to Others. Under the Merck, Aventis, Merial, Centocor, HGS and Corautus agreements, we would be required to pay up to 10 percent of some initial upfront payments, and a small percentage of some royalty payments, to Wisconsin Alumni Research Foundation, or WARF. The CytRx agreement would require us to make payments to CytRx and to WARF only if the results of our research resulted in the generation of revenue. See "—Research Institutions—Wisconsin Alumni Research Foundation." For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties.

Research Institutions

Office of Naval Research. In September 1998, we entered into an agreement with the Office of Naval Research, or ONR, for development of a potential multi-gene DNA vaccine to prevent malaria. Malaria is a severe infectious disease characterized by fever, headache and joint pain, which if untreated can lead to death. Infection normally occurs when the parasite enters a victim's bloodstream during a mosquito bite. There is currently no effective vaccine against the disease.

In August 2000, a Phase I/II clinical trial was initiated to test the safety and efficacy of a DNA vaccine to prevent infection by the malaria parasite. In November 2001, the U.S. Navy presented preliminary trial results at the 50th Annual Meeting of the American Society of Tropical Medicine and Hygiene. The preliminary results indicated that vaccination was safe and well-tolerated, and caused specific T-cell immune responses against encoded antigens. Although all volunteers contracted the disease, measurements after the challenge indicated specific antibody and T-cell immune responses, which were stronger in volunteers receiving the vaccine than in volunteers who did not receive the vaccine, suggesting a vaccine-induced prime and parasite-induced boost effect. Results of this trial provide the basis for planning further development toward a malaria vaccine product. Vical scientists, in cooperation with the U.S. government, are looking to apply several new enhancing technologies to develop a preventive malaria vaccine that uses our DNA technologies to provide six to nine months' protection against the disease. The initial indication for use would be aimed at the travel and military markets, for which the currently licensed medications have limitations such as drug resistance, side effects and duration of treatment both before and after travel.

The agreement with the ONR, as amended, expired in September 2002. Through December 31, 2002, we had recognized revenue of \$5.3 million under the agreement. We intend to pursue additional agreements with ONR to continue funding for this development program, however, we may not be able to enter into any further agreements. If we are unable to secure additional funding, we do not plan to pursue this program independently.

The University of Michigan. In October 1992, we entered into a license agreement with the University of Michigan, under which we obtained an exclusive license to technology for delivering gene-based products into cancer cells and blood vessels by catheters. In April 1997, we entered into a sublicense agreement, the rights under which are currently held by Boston Scientific Corporation, for the development of catheter-based intravascular DNA delivery technology.

Wisconsin Alumni Research Foundation. Under a 1989 research agreement, scientists at the University of Wisconsin, Madison, and our scientists co-invented a core technology related to intramuscular DNA administration. In 1991, we licensed from WARF its interest in that technology. We paid WARF an initial license fee and agreed to pay WARF a royalty on sales of any products incorporating the licensed technology and a percentage of some initial up-front license payments from third parties.

Contract Manufacturing and Regulatory Support

National Institutes of Health. In 2002 and 2001, we performed contract manufacturing of DNA for infectious disease vaccines under three contracts with the NIH. One of these contracts, which continues into 2003 and relates to the production of HIV clinical trial supplies, is with VRC. We also are providing regulatory support services to VRC under another contract. Total revenues recognized under these contracts were \$0.9 million and \$1.3 million in 2002 and 2001, respectively.

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In addition, in July 2002, we entered into an agreement with VRC to provide certain regulatory and manufacturing services to VRC related to the research and development of a DNA vaccine against the Ebola virus. Revenue recognized under this contract was \$1.0 million for the year ended December 31, 2002. R. Gordon Douglas, M.D., Chairman of our Board of Directors, also is the Director of Strategic Planning at the VRC.

International AIDS Vaccine Initiative. In January 2002, we signed a contract with IAVI, a not-for-profit entity, to provide clinical trial supplies. The initial term of this contract extended to December 31, 2002, but has been renewed through December 31, 2003. Thereafter, the term shall be renewed automatically for successive one-year periods unless either party gives at least 90 days prior notice to terminate. In 2002, we recognized \$0.2 million of revenue from IAVI. Dr. Douglas serves on the Board of Directors of IAVI. Our President and Chief Executive Officer, Vijay B. Samant, serves on the Project Management Subcommittee of IAVI.

Biodefense Efforts

In June 2002, we initiated, in collaboration with OSU, preclinical studies of DNA vaccines against anthrax. The research is being funded by a one-year STTR grant from the NIAID. We have submitted an application for a Phase II SBIR grant to support, in part, the clinical development of the anthrax vaccine. We also manufacture clinical-grade supplies of an investigational Ebola vaccine for the VRC, as described above.

Competition

Technological development could result in our product candidates or technologies becoming obsolete before we recover a significant portion of our related research, development, and capital expenditures. We may experience competition both from other companies in our field and from companies which have other forms of treatment for the diseases we are targeting.

We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, which are actively engaged in vaccine research and development. These include AlphaVax, Inc., Avant Immunotherapeutics, Aventis, Chiron Corporation, Crucell N.V., DynPort Vaccine Company LLP, GlaxoSmithKline plc, ID Biomedical Corporation, MedImmune, Inc., Merck, PowderJect Pharmaceuticals plc, Shire Pharmaceuticals Group plc, Solvay S.A., and Wyeth among others. We may also experience competition from companies that have acquired or may acquire technology from companies, universities and other research institutions. As these companies develop their technologies, they may develop proprietary technologies which may materially and adversely affect our business.

In addition, a number of companies are developing products to address the same diseases that we are targeting. For example, AVAX Technologies, Inc., Corixa Corporation, Antigenics, Inc., CancerVax Corporation, Maxim Pharmaceuticals, Inc. and Genta, Inc., among others, are conducting clinical trials for the treatment of melanoma. If these or any other companies develop products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed.

Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technology or products obsolete or noncompetitive, or result in treatments or cures superior to ours.

Regulatory agencies such as the FDA and other government agencies may expand current requirements for public disclosure of DNA-based product development data, which may harm our competitive position with foreign companies and U.S. companies developing DNA-based products for similar indications.

Our competitive position will be affected by the disease indications addressed by our product candidates and those of our competitors, the timing of market introduction for these products and the stage of development of other technologies to address these disease indications. For us and our competitors, proprietary technologies, the ability to complete clinical trials on a timely basis and with the desired results, and the ability to obtain timely regulatory approvals to market these product candidates are likely to be significant competitive factors. Other important competitive factors will include the efficacy, safety, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

Government Regulation

Any products we develop will require regulatory clearances prior to clinical trials and additional regulatory clearances prior to commercialization. New gene-based products for vaccine or therapeutic applications are expected to be subject to extensive regulation by the FDA and comparable agencies in other countries. The precise regulatory requirements with which we will have to comply are uncertain at this time due to the novelty of the gene-based products and indications, or uses, that are currently under development. We believe that our potential products will be regulated either as biological products or as drugs. Drugs are subject to regulation under the Federal Food, Drug and Cosmetic Act; biological products, in addition to being subject to provisions of that Act, are regulated under the Public Health Service Act. Both statutes and related regulations govern, among other things, testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and other promotional practices. FDA approval or other clearances must be obtained before clinical testing, and before marketing of biologics or drugs.

To obtain FDA approval prior to marketing a pharmaceutical product in the United States, requires clinical trials to demonstrate the safety, efficacy and potency of the product candidate. Clinical trials are the means by which experimental drugs or treatments are tested in humans. New therapeutics typically advance from research through preclinical testing, and finally through several phases of clinical trials, or human testing. Clinical trials may be conducted within the United States or in foreign countries. If clinical trials are conducted in foreign countries, the products under development as well as the trials are subject to regulations of the FDA and/or its counterparts in the other countries. Upon successful completion of clinical trials, approval to market the treatment for a particular patient population may be requested from the FDA in the United States and/or its counterparts in other countries.

Clinical trials are normally done in three phases. Phase I clinical trials are typically conducted with a small number of patients or healthy volunteers to determine the safety profile, the pattern of drug distribution and metabolism and early evidence of effectiveness. Phase II clinical trials are conducted with a larger group of patients afflicted with a target disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. Phase III clinical trials involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of safety, efficacy, and potency required by the FDA and other regulatory authorities. For life-threatening diseases, initial human testing generally is done in patients afflicted with the target disease rather than healthy volunteers. These studies may provide results traditionally obtained in Phase II trials and are referred to as "Phase I/II" trials. In some special cases where the efficacy testing of a product may present a special challenge to testing in humans, such as in the case of a vaccine to protect healthy humans from a life-threatening disease that is not a naturally occurring threat, effectiveness testing may be required in animals.

Obtaining FDA approval is a costly and time-consuming process. Generally, in order to gain FDA pre-market approval, preclinical studies must be conducted in the laboratory and in animal model systems to gain preliminary information on efficacy and to identify any major safety concerns. The results of these studies are submitted as a part of an application for an Investigational New Drug, or IND, which the FDA must review and allow before human clinical trials can start. The IND includes a detailed description of the proposed clinical investigations.

A company must sponsor and file an IND for each proposed product and must conduct clinical studies to demonstrate the safety, efficacy, and potency that are necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension, or termination

therapeutics are a new category of therapeutics and the clinical trial period may be lengthy or the number of patients may be numerous in order to establish safety, efficacy, and potency.

After completion of clinical trials of a new product, FDA marketing approval must be obtained. If the product is regulated as a biologic, a BLA is required. If the product is classified as a new drug, a New Drug Application, or NDA, is required. The NDA or BLA must include results of product development activities, preclinical studies, and clinical trials, in addition to detailed manufacturing information.

A new rule recently published by the FDA, known commonly as the "Two-Animal Rule," attempts to establish requirements for demonstrating effectiveness of drugs and biological products in settings where clinical trials for efficacy are not feasible or ethical. The rule requires as conditions for market approval the demonstration of safety and biological activity in humans, and the demonstration of effectiveness under rigorous test conditions in two appropriate species of animal. We believe that with appropriate guidance from the FDA, the Two-Animal Rule will be the rule under which we may seek and win market approval for a gene-based product designed to treat or prevent a disease for which clinical efficacy trials are neither feasible nor ethical, such as our DNA vaccine for anthrax. At the moment, it is not clear whether the application of the Two-Animal Rule would result in expedited or protracted development time or regulatory review of a market application.

Applications submitted to the FDA are subject to an unpredictable and potentially prolonged approval process. Despite good-faith communication and collaboration between the applicant and the FDA during the development process, the FDA may ultimately decide, upon final review of the data, that the application does not satisfy its criteria for approval or requires additional product development or further preclinical or clinical studies. Even if FDA regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Before marketing clearance is secured, the manufacturing facility will be inspected for compliance with current Good Manufacturing Practices, or GMP, by FDA inspectors. The manufacturing facility must satisfy current GMP requirements prior to marketing clearance. In addition, after marketing clearance is secured, the manufacturing facility will be inspected periodically for GMP compliance by FDA inspectors, and, if the facility is located in California, by inspectors from the Food and Drug Branch of the California Department of Health Services.

In addition to the FDA requirements, the NIH has established guidelines for research involving human genetic materials, including recombinant DNA molecules. The FDA cooperates in the enforcement of these guidelines, which apply to all recombinant DNA research that is conducted at facilities supported by the NIH, including proposals to conduct clinical research involving gene therapies. The NIH review of clinical trial proposals and safety information is a public process and often involves review and approval by the Recombinant DNA Advisory Committee of the NIH.

We understand that both the FDA and NIH are considering rules and regulations that would require public disclosure of commercial development data that are presently confidential. This potential disclosure of commercial confidential information, if implemented, may result in loss of competitive secrets, which could be commercially detrimental.

Certain portions of the Health Insurance Portability and Accountability Act, or HIPAA, that become effective this year are expected to impact the rate at which clinical trials may be initiated, however the specific nature and degree of impact are not yet known.

We also are subject to various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

Human Resources

As of March 1, 2003, we had 165 full-time employees, 25 of whom hold doctorate degrees. Of these full-time employees, 133 are engaged in, or directly support, research and development activities, and 32 are in general and administrative positions. A significant number of our management and other employees have prior experience with pharmaceutical and biotechnology companies. None of our employees is covered by collective bargaining agreements, and our management considers relations with our employees to be good.

Executive Officers

The executive officers of Vical are elected annually by the Board of Directors. Our executive officers are as follows:

Name	Age(1)	Position
Vijay B. Samant	50	President, Chief Executive Officer and Director
David C. Kaslow, M.D.	44	Chief Scientific Officer
Martha J. Demski	50	Vice President, Chief Financial Officer, Treasurer and Secretary
Alan E. Dow, J.D., Ph.D.	47	Vice President and General Counsel

(1) As of December 31, 2002.

Vijay B. Samant joined us as President and Chief Executive Officer in November 2000. Mr. Samant has 23 years of diverse U.S. and international sales, marketing, operations, and business development experience with Merck. From 1998 to mid-2000, he was Chief Operating Officer of the Merck Vaccine Division. From 1990 to 1998, he served in the Merck Manufacturing Division as Vice President of Vaccine Operations, Vice President of Business Affairs, and Executive Director of Materials Management. Mr. Samant earned his M.B.A. from the Sloan School of Management at the Massachusetts Institute of Technology in 1983. He received a master's degree in chemical engineering from Columbia University in 1977 and a bachelor's degree in chemical engineering from the University of Bombay, University Department of Chemical Technology, in 1975.

David C. Kaslow, M.D., joined us as Chief Scientific Officer in October 2001. Dr. Kaslow has more than 15 years of vaccine research experience, including the last two at Merck, most recently as Head of the Department of Vaccine Research and Technology. From 1986 to 1999, he held various senior research positions at the NIH, including Head of the Recombinant Protein Development Unit and the Malaria Vaccine Development Unit at the Laboratory of Parasitic Diseases. Dr. Kaslow has been awarded numerous professional honors, including the U.S. Public Health Service Outstanding Service Medal. He has published more than 120 scientific papers, and authored more than 20 review articles and book chapters. He holds or co-holds 13 patents. Dr. Kaslow received his M.D. from the School of Medicine at the University of California, San Francisco, in 1983 and his bachelor's degree from the University of California, Davis, in 1979.

Martha J. Demski joined us as Chief Financial Officer in December 1988 and currently serves as Vice President, Chief Financial Officer, Treasurer and Secretary. From August 1977 until joining us, Ms. Demski held various positions with Bank of America, lastly as Vice President/Section Head of the Technology Section. She also served as an adviser to Bank of America on a statewide basis regarding the biotechnology industry in California. Ms. Demski received an M.B.A. in Finance and Accounting from The University of Chicago Graduate School of Business in 1977 and a B.A. from Michigan State University in 1974.

Alan E. Dow, J.D., Ph.D., joined us in June 2001 as Vice President and General Counsel. Dr. Dow came to Vical from Pillsbury Winthrop LLP, where he was a Senior Attorney practicing general corporate and intellectual property law for clients in the United States and abroad. His focus was in the areas of biotechnology, genomics, pharmaceuticals, agricultural biotechnology and chemistry. From 1998 to 2000, Dr. Dow was Corporate Counsel, Intellectual Property, for Pharmacia Corporation, and from 1994 to 1998 he was an Associate Attorney with Klarquist, Sparkman, Campbell, Leigh & Whinston of Portland, Oregon. Dr. Dow earned his J.D. from Stanford Law School in 1994, his Ph.D. from Harvard University in 1992, and his B.S. degree in chemistry, with high distinction, from the University of Maine at Orono in 1977.

Additional Business Risks

You should carefully consider the risks described below, together with all of the other information included in this report, before deciding whether to invest in or continue to hold our common stock. The risks and uncertainties described below are not the only ones facing us, because we are also subject to additional risks and uncertainties not presently known to us. If any of these known or unknown risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.

None of our products has been approved for sale, and we have only one product candidate in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our potential products are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our products. Very little data exists regarding the safety and efficacy of DNA-based vaccines or therapies. Results of our research and development activities may indicate that our potential products are unsafe or ineffective. In this case, regulatory authorities will not approve them.

For example, we recently announced that the efficacy data from our low-dose Phase III registration trial with Allovectin-7[®] in patients with metastatic melanoma would not support a registration submission with the FDA. We also recently announced that further independent development of Allovectin-7[®] for head and neck cancer, and of Leuvectin[®] for kidney cancer and prostate cancer, was not justified in light of our other priorities. As a result, our only product candidate currently in clinical trials is high-dose Allovectin-7[®] for metastatic melanoma.

Additionally, we are in the early stages of research and development of vaccine candidates for infectious diseases such as CMV and anthrax. These vaccine candidates will require significant costs to advance through the development stages. If such vaccine candidates are advanced to clinical trials, the results of such trials may not support FDA approval. Even if approved, our products may not be commercially successful. If we fail to develop and commercialize our products, we may be forced to curtail or cease operations.

Commercialization of some of our potential products depends on collaborations with others. If our collaborators are not successful or if we are unable to find collaborators in the future, we may not be able to develop these products.

Our strategy for the research, development and commercialization of some of our product candidates requires us to enter into contractual arrangements with corporate collaborators, licensors, licensees and others. Our success depends upon the performance by these collaborators of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect or we may not derive any revenue from these arrangements.

We have collaborative agreements with several pharmaceutical companies. We do not know whether these companies will successfully develop and market any products under their respective agreements. Moreover, some of our collaborators are also researching competing technologies to treat the diseases targeted by our collaborative programs. We may be unsuccessful in entering into and maintaining other collaborative arrangements to develop and commercialize our products.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold or received approval to sell any products and do not expect to sell any products for the next several years. Our net losses were approximately \$27.9 million, \$9.2 million and \$8.5 million for 2002, 2001 and 2000, respectively. As of December 31, 2002, we have incurred cumulative net losses totaling approximately \$90.3 million. Moreover, we expect that our negative cash flow and losses from operations will continue and may increase for the foreseeable future. For 2003, we have forecast a net loss of between \$24 million and \$28 million. We may not be able to achieve our projected results, either because we generate lower revenues or lower investment income than expected, or we incur greater expenses than expected, or all of the above. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. We may not be able to raise additional funds on favorable terms, or at all. If we are unable to obtain additional funds, we may have to reduce our capital expenditures, scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need will depend on many factors, including:

- the progress of our research and development programs,
- the scope and results of our preclinical studies and clinical trials, and
- the time and costs involved in:
 - obtaining necessary regulatory approvals,
 - filing, prosecuting and enforcing patent claims,
 - scaling up our manufacturing capabilities, and
 - the commercial arrangements we may establish.

The regulatory approval process is expensive, time consuming and uncertain, which may prevent us from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators are subject to extensive and rigorous regulations by numerous governmental authorities in

the United States and other countries. The regulations are evolving and uncertain. The regulatory process can take many years and require us to expend substantial resources. For example:

- The FDA has not established guidelines concerning the scope of clinical trials required for gene-based products,
- The FDA has not indicated how many patients it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products, and
- Current regulations are subject to substantial review by various governmental agencies.

Therefore, U.S. or foreign regulations could prevent or delay regulatory approval of our products or limit our ability to develop and commercialize our products. Delays could:

- impose costly procedures on our activities,
- diminish any competitive advantages that we attain, or
- negatively affect our results of operations and cash flows.

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We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we must sponsor and file a regulatory application for each proposed use. We then must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The results obtained so far in our clinical trials may not be replicated in our on-going or future trials. This may prevent any of our potential products from receiving FDA approval.

We use recombinant DNA molecules in our product candidates, and therefore we also must comply with guidelines instituted by the NIH and its Recombinant DNA Advisory Committee. The NIH could restrict or delay the development of our product candidates.

We understand that both the FDA and NIH are considering rules and regulations that would require public disclosure of commercial development data that is presently confidential. This potential disclosure of commercial confidential information, if implemented, may result in loss of advantage of competitive secrets.

Adverse events in the field of gene therapy, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

The death in 1999 of a patient undergoing a viral-delivered gene therapy at the University of Pennsylvania in an investigator-sponsored trial was widely publicized. More recently, two children in France who received retroviral-delivered ex vivo gene transfer for the treatment of X-linked Severe Combined Immunodeficiency Disease, called X-SCID or “bubble boy” syndrome, developed leukemia that is believed to be related to the viral delivery vehicle. The FDA responded to these events in France by temporarily halting all U.S. clinical trials using retroviral vectors to transduce hematopoietic stem cells. Following public advisory committee review by experts in the field, the FDA allowed these trials in the U.S. to continue under careful scrutiny, because the potential benefit of the investigational gene therapy in patients with this life-threatening condition was believed to justify the risk.

Some of our potential products may be administered to patients who are suffering from or vulnerable to diseases which can themselves be life-threatening. For example, one patient who had undergone treatment with Allovectin-7[®] for advanced metastatic melanoma died more than two months later of progressive disease and numerous other factors after receiving multiple other cancer therapies. The death was originally reported as unrelated to the treatment. Following an autopsy, the death was reclassified as “probably related” to the treatment because the possibility could not be ruled out. We do not believe Allovectin-7[®] was a significant factor in the patient’s death.

As another example, we may administer our developmental CMV vaccine to patients who are at risk of CMV reactivation. Likewise, our developmental anthrax vaccine may eventually be administered to patients who have been exposed to anthrax. Although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal.

These adverse events, and real or perceived risks, could result in greater government regulation and stricter labeling requirements for DNA-based vaccines or therapies, and may adversely impact market acceptance of some of our product candidates. Increased scrutiny in the field of gene therapy also may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

We may not receive any patents from our current patent applications. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technology and products. Finally, others may challenge or seek to circumvent or invalidate our patents. In that event, the rights granted under our patents may be inadequate to protect our proprietary technology or to provide any commercial advantage.

Our core DNA delivery technology is covered by patents that have been issued and revoked as a result of oppositions in Europe and Japan. In addition, our core DNA delivery technology is covered by a patent that was withdrawn from issuance as a result of a protest procedure in Canada. If we are not

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successful in appealing the revocation or withdrawal from issuance of our patents in Europe, Japan or Canada, we may lose all or part of our proprietary protection on our product candidates in these countries or regions.

Some components of our gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our success will depend in part on our ability to obtain patent protection for our products and processes both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technology. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation will be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. Moreover, if a competitor were to file a patent application claiming technology also invented by us, we would have to participate in an interference proceeding before the United States Patent and Trademark Office, or PTO, or in a foreign counterpart to determine the priority of the invention. We may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our licensees to commercialize products based on our technology. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technology.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we may have to obtain licenses to test, use or market these products. Our business will suffer if we are not able to obtain licenses at all or on terms commercially reasonable to us and we may not be able to redesign our products or processes to avoid infringement.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies, including major pharmaceutical and biotechnology firms, that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technology from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources. Other companies may succeed in developing products and obtaining FDA approval faster than we do, or in developing products that are more effective than ours. While we will seek to expand our technological capabilities to remain competitive, research and development by others will seek to render our technology or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us. Additionally, even if our product development efforts are successful, and even if the

requisite regulatory approvals are obtained, our product may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our product candidates do not achieve market acceptance, we may lose our investment in that product, which could have a material adverse impact on our operations.

The method of administration of some of our product candidates can cause adverse events in patients, including death.

Some of our potential products are designed to be injected directly into malignant tumors. There are medical risks inherent in direct tumor injections. For example, in clinical trials of our potential products, attending physicians have punctured patients' lungs in less than one percent of procedures, requiring hospitalization. In addition, a physician administering our product in an investigator-sponsored clinical trial inadvertently damaged tissue near the heart of a patient, which may have precipitated the patient's death. These events are reported as adverse events in our clinical trials. These risks may adversely impact market acceptance of some of our product candidates.

We may suffer a financial loss due to impairment which is other than temporary if Corautus is unable to successfully complete its development plans.

In February 2000, we received Series B Preferred Stock in VGI in exchange for granting VGI a license to our technology. This investment was recorded on our balance sheet at its estimated fair value on the date of investment of \$5.0 million. In September 2002, VGI and GenStar Therapeutics announced a proposed merger. At that time, we wrote down our investment to \$0.8 million based on the objective values established as a result of the proposed merger. This merger subsequently closed in February 2003 and the shares of the new entity, Corautus, began trading on the AMEX.

Corautus still needs to raise substantial cash to complete its development plans, and there can be no assurance that its developmental therapy for angiogenesis will work or that the FDA will approve such a treatment. Corautus may not be able to raise such funds or successfully commercialize a product even if it receives FDA approval. Our investment in Corautus is currently recorded on our balance sheet at \$0.8 million. We may incur a further write-down of up to \$0.8 million due to impairment which is other than temporary if we were to sell our shares on the open market at below our cost or if Corautus is unable to successfully complete its development plans.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to pursue collaborations or develop our own products.

We are highly dependent on the principal members of our scientific, manufacturing, clinical, regulatory and management personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as personnel with expertise in clinical trials, government regulation and manufacturing. We may not be successful in hiring or retaining qualified personnel.

We may not be able to manufacture products on a commercial scale.

We have limited experience in manufacturing our product candidates in commercial quantities. We may be dependent initially on corporate collaborators, licensees or others to manufacture our products commercially. We also will be required to comply with extensive regulations applicable to manufacturing facilities. We may be unable to enter into any arrangement for the manufacture of our products.

We may not be able to sublease vacated space in our older manufacturing, research laboratory and office sites.

We currently hold three leases at three sites for our older manufacturing, research laboratories and offices, which do not terminate until 2004. In 2002, we initiated activities to sublease space that we intended to vacate after moving most of our employees to our new facility in 2003. We recorded an expense of \$0.7 million in 2002 for the difference between our remaining lease obligations and the

amounts we expect to recover by subleasing the vacated space, including a \$0.2 million write-down of the unamortized balance of leasehold improvements. In March 2003, we subleased to a third party approximately half of the vacated space. Currently there is excess office space available for rent or sublease in San Diego. This condition may continue or worsen before we are able to sublease the remaining vacated space. If we are unable to sublease this remaining space, or if the final negotiated sublease rates, or the number of months we are able to sublease the remaining vacated space, are less than the amounts we assumed in our net loss calculations for this space, we may need to

significantly adjust our estimated accrual, which in turn could materially affect our results of operations.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. In order to market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time consuming and could delay any product launch. Our inability to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities will harm our business.

Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

- government health administration authorities,
- government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor,
- private health coverage insurers,
- managed care organizations, and
- other organizations.

If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing our potential products.

There are efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

Certain portions of the HIPAA that become effective this year are expected to impact the rate at which clinical trials may be initiated, however the specific nature and degree of impact are not yet known.

Additionally, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of

accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the development of chemical and pharmaceutical products. Although we currently maintain product liability insurance, we may not have sufficient insurance coverage and we may not be able to obtain sufficient coverage at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators. We also have liability for products manufactured by us on a contract basis for third parties. If we are sued for any injury caused by our technology or products, our liability could exceed our insurance coverage and total assets.

Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you paid for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. The following factors, among others, could have a significant impact on the market price of our common stock:

- the results of our preclinical studies and clinical trials or those of our collaborators or competitors or for gene therapies in general,
- evidence or lack of evidence of the safety or efficacy of our potential products or the products of our competitors,
- the announcement by us or our competitors of technological innovations or new products,
- geopolitical developments, natural or man-made disease threats, or other events beyond our control,
- U.S. and foreign governmental regulatory actions,
- changes or announcements in reimbursement policies,
- developments with our collaborators,

- developments concerning our patent or other proprietary rights or those of our competitors, including litigation and challenges to our proprietary rights,
- concern as to the safety of our potential products,
- period-to-period fluctuations in our operating results,
- market conditions for life science stocks in general,
- changes in the collective short interest in our stock,
- changes in estimates of our performance by securities analysts, and
- our cash balances, need for additional capital, and access to capital.

We are at risk of securities class action litigation due to our expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

Our anti-takeover provisions could discourage potential takeover attempts and make attempts by stockholders to change management more difficult.

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan adopted in March 1995, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved by our Board of Directors and may have the effect of deterring hostile takeover attempts.

ITEM 2. PROPERTIES

We lease approximately 120,000 square feet of manufacturing, research laboratory and office space in northern San Diego, California, at four sites and with four leases. Our newest leased facility, known as Pacific Center Court, or PCC, has approximately 68,400 square feet of manufacturing, research laboratory and office space. This site will allow us to consolidate most of our operations and offices while increasing our manufacturing capacity for both clinical and commercial production, with the planned addition of a 500-liter or larger fermenter and associated processing equipment. We began occupying PCC in the first quarter of 2003 and expect to complete our move by mid-year 2003. This lease terminates in 2017. We have the option to renew this lease for three additional five-year periods beyond the expiration, and we have a one-time purchase option at 110 percent of fair market value which we can exercise in year nine of the lease.

We have the option to renew two of the three leases on our older facilities for an additional five-year period and can renew the third for two additional five-year periods. We currently hold three leases at three sites for our older manufacturing, research laboratories and offices, which do not terminate until 2004. In 2002, we initiated activities to sublease space that we intended to vacate after moving most of our employees to our new facility in 2003. We recorded an expense of \$0.7 million in 2002 for the difference between our remaining lease obligations and the amounts we expect to recover by subleasing the vacated space, including a \$0.2 million write-down of the unamortized balance of leasehold improvements. In March 2003, we subleased to a third party approximately half of the vacated space. Currently there is excess office space available for rent or sublease in San Diego. This condition may continue or worsen before we are able to sublease the remaining vacated space.

Under generally accepted accounting principles, we have to recognize level monthly rent expense over the entire lease period. In the case of PCC, this level monthly rent is calculated by adding the total rent payments over the entire lease period and then dividing the result by the 183 months of the lease. The projected level monthly rental on PCC, excluding estimated common area maintenance costs, is approximately \$231,000. The total current monthly rent on our older facilities, net of rental payments to be received pursuant to the March 2003 sublease, and excluding common area maintenance costs, is approximately \$99,000.

Within our older facilities, we have manufactured sufficient quantities of pharmaceutical-grade product to supply our previous and ongoing clinical trials, including the current registration trials. In addition, we have manufactured preclinical and clinical supplies of DNA for our corporate collaborators, government agencies and numerous academic researchers. We anticipate that our manufacturing operations at PCC will be fully productive in the first half of 2004.

ITEM 3. LEGAL PROCEEDINGS

Our core DNA delivery technology was covered by a patent issued in Europe in 1998, which was subsequently opposed by seven companies under European patent procedures. This patent was revoked on formal grounds in October 2001 under an initial ruling by the Opposition Division of the European Patent Office. The Opposition Division ruled that, as a result of amendments to the claims made during the process of obtaining the European patent and during the opposition process, the claims did not comply with European patent laws. In April 2002, we filed an appeal, which is still pending, seeking to overturn this initial ruling. We intend to vigorously defend our patent position in the European opposition proceedings. If we are not successful in the appeal and opposition proceedings, we may lose part or all of our proprietary protection on our product candidates in Europe. However, we may also use additional patent applications that are pending in Europe to secure patent protection for our core DNA delivery technology.

Our core DNA delivery technology is also covered by patent applications filed in Canada. A Canadian patent was issued and then withdrawn from issuance and returned to the examiner for further consideration after protests against the issuance of the patent were filed on behalf of an undisclosed party

Our core DNA delivery technology is also covered by patent applications filed in Japan. On January 2, 2002, Japanese Patent 3250802 was published, and simultaneously opened for third party opposition. We received an Office Action from the JPO notifying us that the patent had been revoked by the examining panel at the JPO. Both formal and substantive grounds for the revocation were given. We intend to file a rebuttal response on or before May 28, 2003.

Licensed DNA Delivery Technology. We have licensed from the University of Michigan rights to various U.S. and international patents related to injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7[®] and Leuvectin[®]. Included in this license is European Patent Number 0591385, which was granted, and simultaneously opened for opposition, on March 20, 2002. We have received notice from the European Patent Office that one company filed an opposition on December 19, 2002, alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible on February 13, 2003. We intend to file a rebuttal response on or before the due date of June 13, 2003, or, if we are granted a six-month extension, on or before the extended due date of December 13, 2003.

In the ordinary course of business, we may become a party to lawsuits involving various matters. We are unaware of any such lawsuits presently pending against us.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the Nasdaq National Market under the symbol "VICL." The following table presents quarterly information on the price range of high and low sales prices for our common stock on the Nasdaq National Market for the periods indicated since January 1, 2001.

	High		Low	
2002				
First Quarter	\$	12.48	\$	7.75
Second Quarter		10.14		4.60
Third Quarter		7.30		2.31
Fourth Quarter		4.24		2.56
2001				
First Quarter	\$	20.50	\$	8.53
Second Quarter		18.00		8.69
Third Quarter		14.10		8.35
Fourth Quarter		14.00		9.56

As of March 19, 2003, there were approximately 450 stockholders of record of our common stock with 20,091,344 shares outstanding. We have never declared or paid any dividends and do not expect to pay any dividends in the foreseeable future.

See Item 12 for information about our two equity compensation plans.

ITEM 6. SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data for each of the five years ended December 31, 2002. The information presented should be read in conjunction with the financial statements and notes included elsewhere in this report.

	Year ended December 31,				
	2002	2001	2000	1999	1998
	(in thousands, except per share amounts)				
Statements of Operations Data:					
Revenues(1):					
License/royalty revenue	\$ 3,999	\$ 7,572	\$ 5,027	\$ 8,294	\$ 5,044
Contract revenue	3,008	3,794	2,593	2,417	876
	<u>7,007</u>	<u>11,366</u>	<u>7,620</u>	<u>10,711</u>	<u>5,920</u>
Operating expenses:					
Research and development	26,374	22,094	18,514	15,344	12,054
General and administrative	8,061	6,501	5,265	4,376	3,650
Write-down of investment(2)	4,200	—	—	—	—
Total operating expenses	<u>38,635</u>	<u>28,595</u>	<u>23,779</u>	<u>19,720</u>	<u>15,704</u>
Loss from operations	<u>(31,628)</u>	<u>(17,229)</u>	<u>(16,159)</u>	<u>(9,009)</u>	<u>(9,784)</u>
Investment income(3),(4)	3,984	8,286	9,357	2,229	2,465
Interest expense	(288)	(297)	(205)	(129)	(162)
Net loss before cumulative effect of accounting change	<u>(27,932)</u>	<u>(9,240)</u>	<u>(7,007)</u>	<u>(6,909)</u>	<u>(7,481)</u>
Cumulative effect of accounting change(1)	—	—	(1,510)	—	—
Net loss	<u>\$ (27,932)</u>	<u>\$ (9,240)</u>	<u>\$ (8,517)</u>	<u>\$ (6,909)</u>	<u>\$ (7,481)</u>
Net loss per share (basic and diluted)	<u>\$ (1.39)</u>	<u>\$ (0.46)</u>	<u>\$ (0.43)</u>	<u>\$ (0.43)</u>	<u>\$ (0.47)</u>
Weighted average shares used in per share calculation(3)	<u>20,079</u>	<u>20,032</u>	<u>19,689</u>	<u>16,136</u>	<u>15,798</u>
	As of December 31,				
	2002	2001	2000	1999	1998
	(in thousands)				
Balance Sheets Data:					
Cash, cash equivalents and marketable securities, including restricted(3)	\$ 111,513	\$ 134,087	\$ 148,144	\$ 37,675	\$ 40,184
Working capital(3)	106,608	130,933	145,569	35,996	38,398
Total assets(3)	129,426	154,495	162,903	45,059	44,844
Long-term obligations	4,319	4,545	5,121	740	801
Stockholders' equity(3)	114,307	142,159	150,794	38,669	40,824

- (1) In the fourth quarter of 2000, we changed our revenue recognition accounting policy to conform to the requirements of SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," SAB 101, as more fully described in Note 3 of the Notes to Financial Statements.
- (2) In the third quarter of 2002, we recorded a write-down of \$4.2 million to our investment in VGI, as more fully described in Note 2 of the Notes to Financial Statements.
- (3) In January 2000, we completed the sale of 3,450,000 shares of Vical common stock in a public offering, raising net proceeds of approximately \$117.5 million.
- (4) Investment income in 2001 included realized gains on the sale of marketable securities of \$1.1 million. Realized gains were not material for other years presented.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" above. This discussion and analysis should be read in conjunction with the financial statements and notes included elsewhere in this report.

Overview

We research and develop biopharmaceutical products based on our patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. In addition to advancing our core technology, we have gained access to additional enhancing technologies through licensing and collaborative agreements. We believe the following areas of research offer the greatest potential for our product development efforts:

- Vaccines for use in high-risk populations for infectious disease targets for which there are significant U.S. needs,
- Vaccines for general pediatric or adult populations for infectious disease applications for which a challenge model or accepted surrogate marker are available, and
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise.

For opportunities outside these areas, we plan to continue leveraging our patented technology through licensing and collaborations. In addition, we plan to use our expertise, infrastructure, and financial strength to explore in-licensing or acquisition opportunities.

We have established relationships through licensing our technology to a number of commercial entities, including:

- Merck & Co., Inc.,
- Two divisions of Aventis S.A.:
 - Aventis Pasteur, and
 - Aventis Pharmaceuticals Inc.,
- Merial,
- Centocor, Inc., a wholly-owned subsidiary of Johnson & Johnson,
- Invitrogen Corporation,
- Human Genome Sciences, Inc., and
- Vascular Genetics Inc., which recently merged into Coraetus Genetics Inc.

We have also licensed poloxamer technologies from CytRx Corporation.

To date, we have not received revenues from the sale of our products. We earn revenue from licensing access to our proprietary technology, and by performing services under research and development contracts and manufacturing contracts. We expect to incur substantial operating losses for at least the next several years, due primarily to the expansion of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, our relocation to PCC, and possible advancement toward commercialization activities.

Losses may fluctuate from quarter to quarter as a result of differences in the levels of expenses incurred and the amounts of revenues received from various sources. Such fluctuations may be significant. As of December 31, 2002, our accumulated deficit was approximately \$90.3 million. We expect our net loss for 2003 to be between \$24 million and \$28 million. Our net loss of \$27.9 million for 2002 included a \$4.2 million write-down of our investment in VGI. The anticipated decrease in net loss for 2003

compared with 2002 is due to the aforementioned VGI write-down, partially offset by the expected higher expenses related to preclinical research and development programs, consolidation of our facilities into a new location, and an anticipated decline in investment income.

Change in Accounting Principle

In the fourth quarter of 2000, we completed an evaluation of payments we received under our various option and license agreements. We identified a 1999 agreement with Pfizer, which we believed, under SEC Staff Accounting Bulletin No. 101, or SAB 101, would require a change in accounting as of SAB 101's implementation date of January 1, 2000. The amount of revenue recognized in 1999 that under SAB 101 was required to be deferred as of January 1, 2000, was \$1.5 million.

We implemented SAB 101 in the fourth quarter of 2000, by restating the first three quarters of our 2000 financial statements to apply SAB 101 effective January 1, 2000. Our statement of operations for 2000 reflects a one-time charge to earnings of \$1.5 million for the cumulative effect of the change in accounting principle as of January 1, 2000. In 2002, we recognized \$0.1 million of the deferred license revenue from Pfizer, after recognizing \$0.7 million per year in 2001 and 2000.

Results of Operations

Revenues for the year ended December 31, 2002, were \$7.0 million, compared with revenues of \$11.4 million for the year ended December 31, 2001. License/royalty revenue in 2002 was \$4.0 million and consisted of recognition of license payments from Merial and Centocor totaling \$1.5 million, recognition of deferred license fees primarily from Merial and VGI totaling \$1.5 million, and royalty revenue of \$1.0 million on the sale of proprietary lipids by Invitrogen. Contract revenue in 2002

was \$3.0 million and included revenues from the NIH, principally for manufacturing of DNA for infectious disease vaccines; and contracts from IAVI and from the ONR, for development work on an investigational DNA vaccine to prevent malaria. The agreement between Vical and the ONR provided revenue of \$5.3 million from its execution in September 1998 through its expiration on September 30, 2002. License/royalty revenue of \$7.6 million in 2001 included scheduled milestone payments of \$3.0 million from Merck and \$1.0 million from Centocor, and royalty and other revenue of \$1.0 million. License revenue in 2001 also included recognition of deferred license fees of \$1.8 million from Merial and VGI, and of \$0.8 million primarily from the Pfizer agreement as a result of applying the change in accounting principle discussed in the section above. Contract revenue of \$3.8 million for 2001 included \$1.5 million of revenues from the contract with the ONR, revenue from contracts and grants with NIH, and revenue from Pfizer and other agreements.

We had revenues of \$7.6 million for the year ended December 31, 2000. License/royalty revenue of \$5.0 million in 2000 included \$1.5 million of license fees from a June 2000 license agreement with Aventis Pharmaceuticals and royalty and other revenue of \$1.0 million. License revenue in 2000 also included recognition of deferred license fees of \$1.8 million from Merial and VGI and of \$0.7 million from the Pfizer agreement as a result of applying the change in accounting principle discussed in the section above. Contract revenue of \$2.6 million for 2000 included \$0.9 million of revenues from the contract with the ONR, revenue from contracts and grants with NIH, and revenue from Pfizer and other agreements.

Research and development expenses increased to \$26.4 million in 2002 compared with \$22.1 million in 2001. This increase primarily was due to increased personnel costs, and higher facilities-related and preclinical costs. Research and development expenses were \$18.5 million in 2000. Research and development expenses were higher in 2001 than in 2000 due to increased personnel, facilities, preclinical and intellectual property costs. Clinical trial costs decreased to \$1.7 million in 2002 due to completion of the low dose Allovectin-7[®] registration trials in 2002 and discontinuing the Leuvectin[®] kidney cancer trial. Clinical trials expense decreased to \$3.2 million in 2001 from \$4.1 million in 2000 due to the discontinuation of the Leuvectin[®] kidney cancer clinical trial. As we move forward in 2003, we expect research and development expense to increase as we expand our preclinical programs to broaden our future pipeline. We further expect these efforts to drive increases in spending for outside services, and costs related to intellectual property. We also expect to incur increased costs as a result of relocation to PCC and possible preparation for commercialization activities.

General and administrative expenses increased to \$8.1 million in 2002 compared with \$6.5 million in 2001, and \$5.3 million in 2000. General and administrative expenses increased in 2002 compared with 2001 primarily due to increased personnel-related costs and increased facilities costs. The increase in

2001 compared with 2000 was attributable primarily to increased costs for support personnel, travel, and increased consultant and professional fees.

Operating expenses in 2002 also included a write-down of our investment in VGI, now Corautus. In February 2000, we received shares of Series B Preferred Stock in VGI in exchange for granting VGI a license to our technology. VGI was a privately-held company developing gene-based delivery of the angiogenic growth factor VEGF-2 for cardiovascular applications. No cash was received or paid by either party to this transaction. The shares were recorded as an investment on our balance sheet at estimated fair value, which was \$5.0 million on the date of investment. The preferred stock was convertible into common stock of VGI. In September 2002, GenStar Therapeutics, a public company listed on the AMEX, and VGI announced a merger that would result in the creation of a new entity, Corautus. We evaluated our investment in VGI based on the five-day average share price of GenStar Therapeutics immediately before and after the merger announcement and concluded that it was necessary to write down our investment in VGI to a fair value of \$0.8 million, reflecting the objective values established as a result of the proposed merger. Accordingly, the results of operations reflected a write-down of \$4.2 million to reduce our recorded investment in VGI to its fair value of \$0.8 million. The merger closed in February 2003 and the shares of Corautus began trading on AMEX.

Investment income decreased to \$4.0 million in 2002 compared with \$8.3 million in 2001, and \$9.4 million in 2000. Investment income included realized gains on sales of marketable securities of \$0.2 million, \$1.1 million and \$0.1 million in 2002, 2001, and 2000, respectively. Investment income, excluding the gains on the sale of investments, decreased in both 2002 and 2001 primarily due to significantly lower investment rates of return. Some of our investments are yielding higher returns than we can expect when reinvesting the proceeds upon maturity. Thus, our interest yields are expected to be lower in 2003. The lower interest yields and lower investment balances are expected to result in lower investment income in 2003.

Interest expense was \$0.3 million in 2002 and 2001 compared with \$0.2 million in 2000. Indebtedness for capital leases was higher in 2002 compared with 2001, but lower outstanding balances on bank debt and lower interest rates offset this increase. The increase in 2001 compared with 2000 was due to higher average balances of capital lease obligations and bank notes payable. Interest expense is expected to increase in 2003 as the capital lease obligation increases due to increased capital spending principally for PCC.

Net loss for 2002 was \$27.9 million or \$1.39 per share. Net loss for 2002 included a \$4.2 million write-down of our investment in VGI. Net loss for 2002 was higher than for 2001 due to lower revenues, higher expenses, the write-down of our VGI investment and lower investment income, as explained above. For 2001, we reported a net loss of \$9.2 million, or \$0.46 per share, compared with a net loss of \$8.5 million, or \$0.43 per share, for 2000. The net loss for 2000 included a one-time charge to earnings of \$1.5 million for the cumulative effect of a change in accounting principle as of January 1, 2000. This one-time charge was to reflect the impact of SEC Staff Accounting Bulletin No. 101, "Revenue Recognition." We reported a loss before cumulative effect of change in accounting principle of \$9.2 million for 2001, compared with \$7.0 million for 2000. The increase in loss for 2001 compared with 2000 before the cumulative effect of the change in accounting principle was primarily a result of lower investment income and higher research and development spending.

Other Matters

Since inception, we estimate that we have spent approximately \$156 million on research and development. Approximately \$64 million of this amount was for our two cancer programs, Allovectin-7[®], which is currently in a high dose Phase II trial in melanoma, but for which we have elected not to proceed with a BLA filing based on low dose clinical trials, and Leuvectin[®], for which development was discontinued in September 2002 due to other priorities. The majority of this \$64 million was for Allovectin-7[®]. We expect this Phase II trial to determine whether higher dosing will provide the level of efficacy needed to support further development. Additionally, we are in the early stages of research and development of vaccine candidates for infectious diseases such as CMV and anthrax. These infectious disease candidates will require significant costs to advance through the development stages. See "Product Development—Cancer Therapies—Allovectin-7[®]" for a more detailed explanation of the status of

Allovectin-7[®]. See also "Product Development—DNA Vaccines for Infectious Diseases—Cytomegalovirus" and "—Anthrax" for more detailed discussions of our CMV and anthrax vaccine programs.

We have several other product candidates in the research stage. It can take many years from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible FDA approval of a product. The outcome of the research is unknown until each stage of the testing is completed, up through and including the registration clinical trials. Accordingly, we are unable to predict which potential product candidates we may proceed with, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of common stock and preferred stock, public offerings of common stock, and revenues from collaborative agreements. As of December 31, 2002, we had working capital of approximately \$106.6 million compared with \$130.9 million at December 31, 2001. Cash and marketable securities, including restricted securities, totaled approximately \$111.5 million at December 31, 2002, compared with \$134.1 million at December 31, 2001. In January 2000, we sold 3,450,000 shares of common stock in a public offering which raised net proceeds of approximately \$117.5 million.

Cash used in operating activities increased to \$19.7 million in 2002 compared with \$8.4 million in 2001, principally due to a higher net loss, and an increase in receivables and other assets. These increases more than offset the positive cash flow from the increases in accounts payable and accrued expenses, accrued level rent adjustment, and non-cash charges such as depreciation. Net loss for 2002 included a non-cash write-down of our investment in VGI. In addition we recorded an expense of \$0.7 million for the difference between our remaining lease obligations and the amounts we expect to recover by subleasing the vacated space in our older facilities, including a \$0.2 million write-down of the unamortized balance of leasehold improvements. Cash used in operating activities was \$8.4 million in 2001 compared with \$8.6 million in 2000, despite a higher net loss, because of increases in non-cash charges such as depreciation and deferred compensation. Positive cash flow from the reduction in receivables together with increased accounts payable and accrued expenses more than offset the negative impact of the increase in deferred revenue.

Cash provided from investing activities was \$10.3 million in 2002 compared with \$35.5 million in 2001. Net sales of securities were lower in 2002 because in 2001 we sold marketable securities and invested in cash equivalents of a shorter term. In 2001, we also paid \$3.8 million for a license to certain technology. Capital expenditures were higher in 2001 because we borrowed under a financing agreement to expand the research facility. In 2002, most of the cash expenditures for PCC were funded by the landlord as part of the tenant improvement allowance provided in the lease agreement. Cash used in investing activities was \$106.0 million in 2000, and related principally to our use of the net proceeds from our public offering in that year to invest in marketable securities.

Cash used in financing activities in 2002 was \$1.7 million compared with cash provided from financing activities of \$0.1 million in 2001. The increased use of cash in 2002 compared with 2001 was primarily a result of having no proceeds from notes payable in 2002 compared with \$1.1 million of proceeds from notes payable in 2001. An increase in payments on notes payable and capital lease obligations in 2002 compared with 2001 also contributed to the increase in cash used in financing activities. To finance certain leasehold improvements we borrowed from a bank \$1.1 million in 2001 and \$1.2 million in 2000. These borrowings converted to term loans payable over 42 months in June 2001 and June 2000, respectively. The term loans bear interest approximating the bank's prime rate. At December 31, 2002, outstanding borrowings under the term loans were \$1.0 million, and had interest rates of 4.25 percent and 4.00 percent, respectively.

Cash provided from financing activities was \$120.0 million in 2000, principally as a result of our January 2000 public offering of 3,450,000 shares of Vical common stock, which raised net proceeds of approximately \$117.5 million. In 2002 and 2001, payments on notes payable and capital leases increased over the respective prior year due to increased balances of notes payable and capital lease obligations.

In 2003, we expect that our total net cash used will exceed our projected net loss principally because of timing of cash receipts on certain contract work.

Capital equipment spending, including amounts financed under capital leases, will be significantly higher in 2003 due to our relocation to PCC. In November 2002, we entered into a new lease line with our primary lender to provide up to \$10.8 million of lease financing through November 30, 2003. This financing replaced our previous capital equipment line which was renewed in January 2002. The new lease line includes approximately \$8.0 million of credit for tenant improvements and equipment for PCC. At December 31, 2002, \$0.3 million of borrowings were made against this lease line.

In the fourth quarter of 2002, we recorded an expense of \$0.7 million for the expected loss on vacant leased space that is expected to be subleased at rental rates less than those incurred by us and on the unamortized balance of leasehold improvements. In March 2003, we subleased to a third party approximately half of the vacated space. We will attempt to sublease the remaining vacant space in our older facilities to recover our existing rent payments plus amortization of leasehold improvements. However, if we are unable to do so, our net loss and cash outlays will increase accordingly.

We expect to incur substantial additional research and development expenses and general and administrative expenses, including continued increases in personnel costs, costs related to preclinical testing, outside services, facilities, intellectual property and possible commercialization costs. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. We cannot assure that additional financing will be available on favorable terms or at all.

If additional funding is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2004.

We do not utilize "special purpose entities" for any transactions. Our only "off balance sheet" obligations are for operating leases that are disclosed in Note 8 of the Notes to Financial Statements.

Critical Accounting Policies

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Specifically, management must make estimates in the following areas:

Investment. In February 2000, we received shares of Series B Preferred Stock in VGI, in exchange for granting VGI a license to our technology. VGI was a privately-held company. No cash was received or paid by either party to this transaction. The shares were recorded as an investment on our balance sheet at estimated fair value, which was \$5.0 million on the date of investment. The preferred stock was convertible into common stock of VGI. In September 2002, GenStar Therapeutics, a public company listed on the AMEX, and VGI announced a merger which resulted in the creation of a new entity, Corautus. The merger closed in February of 2003. Subsequent to the merger, the shares of Corautus are traded on AMEX.

We evaluated our investment in VGI based on the five-day average share price of GenStar Therapeutics immediately before and after the merger announcement and concluded that it was necessary to write down the investment in VGI to a fair value of \$0.8 million, reflecting the objective values established as a result of the proposed merger. Accordingly, our results of operations for the year ended December 31, 2002, reflected a write-down of \$4.2 million to reduce the recorded investment in VGI to

Beginning in 2003, our investment in Corautus is expected to be accounted for as an available-for-sale security. Accordingly, any change in the fair value of the shares we own based on the market price of the traded shares will be reflected as unrealized gain or loss in the stockholders' equity section of our balance sheet at the end of each quarter.

Corautus still needs to raise substantial cash to complete its development plans, and there can be no assurance that its developmental therapy for angiogenesis will work or that the FDA will approve such a treatment. Corautus may not be able to raise such funds or successfully commercialize a product even if it receives FDA approval. We may incur a further write-down of up to \$0.8 million if we were to sell our shares on the open market at below our cost or due to impairment which is other than temporary if Corautus is unable to successfully complete its development plans.

Loss on sublease. In 2002, we initiated activities to sublease space that was vacated when we moved most employees to PCC. We recorded an expense of \$0.7 million for the expected loss on vacant leased space that is expected to be subleased at rental rates less than those incurred by us. The expense also included a \$0.2 million write-down of the unamortized balance of leasehold improvements at the date we expect to vacate the old facilities. In March 2003, we subleased to a third party approximately half of the vacated space. If the final negotiated sublease rates or the number of months we are able to sublease the remaining vacated space are less than the amounts we assumed, we may need to significantly adjust our estimated accrual, which in turn, could affect our results of operations and cash flow.

Intangible assets. We capitalize the license fees we pay to acquire access to proprietary technology if the technology is expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized to expense over the estimated average useful life of the technology, 10 years. We also capitalize certain costs related to patent applications. Accumulated costs are amortized over the estimated economic life of the patent, which is generally 20 years and usually commences at the time the patent application is filed. Costs related to patent applications are written off to expense at the time such costs are deemed to have no continuing value. Intangible assets are amortized using the straight-line method. We review long-lived assets and intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable. An impairment loss is recognized when the estimated future cash flows expected from the use of the asset and the eventual disposition are less than its carrying amount. Loss of legal ownership or rights to patents or licensed technology, or significant changes in our strategic business objectives and utilization of the assets, among other things, could give rise to asset impairment.

Deferred tax assets. Deferred tax assets are recorded net of a 100% valuation allowance. This valuation allowance reduces the gross deferred tax assets to the amount that we believe is more likely than not realizable. We considered projections of future taxable income, past operating results and tax planning strategies in making this determination.

Clinical trial expenses. We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and amortizing this total cost for the patient over the estimated treatment period, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the trial site and patient-related costs, including lab costs, related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the length of treatment period for each patient. Treatment periods vary depending on the clinical trial. As actual costs become known to us, we may need to make a material change in our estimated accrual, which could also materially affect our results of operations.

Accruals for potential disallowed costs on contracts. We have contracts with agencies of the U.S. government under which we bill for direct and indirect costs incurred. These billed costs are subject to audit by government agencies. We have established accruals to provide for potential disallowed costs. In the event that the final costs allowed are lower than we have estimated, we may need to make a material change in our estimated accrual, which could also materially affect our results of operations and cash flow.

Revenue recognition

We earn revenue from licensing access to our proprietary technology, and by performing services under research and development contracts and service contracts. As more fully explained in Note 3 of the Notes to Financial Statements, effective January 1, 2000, we changed our method of accounting for certain payments under our collaborative agreements. In general, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determined, and collection is reasonably assured. Any initial license or option payment received under an agreement under which we also provide research and development services is recognized as revenue over the term of the research and development period. Payments for options on a license to our technology are recognized as revenue over the option period. Fees paid to extend an option are recognized as revenue over the option extension period. Upfront license payments are recognized as revenue upon contract signing if the fee is nonrefundable and noncreditable, and if there are no significant performance obligations remaining. Revenue from milestones is recognized as the milestones are achieved and collection of payment is reasonably assured.

Revenue under research and development contracts and manufacturing service contracts is recognized as the services are performed. We do not recognize revenue on contract change orders until the service is performed and we have a signed modification for additional funding for the contract. Prior to that time, any costs incurred for change orders on contracts are deferred if it is probable that we will receive a signed modification increasing the funding under the contract which will allow us to recover the costs incurred. Once the signed modification for additional funding is received, the deferred costs and any related revenue are both recognized. Advance payments received in excess of amounts earned are classified as deferred revenue on the balance sheets.

Recent Accounting Pronouncements

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of a business, as previously defined in that Opinion. We implemented SFAS No. 144 in the first quarter of 2002. Implementation did not have a material effect on our financial position or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections." SFAS No. 145 updates, clarifies and simplifies existing accounting pronouncements including: rescinding SFAS No. 4, which required all gains and losses from extinguishment of debt to be aggregated and, if material, classified as extraordinary items, net of related income tax effect; and amending SFAS No. 13 to require that certain lease modifications that have economic effects similar to sale-leaseback transactions be accounted for in the same manner as sale-leaseback transactions. SFAS No. 145 is effective for fiscal years beginning after May 15, 2002, although early adoption of the provisions related to the rescission of SFAS No. 4 is encouraged. We do not expect adoption of this statement to have a material impact on our results of operations or financial position.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 requires recognition of costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. SFAS No. 146 will affect only the timing of the recognition of future restructuring costs. This statement is effective prospectively for exit or disposal activities initiated after December 31, 2002. We do not expect adoption of this statement to have a material impact on our results of operations or financial position.

In October 2002, the FASB revised the approach for Emerging Issues Task Force, or EITF, Issue No. 00-21—"Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting under arrangements where a company will perform multiple revenue generating activities. EITF Issue No. 00-21 provides guidance on when and how an arrangement should be divided into a separate unit of accounting, and when and how much revenue can be recognized on the

delivered in particular to license, research and development and contract manufacturing agreements often entered into by companies in the biotechnology industry. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We are currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on our financial statements.

In December 2002, the FASB issued FASB Interpretation No. 45, or FIN 45. "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 would require us to record as a liability in our balance sheet any guarantees upon the issuance of such guarantee or indemnification. Additionally, FIN 45 requires disclosures about such guarantees. The initial recognition and initial measurement of guarantees is effective on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure provisions are applicable for financial statements for interim or annual periods ended after December 15, 2002. The adoption of FIN 45 did not have a material effect on our financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure— an amendment of FASB Statement No. 123." This statement amends SFAS No. 123 by providing alternative methods for transition to companies who voluntarily change to the fair value method of accounting for stock options. Additionally, the statement requires expanded and more prominent disclosure in both annual and interim financial statements of the method used to account for stock options and the effect of the method used on reported results. We have provided the required disclosure in Note 1 of the Notes to Financial Statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. At December 31, 2002, no investments in equity securities are made in our investment portfolio which consists of cash equivalents and marketable securities. As of December 31, 2002, 73 percent of the investments would mature within one year, and an additional 22 percent and 5 percent would mature within two and three years, respectively. The average maturity was nine months. Our investments are all classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and marketable securities using the following assumptions: a twelve-month time horizon, a nine-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$1.0 million lower than the reported fair value of our investments at December 31, 2002. Our rate of return on investments, excluding realized gains on sales of investments, has decreased as the Federal Reserve Board has lowered interest rates. Some of our investments were purchased prior to the reductions, and are currently yielding higher returns than we could expect when reinvesting the proceeds upon sale or maturity. Thus, our interest yields are expected to be lower in 2003. The lower investment yields and lower investment balances are expected to result in lower investment income in 2003.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15(a)(1).

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Effective April 16, 2002, we terminated the engagement of Arthur Andersen LLP, or Andersen, as our independent auditor. The decision to terminate the engagement of Andersen was recommended by our Audit Committee. The reports of Andersen on our financial statements for the fiscal years ended December 31, 2001 and 2000, contained no adverse opinion or disclaimer of opinion, nor were the reports qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended December 31, 2001 and 2000, and the interim period between December 31, 2001, and April 16, 2002, there was no disagreement between Andersen and us on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of Andersen, would have caused it to make reference to the subject matter of the disagreement in connection with its report; and there were no reportable events, as listed in Item 304(a)(1)(v) of Regulation S-K.

Effective April 30, 2002, we engaged KPMGLLP, or KPMG, as our independent auditor for the fiscal year ended December 31, 2002. During the fiscal years ended December 31, 2001 and 2000, and the interim period between December 31, 2001, and April 30, 2002, neither we nor anyone acting on our behalf consulted with KPMG regarding the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on our financial statements, or any matters or reportable events as defined in Item 304(a)(2)(ii) of Regulation S-K.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

Certain information required by this item is incorporated by reference from the information under the captions "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our 2003 Definitive Proxy Statement. Additional required information concerning our executive officers is contained in Part I of this report.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the caption "Executive Compensation" contained in our 2003 Definitive Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information under the caption "Security Ownership of Certain Beneficial Owners and Management" contained in our 2003 Definitive Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the information contained under the caption "Certain Transactions" contained in our 2003 Definitive Proxy Statement.

ITEM 14. CONTROLS AND PROCEDURES

Within the 90 days prior to the filing of this report, we carried out an evaluation, under the supervision and with the participation of our President and Chief Executive Officer and our Vice President and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our periodic reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Based upon that evaluation, our President and Chief Executive Officer and Vice President and Chief Financial Officer concluded that our disclosure controls and procedures are effective. There have been no significant changes in our internal controls or other factors that could significantly affect internal controls subsequent to the date we carried out this evaluation.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) (1) Financial Statements

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this report.

[Independent Auditors' Report—KPMG LLP](#)

[Report of Independent Public Accountants—Arthur Andersen LLP](#)

[Balance Sheets as of December 31, 2002 and 2001](#)

[Statements of Operations for the three years ended December 31, 2002](#)

[Statements of Stockholders' Equity for the three years ended December 31, 2002](#)

[Statements of Cash Flows for the three years ended December 31, 2002](#)

[Notes to Financial Statements](#)

(2) Financial Statement Schedules

The schedules required to be filed by this item have been omitted because of the absence of conditions under which they are required, or because the required information is included in the financial statements or the notes thereto beginning on page F-1 of this report.

(3) Exhibits

See the list in paragraph (c) below. Each management contract or compensatory plan or arrangement required to be identified by this item is so designated in such list.

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the quarter ended December 31, 2002.

(c) Exhibits

Exhibit Number	Description of Document
3.1(i)(9)	Restated Certificate of Incorporation.
3.1(ii)(9)	Amended and Restated Bylaws of the Company.
4.1(9)	Specimen Common Stock Certificate.
4.2(2)	Rights Agreement dated as of March 20, 1995, between the Company and First Interstate Bank of California.
4.3(10)	Stock Purchase Agreement dated November 3, 1997, between the Company and Merck & Co., Inc.
4.4(11)	Stock Purchase Agreement dated as of January 22, 1999, between the Company and Pfizer Inc.
10.1(4)(a)	Amended and Restated Stock Incentive Plan of Vical Incorporated.
10.2(5)(a)	1992 Directors' Stock Option Plan of Vical Incorporated.
10.3(a)	Form of Indemnity Agreement between the Company and its directors and officers.
10.6(3)(a)	Employment Agreement dated November 2, 1992, between the Company and Dr. Jon A. Norman.
10.7(3)	Stock Purchase Agreement dated February 20, 1992.
10.8(3)	Lease dated December 4, 1987, between the Company and Nexus/GADCo.—UTC, a California Joint Venture, as amended.
10.9(6)(b)	Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.

10.12(1)(b)	License Agreement dated January 1, 1991, between the Company and Wisconsin Alumni Research Foundation.
10.14(1)(b)	License Agreement dated October 23, 1992, between the Company and the Regents of University of Michigan.
10.16(7)	Research, Option and License Agreement dated September 29, 1994, between the Company and Pasteur Mérieux Sérums & Vaccins (subsequently Aventis Pasteur).
10.17(8)	Amendment dated April 27, 1994, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.19(10)(b)	Amendment dated November 3, 1997, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.20(12)	Amendment No. 4 to the Lease dated December 4, 1987, between the Company and Nippon Landic (U.S.A.), Inc., a Delaware Corporation (as successor in interest to Nexus/GADCo.—UTC).
10.21(13)(b)	License Agreement dated February 24, 2000, between the Company and Human Genome Sciences, Inc.
10.22(13)(b)	License Agreement dated February 24, 2000, between the Company and Vascular Genetics Inc.
10.23(14)(a)	Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.24(15)(a)	Employment Agreement dated May 30, 2001, between the Company and Alan E. Dow.
10.25(16)(a)	Employment Agreement dated September 13, 2001, between the Company and David C. Kaslow.
10.26(18)(b)	Amendment No. 4 dated December 7, 2001, to Research, Option and License Agreement between the Company and Aventis Pasteur (formerly Pasteur Mérieux Sérums & Vaccins).
10.27(18)	Lease dated January 30, 2002, between the Company and Kilroy Realty, L.P. a Delaware Limited Partnership.

/s/ GARY A. LYONS
Gary A. Lyons

Director

March 31, 2003

/s/ ROBERT C. MERTON
Robert C. Merton

Director

March 31, 2003

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**CERTIFICATION UNDER SECTION 302 OF THE
SARBANES-OXLEY ACT**

I, Vijay B. Samant, certify that:

1. I have reviewed this annual report on Form 10-K of Vical Incorporated;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
 - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

By: /s/ VIJAY B. SAMANT
Vijay B. Samant
President and Chief Executive Officer

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**CERTIFICATION UNDER SECTION 302 OF THE
SARBANES-OXLEY ACT (CONT'D.)**

I, Martha J. Demski, certify that:

1. I have reviewed this annual report on Form 10-K of Vical Incorporated;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
 - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

By: /s/ MARTHA J. DEMSKI
Martha J. Demski
Vice President and Chief Financial Officer

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INDEPENDENT AUDITORS' REPORT

Board of Directors and Shareholders
Vical Incorporated:

We have audited the 2002 financial statements of Vical Incorporated as listed in the accompanying index. 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 audit. The 2001 and 2000 financial statements of Vical Incorporated as listed in the accompanying index were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated February 1, 2002.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. 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 audit provides a reasonable basis for our opinion.

In our opinion, the 2002 financial statements referred to above present fairly, in all material respects, the financial position of Vical Incorporated as of December 31, 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP
San Diego, California
February 6, 2003

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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Vical Incorporated:

We have audited the accompanying balance sheets of Vical Incorporated, a Delaware corporation, as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. 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 financial position of Vical Incorporated as of December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP
San Diego, California
February 1, 2002

NOTE: THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP ("ANDERSEN") IN CONNECTION WITH VICAL INCORPORATED'S FORM 10-K FILING FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001. THE INCLUSION OF THIS PREVIOUSLY ISSUED ANDERSEN REPORT IS PURSUANT TO THE "TEMPORARY FINAL RULE AND FINAL RULE REQUIREMENTS FOR ARTHUR ANDERSEN LLP AUDITING CLIENTS," ISSUED BY THE U.S. SECURITIES AND EXCHANGE COMMISSION IN MARCH 2002. NOTE THAT THIS PREVIOUSLY ISSUED ANDERSEN REPORT INCLUDES REFERENCES TO CERTAIN FISCAL YEARS, WHICH ARE NOT REQUIRED TO BE PRESENTED IN THE ACCOMPANYING FINANCIAL STATEMENTS AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2002. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH THIS FILING ON FORM 10-K. SEE EXHIBIT 23.2 FOR FURTHER DISCUSSION.

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VICAL INCORPORATED BALANCE SHEETS

	December 31,	
	2002	2001
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 32,608,954	\$ 43,736,068
Marketable securities-available-for-sale	76,606,286	90,351,409

Marketable security-restricted	2,298,240	—
Receivables and other	5,893,491	4,635,534
Total current assets	117,406,971	138,723,011
Investment	800,000	5,000,000
Property and Equipment:		
Equipment	10,180,279	8,225,632
Leasehold improvements	4,687,877	4,800,503
	14,868,156	13,026,135
Less-accumulated depreciation and amortization	(9,925,642)	(7,966,257)
	4,942,514	5,059,878
Intangible Assets, net	5,642,372	5,406,500
Other Assets	634,091	305,345
	<u>\$ 129,425,948</u>	<u>\$ 154,494,734</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,369,546	\$ 4,492,005
Current portion of capital lease obligations	1,267,974	846,348
Current portion of notes payable	633,333	657,143
Current portion of deferred revenue	1,528,409	1,794,857
Total current liabilities	10,799,262	7,790,353
Long-Term Obligations:		
Long-term obligations under capital leases	1,976,920	1,616,677
Notes payable	340,476	973,810
Deferred revenue	949,315	1,954,926
Deferred lease credits	1,052,726	—
Total long-term obligations	4,319,437	4,545,413

Commitments and Contingencies

Stockholders' Equity:

Preferred stock, \$0.01 par value—5,000,000 shares authorized—none outstanding	—	—
Common stock, \$0.01 par value—40,000,000 shares authorized—20,091,344 and 20,056,344 shares issued and outstanding at December 31, 2002, and December 31, 2001, respectively	200,913	200,563
Additional paid-in capital	203,554,007	203,543,985
Accumulated other comprehensive income	887,068	816,665
Accumulated deficit	(90,334,739)	(62,402,245)
Total stockholders' equity	114,307,249	142,158,968
	<u>\$ 129,425,948</u>	<u>\$ 154,494,734</u>

See accompanying notes to financial statements.

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VICAL INCORPORATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2002	2001	2000
Revenues:			
License/royalty revenue	\$ 3,999,363	\$ 7,572,190	\$ 5,027,407
Contract revenue	3,007,848	3,793,900	2,592,643
	<u>7,007,211</u>	<u>11,366,090</u>	<u>7,620,050</u>
Operating expenses:			
Research and development	26,374,443	22,094,460	18,513,744
General and administrative	8,060,610	6,500,933	5,265,270
Write-down of investment	4,200,000	—	—
	<u>38,635,053</u>	<u>28,595,393</u>	<u>23,779,014</u>
Loss from operations	(31,627,842)	(17,229,303)	(16,158,964)
Other income (expense):			
Investment income	3,983,594	8,285,889	9,356,722
Interest expense	(288,246)	(296,577)	(204,595)
	<u>3,695,348</u>	<u>7,989,312</u>	<u>9,152,127</u>
Loss before cumulative effect of change in accounting principle	(27,932,494)	(9,239,991)	(7,006,837)
Cumulative effect of change in accounting principle	—	—	(1,510,036)
Net loss	<u>\$ (27,932,494)</u>	<u>\$ (9,239,991)</u>	<u>\$ (8,516,873)</u>
Net loss per common share (basic and diluted):			
Loss per share before cumulative effect of change in accounting principle	\$ (1.39)	\$ (0.46)	\$ (0.36)
Cumulative effect of change in accounting principle	—	—	(0.07)
Net loss per common share	<u>\$ (1.39)</u>	<u>\$ (0.46)</u>	<u>\$ (0.43)</u>
Weighted average shares used in computing net loss per common share	<u>20,078,591</u>	<u>20,032,360</u>	<u>19,688,754</u>

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE YEARS ENDED DECEMBER 31, 2002

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity	Total Comprehensive Loss
	Shares	Amount					
BALANCE, December 31, 1999	16,201,136	\$ 162,011	\$ 83,292,870	\$ (140,801)	\$ (44,645,381)	\$ 38,668,699	\$ (7,119,458)
Issuance of common stock	3,450,000	34,500	117,430,126	—	—	117,464,626	
Stock option exercises	487,211	4,872	5,829,891	—	—	5,834,763	
Retirement of optionee shares used in stock swap to exercise stock options	(127,103)	(1,271)	(3,446,207)	—	—	(3,447,478)	
Unrealized gain on marketable securities arising during holding period							\$ 865,942
Reclassification of realized gain included in net loss							(75,483)
Unrealized gain on marketable securities	—	—	—	790,459	—	790,459	790,459
Net loss	—	—	—	—	(8,516,873)	(8,516,873)	(8,516,873)
BALANCE, December 31, 2000	20,011,244	200,112	203,106,680	649,658	(53,162,254)	150,794,196	\$ (7,726,414)
Stock option exercises	45,100	451	281,889	—	—	282,340	
Non-cash compensation expense related to grant of stock options	—	—	155,416	—	—	155,416	
Unrealized gain on marketable securities arising during holding period							\$ 1,250,651
Reclassification of realized gain included in net loss							(1,083,644)
Unrealized gain on marketable securities	—	—	—	167,007	—	167,007	167,007
Net loss	—	—	—	—	(9,239,991)	(9,239,991)	(9,239,991)
BALANCE, December 31, 2001	20,056,344	\$ 200,563	\$ 203,543,985	\$ 816,665	\$ (62,402,245)	\$ 142,158,968	\$ (9,072,984)
Stock option exercises	35,000	350	8,451	—	—	8,801	
Non-cash compensation expense related to grant of stock options	—	—	1,571	—	—	1,571	
Unrealized gain on marketable securities arising during holding period							\$ 282,790
Reclassification of realized gain included in net loss							(212,387)
Unrealized gain on marketable securities	—	—	—	70,403	—	70,403	70,403
Net loss	—	—	—	—	(27,932,494)	(27,932,494)	(27,932,494)
BALANCE, December 31, 2002	20,091,344	\$ 200,913	\$ 203,554,007	\$ 887,068	\$ (90,334,739)	\$ 114,307,249	\$ (27,862,091)

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2002	2001	2000
OPERATING ACTIVITIES:			
Net loss	\$ (27,932,494)	\$ (9,239,991)	\$ (8,516,873)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-down of investment	4,200,000	—	—
Depreciation and amortization	2,736,305	1,882,877	1,200,328
Loss on sublease	720,000	—	—
Compensation expense related to grant of stock options	1,571	155,416	—
Change in operating assets and liabilities:			
Receivables and other	(1,257,957)	(222,457)	(441,456)
Other assets	(328,746)	(135,043)	(23,832)
Accounts payable and accrued expenses	2,360,541	596,474	55,889
Deferred revenue	(1,272,059)	(1,412,692)	(913,691)
Deferred lease credits	1,052,726	—	—
Net cash used in operating activities	(19,720,113)	(8,375,416)	(8,639,635)
INVESTING ACTIVITIES:			
Sales of marketable securities	101,610,544	188,382,838	69,433,851
Purchases of marketable securities	(90,093,258)	(146,903,472)	(173,781,977)
Capital expenditures	(497,657)	(2,004,907)	(1,317,547)
Licensed technology expenditures	—	(3,750,000)	—
Patent expenditures	(762,562)	(188,140)	(364,232)
Net cash provided from (used in) investing activities	10,257,067	35,536,319	(106,029,905)
FINANCING ACTIVITIES:			
Issuance of common stock, net	8,801	282,340	119,851,911
Proceeds from notes payable	—	1,107,700	1,192,300
Payments on notes payable	(657,144)	(502,380)	(273,554)
Principal payments under capital lease obligations	(1,015,725)	(792,582)	(770,617)
Net cash (used in) provided from financing activities	(1,664,068)	95,078	120,000,040

Net (decrease) increase in cash and cash equivalents	(11,127,114)	27,255,981	5,330,500
Cash and cash equivalents at beginning of year	43,736,068	16,480,087	11,149,587
Cash and cash equivalents at end of year	\$ 32,608,954	\$ 43,736,068	\$ 16,480,087
Supplemental Information:			
Cash paid during the year for interest	\$ 291,425	\$ 326,704	\$ 196,384
Non-Cash Investing and Financing Activities:			
Investment in preferred stock of Vascular Genetics Inc. in exchange for grant of license	\$ —	\$ —	\$ 5,000,000
Equipment acquired under capital lease financing	\$ 1,797,594	\$ 1,230,230	\$ 1,428,151
Stock options exercised through swap of outstanding shares owned by optionee, which shares received by the Company were then retired	\$ —	\$ —	\$ 3,447,478

See accompanying notes to financial statements.

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VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2002

1. Summary of Significant Accounting Policies

Organization and Business Activity

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from licensing access to its proprietary technology, and by performing services under research and development contracts and service contracts. The Company is currently dependent on collaborative license arrangements, and contract arrangements with government entities, including the National Institutes of Health, or NIH, for generating revenue. The product candidates currently under development by the Company are in various stages of development. Most product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical trial testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful and that any of the Company's or its collaborators' potential products will prove to be safe and effective in clinical trials. Even if developed, these products may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The Company expects to continue to incur substantial losses and not generate positive cash flow from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flow from operations at all or on a sustained basis.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Property and Equipment

Equipment is recorded at cost and depreciated over the estimated useful lives of the assets, 3 to 5 years, using the straight-line method. Leasehold improvements are recorded at cost and amortized over the shorter of the life of the remaining lease term or the remaining useful life of the asset using the straight-line method.

Intangible Assets

The Company capitalizes license fees paid to acquire access to proprietary technology if the technology is expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized to expense over the estimated average useful life of the technology, 10 years. The Company capitalizes certain costs related to patent applications. Accumulated costs are amortized over the estimated economic lives of the patents, which is generally 20 years and usually commences at the time the patent application is filed. Costs related to patent applications are written off to expense at the time such costs are deemed to have no continuing value. Intangible assets are being amortized using the straight-line method.

Asset Impairment

The Company reviews long-lived assets and intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and the eventual disposition are less than its carrying amount.

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Research and Development Costs

All research and development costs are expensed as incurred, including costs incurred to perform research and manufacturing service contracts. Research and development costs include salaries and personnel-related costs, supplies and materials, outside services, costs of conducting clinical trials, facilities costs and amortization of intangible assets consisting of intellectual property and licensed technology rights. The Company accounts for its clinical trial costs by estimating the total cost to treat a patient in each clinical trial, and amortizing this total cost for the patient over the estimated treatment period beginning when the patient enrolls in the clinical trial. This

estimated cost includes payments to the site conducting the trial, and patient-related lab and other costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the length of treatment that a patient receives.

Revenue Recognition

The Company earns revenue from licensing access to its proprietary technology, and by performing services under research and development contracts and service contracts. As more fully explained in Note 3, effective January 1, 2000, the Company changed its method of accounting for certain payments under its collaborative agreements. In general, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determined, and collection is reasonably assured. Any initial license or option payment received under an agreement under which the Company also provides research and development services is recognized as revenue over the term of the research and development period. Payments for options on a license to the Company's technology are recognized as revenue over the option period. Fees paid to extend an option are recognized as revenue over the option extension period. Upfront license payments are recognized as revenue upon contract signing if the fee is nonrefundable and noncreditable, and if there are no significant performance obligations remaining. Revenue from milestones is recognized as the milestones are achieved and collection of payment is reasonably assured.

Revenue under research and development contracts and manufacturing service contracts is recognized as the services are performed. The Company does not recognize revenue on contract change orders until the service is performed and the Company has a signed modification for additional funding for the contract. Prior to that time, any costs incurred for change orders on contracts are deferred if it is probable that the Company will receive a signed modification increasing the funding under the contract which will allow the Company to recover the costs incurred. Once the signed modification for additional funding is received, the deferred costs and any related revenue are both recognized. Advance payments received in excess of amounts earned are classified as deferred revenue on the balance sheets.

Net Loss Per Common Share

Basic and diluted net loss per common share for each of the three years in the period ended December 31, 2002, has been computed using the weighted average number of shares of common stock outstanding during the three years ended December 31, 2002. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, as the effect would be antidilutive. The weighted average number of shares so excluded was 2,875,270, 2,093,072 and 63,420, for the years ended December 31, 2002, 2001 and 2000, respectively. See Note 10 for options outstanding and average exercise prices.

Accounting for Stock Options

The Company accounts for stock options issued to its employees and non-employee directors using the intrinsic value method. Under this method, no compensation expense is recorded for the fair value of options issued to employees and non-employee directors. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, "Accounting for Stock Based Compensation," as amended by SFAS No. 148. Had compensation cost for the Company's stock option plans been determined consistent with the provisions of SFAS No. 123, the Company's net loss and net loss per common share would have increased to the pro forma amounts indicated below:

	2002	2001	2000
Net loss - as reported	\$ (27,932,494)	\$ (9,239,991)	\$ (8,516,873)
Stock-based compensation expense - pro forma	(4,846,622)	(6,206,917)	(6,760,568)
Net loss - pro forma	<u>\$ (32,779,116)</u>	<u>\$ (15,446,908)</u>	<u>\$ (15,277,441)</u>
Net loss per common share (basic and diluted) - as reported	\$ (1.39)	\$ (0.46)	\$ (0.43)
Net loss per common share (basic and diluted) - pro forma	\$ (1.63)	\$ (0.77)	\$ (0.78)

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The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants: risk free interest rates of 3.86% (2002), 4.24% (2001) and 5.79% (2000); and expected volatility of 82% (2002) and 81% (2001 and 2000). An expected option life of four years and a dividend rate of zero are assumed for the years presented.

The Company accounts for stock options granted to consultants in accordance with Emerging Issues Task Force, or EITF, Issue 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring or in Conjunction with Selling Goods or Services." In September 2001, the Company created a Scientific Advisory Board composed of non-employee advisors. These advisors were issued 60,000 options under the Company's stock incentive plan at an exercise price of \$11.63. The options expire on September 4, 2011. In accordance with EITF Issue 96-18, the estimated fair value of these options is being amortized to expense over the four-year vesting period of the options. Compensation expense is reflected in research and development expense in the accompanying statement of operations and was \$0.0 million and \$0.2 million for the years ended December 31, 2002 and 2001, respectively. The estimated fair value of the options is remeasured at each quarter end during the vesting period and compensation expense is recognized based on the remeasured fair value.

Income Taxes

Deferred tax liabilities and assets 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.

Fair Value of Financial Instruments

The carrying amounts of financial instruments such as receivables, other assets, accounts payable and accrued expenses reasonably approximate fair value because of the short maturity of these items. The Company believes the carrying amounts of the Company's notes payable and obligations under capital leases approximate fair value because the interest rates on these instruments change with, or approximate, market interest rates. See Note 4 for fair value of cash equivalents and marketable securities. For the year ended December 31, 2002, as well as prior periods, the Company did not hold derivative financial instruments and did not engage in hedging activities.

Comprehensive Loss

The Company has implemented SFAS No. 130, "Reporting Comprehensive Income." Accordingly, in addition to reporting net loss, the Company has displayed the impact of any unrealized gain or loss on marketable securities as a component of comprehensive loss and has displayed an amount representing total comprehensive loss for each period presented. The Company has presented the required information in the statements of stockholders' equity.

Business Segments

The Company has adopted SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," and has determined that it operates in one business segment dedicated to research and development of DNA delivery technology. The Company's operations are in the United States. All revenues are generated from the United States, and all long-lived assets are maintained in the United States.

Reclassifications

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

2. Write-down of Investment

In February 2000, the Company received shares of Series B Preferred Stock in Vascular Genetics Inc., or VGI, in exchange for granting VGI a license to Vical technology. VGI was a privately-held company developing gene-based delivery of the angiogenic growth factor VEGF-2 for cardiovascular applications. No cash was received or paid by either party to this transaction. The shares were recorded as an investment on the balance

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sheet at estimated fair value, which was \$5.0 million on the date of investment. The preferred stock was convertible into common stock of VGI. In September 2002, GenStar Therapeutics, a public company listed on the American Stock Exchange, or AMEX, and VGI announced a merger that resulted in the creation of a new entity, called Corautus Genetics Inc., or Corautus. The merger closed in February 2003. Subsequent to the merger, the shares of Corautus are traded on AMEX.

Management of the Company evaluated the investment in VGI based on the five-day average share price of GenStar Therapeutics immediately before and after the merger announcement and concluded that it was necessary to write down the investment in VGI to a fair value of \$0.8 million, reflecting the objective values established as a result of the proposed merger. Accordingly, the results of operations for the year ended December 31, 2002, reflected a write-down of \$4.2 million to reduce the recorded investment in VGI to \$0.8 million. This investment is reflected as "investment" in the accompanying balance sheets. The investment continues to be accounted for using the cost method.

Beginning in 2003, the Company expects to change its accounting for its investment in Corautus to an available-for-sale security. Accordingly, any change in the fair value of the shares owned by the Company based on the market price of the traded shares would be reflected as unrealized gain or loss in the stockholders' equity section of the balance sheet at the end of each quarter.

3. Change In Accounting Principle

In 2000, the Company completed its evaluation of payments the Company received under its various option and license agreements and identified a 1999 agreement with Pfizer, which the Company believes under SEC Staff Accounting Bulletin No. 101- "Revenue Recognition in Financial Statements," or SAB 101, would require a change in accounting as of the implementation date of January 1, 2000. The amount of revenue recognized in 1999 that under SAB 101 was required to be deferred as of January 1, 2000, was \$1.5 million.

The Company implemented SAB 101 in the fourth quarter of 2000 by restating the first three quarters of its 2000 financial statements to apply SAB 101 effective January 1, 2000. The statement of operations for 2000 reflects a one-time charge to earnings for the cumulative effect of the change in accounting principle as of January 1, 2000, of \$1.5 million. In 2002, 2001 and 2000, the Company recognized \$0.1 million, \$0.7 million and \$0.7 million, respectively, of the deferred license revenue from Pfizer.

4. Cash Equivalents and Marketable Securities

The Company invests its excess cash in debt instruments of financial institutions and of corporations with strong credit ratings, in U.S. government obligations, and in money market funds and certificates of deposit in financial institutions. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. Cash equivalents are short-term, highly liquid investments with original maturities of less than three months. Cash equivalents of \$29.3 million and \$43.0 million at December 31, 2002 and 2001, respectively, consist primarily of commercial paper, corporate asset backed securities, federal agency discount notes and money market funds.

The Company classifies its marketable securities as available-for-sale or restricted. The restricted marketable security represents a security that is pledged as collateral for a standby letter of credit in the amount of \$2.3 million. Unrealized holding gains or losses are recorded as a separate component of stockholders' equity. Realized gains or losses are calculated based on the specific identification method. Net investment income in 2001 included realized gains on the sale of marketable securities of \$1.1 million. Realized gains were \$0.2 million in 2002 and \$0.1 million in 2000. At December 31, 2002, marketable securities consisted of the following:

	Amortized Cost	Market Value	Unrealized Gain
U.S. government obligations	\$ 59,528,227	\$ 60,303,509	\$ 775,282
Corporate bonds	10,119,388	10,176,817	57,429
Corporate asset backed securities	7,368,710	7,419,680	50,970
International bond	1,001,133	1,004,520	3,387
	<u>\$ 78,017,458</u>	<u>\$ 78,904,526</u>	<u>\$ 887,068</u>

At December 31, 2002, approximately 73 percent of these securities mature within one year, and an additional 22 percent and 5 percent mature within two and three years, respectively.

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At December 31, 2001, marketable securities consisted of the following:

	Amortized Cost	Market Value	Unrealized Gain
U.S. government obligations	\$ 50,508,042	\$ 50,649,391	\$ 141,349
Corporate bonds	22,370,293	22,760,558	390,265
Corporate asset backed securities	11,622,369	11,819,260	196,891
Certificates of deposit	2,999,951	3,017,220	17,269
International bond	2,034,089	2,104,980	70,891
	<u>\$ 89,534,744</u>	<u>\$ 90,351,409</u>	<u>\$ 816,665</u>

5. Intangible Assets

At December 31, intangible assets consisted of the following:

	2002		2001	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents and patent applications	\$ 2,915,894	\$ 617,272	\$ 2,153,332	\$ 465,582

Licensed technology rights	3,750,000	406,250	3,750,000	31,250
	<u>\$ 6,665,894</u>	<u>\$ 1,023,522</u>	<u>\$ 5,903,332</u>	<u>\$ 496,832</u>

Certain accumulated costs related to patent applications are amortized over the estimated economic lives of the patents, which is generally 20 years and usually commences at the time the patent application is filed. The cost of licensed technology rights is amortized to expense over the estimated average useful life of the technology, 10 years.

Amortization expense is included in research and development expense in the accompanying statements of operations. Aggregate amortization expense was \$0.5 million, \$0.2 million and \$0.1 million, for the years ended December 31, 2002, 2001 and 2000, respectively. Assuming no change in the gross carrying amounts of intangible assets, the Company expects the aggregate amortization expense for each of the years ending December 31, 2003 through 2007 to be approximately \$0.6 million.

6. Significant Contracts and License Agreements

Merck & Co., Inc.

The Company is a party to amended agreements with Merck & Co., Inc., or Merck, which provide Merck with certain exclusive rights to develop and commercialize vaccines using the Company's DNA delivery technology for certain disease targets. The agreements are for human vaccine targets and for animal vaccine targets. Merck has licensed seven preventive human infectious disease vaccines using the Company's DNA delivery technology and has licensed the rights to develop and market therapeutic vaccines against the human immunodeficiency virus, or HIV, and hepatitis B virus, or HBV.

In December 1999, Merck started a Phase I clinical trial of a preventive DNA vaccine to protect against HIV infection. This event triggered a milestone payment of \$1.0 million which the Company received in January 2000. In November 2001, the Company received a \$3.0 million payment from Merck in accordance with its licensing agreement. The payment extends the term of Merck's worldwide rights to use the Company's DNA delivery technology to develop and market therapeutic vaccines against both HIV and HBV. The Company recognized this \$3.0 million as license revenue in the fourth quarter of 2001. Through December 31, 2002, the Company had received a total of \$25.1 million under these agreements, including a \$5.0 million investment in the Company's common stock in 1997. License revenues recognized under these agreements were \$3.0 million in 2001. No revenue was recognized in 2002 or 2000. These two agreements provide for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

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Aventis Pasteur

In December 2001 and December 2002, the Company restructured agreements with Aventis Pasteur, a division of Aventis S.A., in which Aventis Pasteur obtained rights to use the Company's patented DNA delivery technology for specific oncology applications. In exchange, Aventis Pasteur gave up rights to develop and commercialize infectious disease DNA vaccines against malaria, cytomegalovirus, *Helicobacter pylori*, and respiratory syncytial virus, which had been licensed under the Company's original September 1994 agreement with Pasteur Mérieux Sérums & Vaccins, the predecessor of Aventis Pasteur. Through December 31, 2002, the Company had received \$7.9 million under this agreement. The restructured agreement provides for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

Aventis Pharmaceuticals

The Company and Aventis Pharmaceuticals Inc., a division of Aventis S.A., have an agreement that originally granted Aventis Pharmaceuticals an exclusive worldwide license to use the Company's DNA delivery technology to develop certain potential treatments for neurodegenerative diseases. Simultaneously with the restructuring of the Aventis Pasteur agreement in December 2001, the Company reacquired rights to treatments for neurodegenerative diseases from Aventis Pharmaceuticals. In June 2000, the Company and Aventis Pharmaceuticals entered into a license agreement granting Aventis Pharmaceuticals rights to use the Company's technology to deliver a growth factor gene for which Aventis Pharmaceuticals holds rights. The Company received \$1.5 million under this agreement, which was recognized as revenue in June 2000. This agreement provides for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

Merial

The Company has a corporate alliance relating to DNA vaccines in the animal health area with Merial, a joint venture between Merck and Aventis S.A. Merial has exclusive licenses to the Company's DNA delivery technology to develop and commercialize DNA vaccines to prevent certain infectious diseases in domesticated animals. In March 2000, Merial paid \$0.2 million to extend the options to March 2001. In 2001, Merial paid \$1.0 million to extend the options to March 31, 2002. In April 2002, Merial paid the Company \$1.0 million to exercise options for selected targets. This payment was recognized as revenue in the second quarter of 2002. Through December 31, 2002, the Company had received a total of \$7.0 million under this agreement. License revenue recognized under this agreement was \$1.5 million, \$0.7 million and \$0.9 million in 2002, 2001 and 2000, respectively. If Merial markets these vaccines, cash payments and royalties on net product sales would be due to the Company.

Centocor, Inc.

The Company has an agreement allowing Centocor, Inc., or Centocor, a company subsequently acquired by Johnson & Johnson, Inc., to use the Company's DNA delivery technology to develop and market DNA vaccines for the potential treatment of certain types of cancer. In 2001, the Company recognized license revenue of \$1.0 million from scheduled milestone payments from Centocor. In 2002, the parties expanded the agreement and Centocor paid \$0.5 million, which was recognized as revenue in the second quarter of 2002. Through December 31, 2002, the Company had received \$3.7 million under this agreement. The Company may receive further payments plus royalties if Centocor successfully develops products using the Company's technology.

Invitrogen Corporation

In April 1991, the Company licensed the use of certain proprietary lipids for research products applications to Life Technologies, Inc., or Life Technologies, which was subsequently acquired by Invitrogen Corporation, or Invitrogen, in September 2000. Invitrogen manufactures and markets these lipid compounds, and pays royalties to the Company on the sales of the lipids. Through December 31, 2002, the Company had received approximately \$6.2 million in royalty revenues under the Invitrogen/Life Technologies agreement.

Human Genome Sciences, Inc.

In February 2000, the Company and Human Genome Sciences, Inc., or HGS, entered into a reciprocal royalty-bearing license agreement. Under the agreement, the Company has the option to exclusively license up to three genes from HGS for gene-based product development. HGS has the option to license the Company's DNA delivery technology for use in up to three gene-based products. Each party has until September 30, 2004, to exercise its respective options. At December 31, 2002, neither party has selected any gene for an initial option exercise.

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Vascular Genetics Inc.

Under a February 2000 license agreement, the Company granted an exclusive, royalty-bearing license to VGI for DNA delivery of a gene with potential use for revascularization. In exchange, the Company received VGI preferred stock which will be exchanged for common stock of Corautus in 2003. See also Note 2. The Company recorded deferred revenue of \$5.0 million at the date of investment. The deferred revenue balance at December 31, 2002, of \$2.0 million from this agreement is being recognized ratably each month through September 30, 2004. License revenue recognized under this agreement was \$1.1 million in both 2002 and 2001, and was \$0.9 million in 2000.

Office of Naval Research

The Company had a cooperative agreement with the Office of Naval Research to develop a multi-gene malaria DNA vaccine and test its ability to protect humans against malaria. This agreement, as amended, expired in September 2002, and provided approximately \$5.3 million of funding to the Company, of which \$0.3 million, \$1.5 million, and \$0.9 million of contract revenue was recognized in 2002, 2001 and 2000, respectively.

Pfizer Inc

The Company was a party to a collaborative and option agreement and a stock purchase agreement with Pfizer Inc, or Pfizer. Under the agreement, Pfizer paid the Company \$1.0 million in option fees and \$0.5 million of research and development expenses annually for three years, beginning in January 1999. Under the terms of the stock purchase agreement, Pfizer invested \$6.0 million in the Company's common stock. The collaborative and option agreement expired in January 2002.

Other Research and Licensing Agreements

The Company also received revenue under research and licensing agreements and contract service agreements with other entities, including the U.S. government, of which approximately \$3.7 million, \$2.8 million and \$2.0 million was recognized as revenue in 2002, 2001 and 2000, respectively.

Ichor Medical Systems, Inc. In October 2001, the Company and Ichor Medical Systems, Inc., or Ichor, entered into an exclusive agreement to develop products based on the Company's DNA delivery technology and delivered using Ichor's proprietary electroporation systems. This agreement was concluded in December 2002.

CytRx Corporation. In December 2001, the Company entered into an exclusive agreement with CytRx Corporation granting the Company rights to use or sublicense CytRx's poloxamer technology to enhance viral or non-viral delivery of polynucleotides in all preventive and therapeutic human and animal health applications. The agreement excludes applications for four infectious disease vaccine targets licensed to Merck and prostate-specific membrane antigen. In addition, the license agreement permits the Company's use of CytRx's technology to enhance the delivery of proteins in prime-boost vaccine applications that involve the use of polynucleotides. As part of the agreement, the Company made a \$3.8 million up-front payment in December 2001, and will potentially make future milestone and royalty payments. The fees paid for the licensed technology rights are being amortized to expense over the estimated ten-year average useful life of the technology.

Wisconsin Alumni Research Foundation and University of Michigan License Agreements. The Company has research and exclusive license agreements with the Wisconsin Alumni Research Foundation, or WARF, and the University of Michigan for continuing research and license rights to technology related to DNA delivery. The agreements grant the Company the right to commercialize any product derived from specified technology. The fees paid by the Company under these agreements are expensed as incurred.

The Company would be required to pay WARF up to 10 percent of some initial upfront payments and a small percentage of some royalty payments received under the Merck, Aventis Pasteur, Merial, Aventis Pharmaceuticals, Centocor, HGS and VGI agreements. If the Company's research under the CytRx agreement results in the generation of revenue, the Company would be required to make payments to CytRx and to WARF. If the Company were to receive milestone or royalty payments under an agreement with Boston Scientific Corporation, the Company would be required to pay up to 25 percent of some of these payments to the University of Michigan. Royalty expense for these agreements was \$0.2 million in 2002, \$0.4 million in 2001 and \$0.2 million in 2000.

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7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following at December 31:

	2002	2001
Employee compensation	\$ 1,843,404	\$ 1,410,226
Accrued construction liabilities	1,696,332	—
Accrued clinical trials cost	776,273	1,810,435
Accrued contract liabilities	630,720	—
Accrued sub-lease liabilities	517,000	—
Accounts payable	393,333	43,852
Other accrued liabilities	1,512,484	1,227,492
	<u>\$ 7,369,546</u>	<u>\$ 4,492,005</u>

8. Leases and Notes Payable

Leases

The Company leases its office, research and development and manufacturing facilities as well as certain equipment, under operating and capital leases. The minimum annual rents on the facilities are subject to increases specified in the lease or based on changes in the Consumer Price Index subject to certain minimum and maximum annual increases. The Company is also required to pay taxes, insurance and operating costs under the facilities leases. In January 2002, the Company signed a 15-year lease for a new building in northern San Diego, California, known as Pacific Center Court, or PCC. The new facility has approximately 68,400 square feet of manufacturing, research laboratory and office space. The PCC lease provides for specified scheduled rent increases annually. We recognize level monthly rent over the entire lease period. This level monthly rent expense is calculated by adding the total rent payments over the entire lease period and then dividing the result by the total term of the lease. Accordingly, this level rent per square foot will vary from the actual base rent per square foot that the Company pays monthly. The difference between the base rent paid and the level rent expensed of \$1.1 million through December 31, 2002, is recorded as "deferred lease credits" in the balance sheet. The Company has the option to renew the PCC lease for three additional five-year periods beyond its expiration, and has a one-time purchase option at 110 percent of fair market value which the Company can exercise in year nine of the lease.

The Company also holds leases on three older facilities totaling approximately 51,200 square feet, and will continue to hold these leases until they expire in 2004. The Company intends to sublease the majority of this older space as it becomes available. In March 2003, the Company subleased to a third party approximately half of the vacated space. Two of the three older facilities leases can be renewed for one additional five-year period, and the third facility lease can be renewed for two additional five-year periods, beyond their expiration in 2004.

The equipment capital leases are secured by substantially all equipment of the Company. Information about operating and capital leases at December 31, 2002, is set forth below.

	Operating Leases	Capital Leases
Years ending December 31,		
2003	\$ 4,411,669	\$ 1,482,493
2004	4,389,927	1,192,026
2005	2,755,000	619,398
2006	2,837,649	313,835
2007	2,922,778	22,567
Thereafter	32,638,589	—
Total minimum lease payments	<u>\$ 49,955,612</u>	<u>3,630,319</u>
Less amount representing interest		(385,425)
Present value of capital lease payments		3,244,894
Less current portion		(1,267,974)
Long-term obligations under capital leases		<u>\$ 1,976,920</u>

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Rent expense for the years ended December 31, 2002, 2001 and 2000, was \$3.7 million, \$1.6 million and \$1.4 million, respectively. Rent expense for 2002 included \$0.5 million for the expected loss on vacant space in the Company's older facilities that is expected to be subleased at rental rates less than those incurred by the Company. The amount of rent that the Company is obligated to pay under the leases in excess of the sublease rent was approximately \$0.5 million, and is reflected in "accounts payable and accrued expenses" in the accompanying balance sheet. See also Note 7. The Company also recorded a \$0.2 million write-down of the unamortized balance of leasehold improvements at the Company's older facilities.

Cost and accumulated depreciation of equipment, software and other assets under capital leases were as follows:

	Cost	Accumulated Depreciation	Net
December 31, 2002	\$ 5,163,418	\$ 2,216,340	\$ 2,947,078
December 31, 2001	\$ 3,590,286	\$ 1,399,286	\$ 2,191,000

In November 2002, the Company entered into a new lease line with its primary lender to provide up to \$10.8 million of financing through November 30, 2003. This financing replaced a previous capital equipment line which was renewed in January 2002. The new lease line includes approximately \$8.0 million of credit for tenant improvements and equipment for the new leased facility. At December 31, 2002, \$0.3 million of borrowings were made against this lease line. The financial covenants of this lease line require maintaining an unrestricted cash balance of greater than \$45 million or twelve months cash burn, each as defined in the lease agreement.

Notes Payable

During 1999, the Company entered into a financing agreement with a bank to finance certain leasehold improvements at the bank's prime rate less 0.25 percentage points. Under the terms of this financing agreement, outstanding borrowings of \$1.0 million at June 1, 2000, converted from the financing agreement to a note payable over 42 months, as described below.

During 2000, the Company entered into a similar financing agreement to finance certain leasehold improvements at the bank's prime rate. Under the terms of this financing agreement, outstanding borrowings at June 1, 2001, of \$1.3 million converted to a term loan payable over 42 months, as described below. During 2001, the maximum borrowings on this financing agreement were \$1.3 million, the weighted average borrowings were \$0.6 million and the weighted average interest rate was 8.2 percent.

Notes payable consisted of the following at December 31:

	2002	2001
Note payable to bank, payable in monthly installments of \$30,952 through 2004, plus interest at the bank's prime rate (4.25% and 4.75% at December 31, 2002 and 2001, respectively)	\$ 711,904	\$ 1,083,333
Note payable to bank, payable in monthly installments of \$23,810 through 2003, plus interest at the bank's prime rate less 0.25%(4.0% and 4.50% at December 31, 2002 and 2001, respectively)	261,905	547,620
	973,809	1,630,953
Less current portion	(633,333)	(657,143)
Notes payable	<u>\$ 340,476</u>	<u>\$ 973,810</u>
Annual maturities of the notes payable are as follows:		
2003	\$ 633,333	
2004	340,476	
	<u>\$ 973,809</u>	

Financial covenants under the agreement require, among other things, that the ratio of liabilities to tangible net worth not exceed 0.3 to 1.0, and that the Company maintain liquid assets such as cash and certificates of deposit, U.S. treasury bills and other obligations of the federal government, and readily marketable securities of at least \$20 million. In addition, the agreement limits the outstanding borrowings to other lenders to \$13 million.

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9. Contingencies

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against the Company.

10. Stockholders' Equity

Preferred Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 5,000,000 shares of preferred stock. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and to determine the designation of such shares. However, the amended certificate of incorporation specifies the initial series and the rights of that series. No shares of preferred stock were outstanding at December 31, 2002 or 2001.

Common Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 40,000,000 shares of common stock. On January 20, 2000, the Company completed a public offering of 3,450,000 shares of its common stock at a price of \$36.50 per share. Proceeds to the Company, net of underwriting fees and offering expenses, were approximately \$117.5 million.

Stock Plan and Directors Option Plan

The Company has a stock incentive plan, under which 5,200,000 shares of common stock, subject to adjustment as provided in the plan, and including up to a 500,000 share increase that has been approved by the Board of Directors but remains subject to certain conditions and stockholder approval at the Company's 2003 Annual Meeting of Stockholders, are reserved for issuance to employees, non-employee directors and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares. The exercise price of stock options must equal at least the fair market value on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to non-employee directors which vest at the next annual meeting, options generally vest 25 percent on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. The plan has also limited the number of options that may be granted to any plan participant in a single calendar year to 300,000 shares.

The Company also has a directors' stock option plan that provides for the issuance to non-employee directors of up to 210,000 shares of common stock, of which options for 202,500 shares have been granted through December 31, 2002. It is not anticipated that there will be any future grants under the directors' plan.

The following table summarizes stock option transactions for the Company's stock option plans for the years ended December 31, 2002, 2001 and 2000:

	Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Grants
Outstanding December 31, 1999	2,295,265	\$ 14.45	
Granted	783,675	\$ 21.18	\$ 15.62
Exercised	(487,211)	\$ 11.98	
Forfeited	(132,322)	\$ 20.26	
Outstanding December 31, 2000	2,459,407	\$ 16.77	
Granted	662,800	\$ 12.23	\$ 8.89
Exercised	(45,100)	\$ 6.26	
Forfeited	(439,038)	\$ 17.09	
Outstanding December 31, 2001	2,638,069	\$ 15.76	
Granted	814,350	\$ 8.02	\$ 5.87
Exercised	(35,000)	\$ 0.25	
Forfeited	(507,072)	\$ 17.06	
Outstanding December 31, 2002	2,910,347	\$ 13.55	

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The following table summarizes information about stock options outstanding under the Company's stock option plans at December 31, 2002:

Range of Exercise Prices	Options Outstanding		Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable	Weighted Average Exercise Price
\$2.31 — \$9.40	828,250	8.7	80,788	\$ 8.31
\$9.60 — \$13.56	627,171	7.3	361,384	\$ 12.01
\$13.62 — \$16.31	593,821	5.2	563,931	\$ 15.04
\$16.50 — \$20.75	761,930	7.2	499,735	\$ 18.97
\$20.94 — \$59.06	99,175	7.4	88,999	\$ 23.45
	<u>2,910,347</u>	7.2	<u>1,594,837</u>	\$ 15.71

The number of shares and weighted average price of options exercisable at December 31, 2002, 2001 and 2000, were 1,594,837 shares at \$15.71, 1,440,071 shares at \$15.79, and 1,191,609 shares at \$14.01, respectively. At December 31, 2002, shares available for grant under the Company's stock option plans were 1,134,673.

11. Related Parties

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, also is the Director of Strategic Planning at the National Institutes of Health, Dale and Betty Bumpers Vaccine Research Center, or VRC. For the period from November 2000 to March 2003, VRC has contracted with Vical for approximately \$1.8 million for the production of HIV clinical trial supplies. Additionally, for varying periods commencing in February 2001 and ending in February 2003, VRC contracted with Vical for approximately \$0.9 million for providing regulatory support services. Revenue recognized under these contracts was \$0.9 million, \$1.3 million and \$0.1 million, for the years ended December 31, 2002, 2001 and 2000, respectively. Additionally, In July 2002, the Company entered into an agreement with VRC to provide certain regulatory and manufacturing services to VRC related to the research and development of a DNA vaccine against the Ebola virus. Revenue recognized under this contract was \$1.0 million for the year ended December 31, 2002.

Dr. Douglas is on the board of directors of the International AIDS Vaccine Initiative, or IAVI, a not-for-profit entity. Vijay B. Samant, President and CEO of the Company, serves on the Project Management Subcommittee of IAVI. In 2002, the Company signed an agreement with IAVI to provide clinical trial supplies. As of December 31, 2002, IAVI had issued purchase orders under this agreement totaling approximately \$1.1 million. Revenue recognized under this agreement for the year ended December 31, 2002, was \$0.2 million.

The above related-party transactions were approved by a majority or more of the disinterested members of the Company's Board of Directors.

Included in "other assets" at December 31, 2002 and 2001, is the long-term portion of notes receivable, representing amounts due from officers and employees of the Company. The loan agreements allow for the notes to be forgiven under certain circumstances over the next three or four years. Imputed interest is applied at the applicable federal rate. The long-term portion is \$0.4 million and \$0.2 million at December 31, 2002 and 2001, respectively. The current portion, included in "receivables and other", is \$0.1 million at December 31, 2002 and 2001. "Receivables and other" also included \$0.4 million at December 31, 2001, due to the Company from a third party for the sale of the home of an executive officer as part of his employment agreement. This receivable was collected in 2002.

The Company has employment agreements under which salary continuation payments could be required under certain circumstances for four officers. Under the terms of these agreements, if the Company terminates the officer's employment without "cause," or the officer resigns for "good reason," as defined in the agreements, the Company will continue to pay base compensation, plus the prior year's cash bonus in the case of the CEO, for between six and twelve months depending on the agreement. These agreements also specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from the Company.

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Three of the officer agreements also provide for certain relocation payments, for temporary living expenses and housing differentials to be paid for specified periods of time. These payments totaled \$0.3 million in 2002 and \$0.2 million in 2001, including payroll taxes paid by the Company on the officers' behalf. In August 2002 and December 2001, the Company purchased and resold officers' homes and incurred losses of \$0.1 million and \$0.2 million, respectively. In 2001, the Company made a \$0.3 million, interest free loan to one of these officers. This loan is forgivable over four years and interest is imputed at the applicable federal rate. In January 2002, the Company entered into another loan agreement with this same officer. The agreement provides for the loan in the amount of \$0.2 million to be repaid after four years and to be secured by a second deed of trust on the residence. Interest, at the applicable federal rate, is due and payable monthly.

12. Income Taxes

The difference between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate were as follows for the years ended December 31:

	2002	2001
Computed "expected" tax benefit	\$ (9,496,776)	\$ (3,141,324)
State income taxes, net of federal benefit	(1,675,902)	(554,351)
Tax effect of:		
Meals & entertainment	16,633	28,854
Change in valuation allowance	15,421,675	12,640,270
Adjustment to prior year credits and deferred taxes	(3,031,156)	(8,973,449)
Various tax credits	(1,234,474)	—
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets as of December 31 are as follows:

Deferred Tax Assets	2002	2001
Accruals and reserves	\$ 2,146,884	\$ 531,511
Depreciation and amortization	5,557,016	5,509,838
Deferred revenue	789,113	2,492,049
Other	1,913,665	—
Net operating losses	29,168,043	21,021,654
Various tax credits	12,166,687	6,768,613
Total gross deferred tax assets	<u>51,741,408</u>	<u>36,323,665</u>
Less valuation allowance	(51,741,408)	(36,323,665)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2002 and 2001, the Company has available net operating loss carryforwards of approximately \$82.8 million and \$61.7 million, respectively. In addition, the Company has research and development credit and orphan drug credit carryforwards of \$8.9 million as of December 31, 2002, and \$5.5 million as of December 31, 2001, to reduce future federal income taxes, if any. These carryforwards expire through 2022 and are subject to review and possible adjustment by the Internal Revenue Service.

The tax benefit associated with the Company's stock incentive plan was \$4,977,664 as of December 31, 2002, which benefit will be reflected in additional paid-in capital, if realized.

In 1999, one of the Company's product candidates, Allovectin-7[®], was granted orphan drug designation for the treatment of invasive and metastatic melanoma by the FDA's Office of Orphan Products Development. Orphan drug designation provides certain tax benefits for qualifying expenses. In 2000, another of the Company's product candidates, Leuvectin[®], was granted orphan drug designation for treatment of renal cell carcinoma. The Company has discontinued clinical trials for Leuvectin[®] and low dose applications of Allovectin-7[®].

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The Tax Reform Act of 1986 limits a company's ability to utilize certain net operating loss and tax carryforwards in the event of a cumulative change in ownership in excess of 50 percent, as defined in the Act. The Company has completed numerous financings that have cumulatively resulted in a change in ownership in excess of 50 percent, as so defined. The utilization of net operating loss and tax credit carryforwards may be limited due to these ownership changes.

The Company has deferred tax assets of approximately \$51.7 million and \$36.3 million as of December 31, 2002 and 2001, respectively, related primarily to its net operating loss and tax credit carryforwards. A valuation allowance has been recognized to offset the entire amount of the deferred tax asset as it is more likely than not that some or all of the deferred tax asset will not be realized.

13. Employee Benefit Plans

The Company has a net defined contribution savings plan under section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$0.2 million in 2002, and \$0.1 million in 2001 and 2000.

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14. Summary of Unaudited Quarterly Financial Information

The following is a summary of the Company's unaudited quarterly results of operations for the years ended December 31, 2002 and 2001 (in thousands, except per share amounts):

2002	March 31,	June 30,	September 30,	December 31,
Revenues	\$ 1,511	\$ 2,448	\$ 2,520	\$ 528
Research and development costs	6,000	6,368	7,516	6,490
Total operating expenses	7,720	8,420	13,691	8,804
Net loss	\$ (5,224)	\$ (5,019)	\$ (10,216)	\$ (7,473)
Net loss per common share (basic and diluted):	\$ (.26)	\$ (.25)	\$ (.51)	\$ (.37)
Weighted average shares used in per share calculation	20,059	20,077	20,083	20,091

2001	March 31,	June 30,	September 30,	December 31,
Revenues	\$ 2,432	\$ 1,777	\$ 2,386	\$ 4,771
Research and development costs	5,290	5,355	5,424	6,025
Total operating expenses	6,970	7,192	6,904	7,529
Net loss	\$ (1,978)	\$ (3,276)	\$ (2,557)	\$ (1,429)
Net loss per common share (basic and diluted)	\$ (0.10)	\$ (0.16)	\$ (0.13)	\$ (0.07)
Weighted average shares used in per share calculation	20,014	20,021	20,040	20,054

As more fully explained in Note 2, the results of operations for the three months ended September 30, 2002, included a \$4.2 million write-down of the Company's investment in VGI. Also, in the fourth quarter of 2002, the Company recorded an expense of \$0.7 million for the expected loss on vacant leased space that is expected to be subleased at rental rates less than those incurred by the Company, and on the unamortized balance of leasehold improvements when the Company vacates its older facilities.

INDEMNITY AGREEMENT

THIS INDEMNITY AGREEMENT, dated as of [DATE], between VICAL INCORPORATED, a Delaware corporation (hereinafter referred to, together with its subsidiaries, if any, as the "Corporation"), and [NAME OF INDEMNITEE] (the "Indemnitee"),

W I T N E S S E T H:

WHEREAS, Indemnitee is a director, officer, employee or other agent of the Corporation, or is serving at the request of the Corporation as a director, officer, employee or other agent of another corporation, partnership, joint venture, trust or other enterprise (an "Alternate Enterprise") and in such capacity is performing a valuable service for the Corporation; and

WHEREAS, Indemnitee is willing to serve, continue to serve, and take on additional service for or on behalf of the Corporation on the condition that he or she be indemnified as herein provided; and

WHEREAS, it is intended that Indemnitee shall be paid promptly by the Corporation all amounts necessary to effectuate in full the indemnity provided herein.

NOW THEREFORE, in consideration of the premises and the covenants in this Agreement, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Services by Indemnitee. Indemnitee agrees to serve as a director, officer, employee or other agent of the Corporation, or at the request of the Corporation as a director, officer, employee or other agent of an Alternate Enterprise, so long as he or she is duly appointed or elected and qualified in accordance with the applicable provisions of the Restated Certificate of Incorporation and Bylaws of the Corporation or the applicable charter documents of any Alternate Enterprise, and until such time as he or she resigns or fails to stand for election or is removed from his or her position. Indemnitee may at any time and for any reason resign or be removed from such position (subject to any other contractual obligation or other obligation imposed by operation of law), in which event the Corporation shall have no obligation under this Agreement to continue Indemnitee in any such position.

2. Indemnification.

(a) The Corporation shall indemnify Indemnitee against Expenses and Liabilities in connection with any Proceeding arising out of acts or omissions of Indemnitee occurring during Indemnitee's service as a director, officer, employee or other agent of the Corporation, or during Indemnitee's service at the request of the Corporation as a director, officer, employee or other agent of an Alternate Enterprise, or to the fullest extent permitted by the Delaware General Corporation Law (the "DGCL") or the Restated Certificate of Incorporation or Bylaws of the Corporation in effect on the date hereof or as the DGCL or such Restated Certificate of

Incorporation or Bylaws may from time to time be amended (but, in the case of any such amendment, only to the extent such amendment permits the Corporation to provide broader indemnification rights than the DGCL or such Restated Certificate of Incorporation or Bylaws permitted the Corporation to provide before such amendment). The right to indemnification provided in the Restated Certificate of Incorporation and Bylaws of the Corporation shall be presumed to have been relied upon by Indemnitee in serving or continuing to serve the Corporation and shall be enforceable as a contract right. Without diminishing the scope of the indemnification provided by this Section 2, the Corporation shall indemnify Indemnitee whenever he or she is or was a party or is threatened to be made a party to any Proceeding, including without limitation any such Proceeding brought by or in the right of the Corporation, because he or she is or was a director, officer, employee or other agent of the Corporation, or is serving at the request of the Corporation as a director, officer, employee or other agent of an Alternate Enterprise, or because of anything done or not done by Indemnitee in any such capacity, against Expenses and Liabilities actually and reasonably incurred by Indemnitee or on his or her behalf in connection with such Proceeding, including the costs of any investigation, defense, settlement or appeal, except that no indemnification shall be made with respect to any claim, issue or matter if Indemnitee was finally adjudged to be liable to the Corporation by a court of competent jurisdiction due to his or her gross negligence or willful misconduct unless and to the extent that a Delaware Court of Chancery or the court in which the action was heard determines that Indemnitee is entitled to indemnification for such amounts as the court deems proper. For example, if Indemnitee is adjudged liable due to gross negligence or willful misconduct with respect to some but not all claims advanced against him or her, Indemnitee shall be indemnified against those claims as to which he or she was adjudged not to have been grossly negligent or to have engaged in willful misconduct. In addition to, and not as a limitation of, the foregoing, the rights of indemnification of Indemnitee provided under this Agreement shall include those rights set forth in Sections 3, 7, 8 and 12 below.

(b) Indemnitee shall be paid promptly by the Corporation all amounts necessary to effectuate the foregoing indemnity.

(c) Indemnitee shall be entitled under this Agreement to indemnification by the Corporation for a portion of the Expenses and Liabilities that Indemnitee becomes legally obligated to pay in connection with any Proceeding referred to in paragraph (a) above even if not entitled hereunder to indemnification for the total amount thereof, and the Corporation shall indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

3. Advancement of Expenses. All reasonable Expenses incurred by or on behalf of Indemnitee shall be advanced from time to time by the Corporation to Indemnitee within thirty (30) days after the Corporation's receipt of a written request for an advance of Expenses, whether prior to or after final disposition of a Proceeding (except to the extent that there has been a Final Adverse Determination that Indemnitee is not entitled to be indemnified for such Expenses), including without limitation any Proceeding brought by or in the right of the Corporation. The written request for an advancement of any and all Expenses under this paragraph shall contain reasonable detail of the Expenses incurred by Indemnitee. If required by the DGCL at the time of such advance, Indemnitee hereby agrees to repay the amounts advanced if it is ultimately determined that Indemnitee is not entitled to be indemnified pursuant to the terms of this Agreement.

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4. Limitations. The foregoing indemnity and advancement of Expenses shall not apply:

(a) to the extent that Indemnitee has been indemnified and reimbursed pursuant to such insurance as the Corporation may maintain for Indemnitee's benefit, or otherwise; provided, however, that notwithstanding the availability of such other indemnification and reimbursement, Indemnitee may claim indemnification and advancement of Expenses pursuant to this Agreement by assigning to the Corporation, at its request, Indemnitee's claims under such insurance to the extent Indemnitee has been paid by the Corporation;

(b) on account of any claim against Indemnitee solely for an accounting of profits made from the purchase or sale by Indemnitee of securities of the Corporation pursuant to the provisions of Section 16(b) of the Securities Exchange Act of 1934 and amendments thereto or similar provisions of any federal, state or local statutory law;

(c) on account of Indemnitee's conduct that is established by a final judgment as constituting a breach of Indemnitee's duty of loyalty to the Corporation or resulting in any personal profit or advantage to which Indemnitee was not legally entitled;

(d) if indemnification is not lawful (and, in this respect, both the Corporation and Indemnitee have been advised that the Securities and Exchange

Commission believes that indemnification for liabilities arising under the federal securities laws is against public policy and is, therefore, unenforceable and that claims for indemnification should be submitted to appropriate courts for adjudication); or

(e) in connection with any proceeding (or part thereof) initiated by Indemnitee, or any proceeding by Indemnitee against the Corporation or its directors, officers, employees or other agents, unless (i) such indemnification is expressly required to be made by the DGCL, (ii) the proceeding was authorized by the Board of Directors of the Corporation (the "Board of Directors"), (iii) such indemnification is provided by the Corporation, in its sole discretion, pursuant to the powers vested in the Corporation under the DGCL, or (iv) the proceeding is initiated pursuant to Section 8 hereof.

5. Insurance and Funding. The Corporation may purchase and maintain insurance to protect itself and/or Indemnitee against any Expenses and Liabilities in connection with any Proceeding to the fullest extent permitted by the DGCL. The Corporation may create a trust fund, grant an interest or use other means (including, without limitation, a letter of credit) to ensure the payment of such amounts as may be necessary to effect indemnification or advancement of Expenses as provided in this Agreement.

6. Procedure for Determination of Entitlement to Indemnification.

(a) Whenever Indemnitee believes that he or she is entitled to indemnification pursuant to this Agreement, Indemnitee shall submit a written request for indemnification to the Corporation. Any request for indemnification shall include sufficient documentation or information reasonably available to Indemnitee to support his or her claim for indemnification. Indemnitee shall submit such claim for indemnification within a reasonable time not to exceed five (5) years after any judgment, order, settlement, dismissal, arbitration award, conviction,

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acceptance of a plea of nolo contendere or its equivalent, final termination or other disposition or partial disposition of any Proceeding, whichever is the later date for which Indemnitee requests indemnification. The President or the Secretary or other appropriate officer shall, promptly upon receipt of Indemnitee's request for indemnification, advise the Board of Directors in writing that Indemnitee has made such request. Determination of Indemnitee's entitlement to indemnification shall be made not later than ninety (90) days after the Corporation's receipt of his or her written request for such indemnification.

(b) The Indemnitee shall be entitled to select the forum in which Indemnitee's request for indemnification will be heard, which selection shall be included in the written request for indemnification required in Section 6(a). The forum shall be any one of the following:

(i) The stockholders of the Corporation, who shall make the determination by majority vote or written consent;

(ii) The Disinterested Directors, or if designated by a majority of such Disinterested Directors, a committee of the Board of Directors consisting entirely of Disinterested Directors, who shall make the determination by majority vote or written consent; or

(iii) If there are no Disinterested Directors, by Independent Legal Counsel, who shall make the determination in a written opinion.

If Indemnitee fails to make such designation, his or her claim shall be heard in a forum selected by the Corporation in accordance with the DGCL, or shall be determined by an appropriate court of the State of Delaware.

7. Fees and Expenses of Independent Legal Counsel. The Corporation agrees to pay the reasonable fees and expenses of Independent Legal Counsel should such Independent Legal Counsel be retained to make a determination of Indemnitee's entitlement to indemnification pursuant to Section 6 of this Agreement, and to fully indemnify such Independent Legal Counsel against any and all expenses and losses incurred by any of them arising out of or relating to this Agreement or their engagement pursuant hereto.

8. Remedies of Indemnitee.

(a) In the event that (i) a determination pursuant to Section 6 hereof is made that Indemnitee is not entitled to indemnification, (ii) advances of Expenses are not made pursuant to this Agreement, (iii) payment has not been timely made following a determination of entitlement to indemnification pursuant to this Agreement, or (iv) Indemnitee otherwise seeks enforcement of this Agreement, Indemnitee shall be entitled to a final adjudication in an appropriate court of the State of Delaware of his or her rights. The Corporation shall not oppose Indemnitee's right to seek any such adjudication.

(b) In the event that a determination that Indemnitee is not entitled to indemnification, in whole or in part, has been made pursuant to Section 6 hereof, the decision in the judicial proceeding provided in paragraph (a) of this Section 8 shall be made de novo and Indemnitee shall not be prejudiced by reason of a determination that he or she is not entitled to indemnification.

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(c) If a determination that Indemnitee is entitled to indemnification has been made pursuant to Section 6 hereof or otherwise pursuant to the terms of this Agreement, the Corporation shall be bound by such determination in the absence of (i) a misrepresentation of a material fact by Indemnitee or (ii) a specific finding (which has become final) by an appropriate court of the State of Delaware that all or any part of such indemnification is expressly prohibited by law.

(d) In any court proceeding pursuant to this Section 8, the Corporation shall be precluded from asserting that the procedures and presumptions of this Agreement are not valid, binding and enforceable. The Corporation shall stipulate in any such court that the Corporation is bound by all the provisions of this Agreement and is precluded from making any assertion to the contrary.

(e) Expenses reasonably incurred by Indemnitee in connection with his or her request for indemnification under this Agreement, seeking enforcement of this Agreement or to recover damages for breach of this Agreement shall be borne by the Corporation.

9. Modification, Waiver, Termination and Cancellation. No supplement, modification, termination, cancellation or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar), nor shall such waiver constitute a continuing waiver.

10. Notice by Indemnitee and Defense of Claim. Indemnitee shall promptly notify the Corporation in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding, if an claim for indemnification in respect thereof is to be made against the Corporation under this Agreement, but the omission so to notify the Corporation will not relieve it from any liability which it may have to Indemnitee if such omission does not prejudice the Corporation's rights. If such omission does prejudice the Corporation's rights, the Corporation will be relieved from liability only to the extent of such prejudice; nor will such omission relieve the Corporation from any liability which it may have to Indemnitee otherwise than under this Agreement. With respect to any Proceeding as to which Indemnitee notifies the Corporation of the commencement thereof:

(a) The Corporation will be entitled to participate therein at its own expense; and

(b) The Corporation jointly with any other indemnifying party similarly notified will be entitled to assume the defense thereof, with counsel reasonably satisfactory to Indemnitee; provided, however, that the Corporation shall not be entitled to assume the defense of any Proceeding if Indemnitee shall have reasonably concluded, and so notified the Corporation, that there may be a conflict of interest between the Corporation and Indemnitee with respect to such Proceeding. After notice from the Corporation to Indemnitee of its election to assume the defense thereof, the Corporation will not be liable to Indemnitee under this Agreement for any Expenses subsequently incurred by Indemnitee in connection with the defense thereof, other than reasonable costs of investigation or as otherwise provided below. Indemnitee shall have the right

to employ his or her own counsel in such Proceeding but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless:

(i) The employment of counsel by Indemnitee has been authorized by the Corporation; or

(ii) The Corporation shall not in fact have employed counsel to assume the defense in such Proceeding or shall not in fact have assumed such defense and be acting in connection therewith with reasonable diligence;

in each of which cases the fees and expenses of such counsel shall be at the expense of the Corporation.

(c) The Corporation shall not settle any Proceeding in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent; provided, however, that Indemnitee will not unreasonably withhold his or her consent to any proposed settlement. The Corporation shall not be liable to indemnify Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without the Corporation's written consent; provided, however, that the Corporation will not unreasonably withhold its consent to any proposed settlement.

11. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if (i) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, or (ii) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed:

(a) If to Indemnitee, to:

[Name of Indemnitee]
[Address of Indemnitee]

(b) If to the Corporation, to:

Vical Incorporated
9373 Towne Centre Drive, Suite 100
San Diego, CA 92121
Attention: Chief Executive Officer

or to such other address as may have been furnished to Indemnitee by the Corporation or to the Corporation by Indemnitee, as the case may be.

12. Nonexclusivity. The rights of Indemnitee hereunder shall not be deemed exclusive of any other rights to which Indemnitee may now or in the future be entitled under the DGCL, the Corporation's Restated Certificate of Incorporation or Bylaws, or any agreements, vote of stockholders, resolution of the Board of Directors or otherwise.

13. Certain Definitions.

(a) "Disinterested Director" shall mean a director of the Corporation who is not or was not a party to the Proceeding in respect of which indemnification is being sought by Indemnitee.

(b) "Expenses" shall include all direct and indirect costs (including, without limitation, attorneys' fees, retainers, court costs, transcripts, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, all other disbursements or out-of-pocket expenses and reasonable compensation for time spent by Indemnitee for which he or she is otherwise not compensated by the Corporation) actually and reasonably incurred in connection with a Proceeding or establishing or enforcing a right to indemnification under this Agreement, the DGCL or otherwise; provided, however, that "Expenses" shall not include any Liabilities.

(c) "Final Adverse Determination" shall mean that a determination that Indemnitee is not entitled to indemnification shall have been made pursuant to Section 6 hereof and either (1) a final adjudication in a Delaware court pursuant to Section 8(a) hereof shall have denied Indemnitee's right to indemnification hereunder, or (2) Indemnitee shall have failed to file a complaint in a Delaware court pursuant to Section 8(a) for a period of one hundred twenty (120) days after the determination made pursuant to Section 6 hereof.

(d) "Indemnification Period" shall mean the period of time during which Indemnitee shall continue to serve as a director, officer, employee or other agent of the Corporation, or at the request of the Corporation as a director, officer, employee or other agent of an Alternate Enterprise, and thereafter so long as Indemnitee shall be subject to any possible Proceeding arising out of acts or omissions of Indemnitee while serving as a director, officer, employee or other agent of the Corporation, or while serving at the request of the Corporation as a director, officer, employee or other agent of an Alternate Enterprise.

(e) "Independent Legal Counsel" shall mean a law firm or a member of a law firm selected by the Corporation and approved by Indemnitee (which approval shall not be unreasonably withheld) and that neither is presently nor in the past five (5) years has been retained to represent: (i) the Corporation, in any material matter, or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Legal Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Corporation or Indemnitee in an action to determine Indemnitee's right to indemnification under this Agreement.

(f) "Liabilities" shall mean liabilities of any type whatsoever including, but not limited to, any judgments, fines, ERISA excise taxes and penalties, penalties and amounts paid in settlement (including all interest assessments and other charges paid or payable in connection with or in respect of such judgments, fines, penalties or amounts paid in settlement) of any proceeding.

(g) "Proceeding" shall mean any threatened, pending or completed action, claim, suit, arbitration, alternate dispute resolution mechanism, investigation, administrative hearing or any other proceeding whether civil, criminal, administrative or investigative, including any appeal therefrom.

14. Binding Effect, Duration and Scope of Agreement. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Corporation), spouses, heirs and personal and legal representatives. This Agreement shall continue in effect during the Indemnification Period, regardless of whether Indemnitee continues to serve as a director or as an officer.

15. Severability. If any provision or provisions of this Agreement (or any portion thereof) shall be held to be invalid, illegal or unenforceable for any reason whatsoever:

(a) the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby; and

(b) to the fullest extent legally possible, the provisions of this Agreement shall be construed so as to give effect to the intent of any provision held invalid, illegal or unenforceable.

16. Governing Law and Interpretation of Agreement. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, as applied to contracts between Delaware residents entered into and to be performed entirely within Delaware. If the laws of the State of Delaware are hereafter amended to permit the Corporation to provide broader indemnification rights than said laws permitted the Corporation to provide prior to such amendment, the rights of indemnification and advancement of expenses conferred by this Agreement shall automatically be broadened to the fullest extent permitted by the laws of the State of Delaware, as so amended.

17. Consent to Jurisdiction. The Corporation and Indemnitee each irrevocably consent to the jurisdiction of the courts of the State of Delaware for all purposes in connection with any action or proceeding which arises out of or relates to this Agreement and agree that any action instituted under this Agreement shall be brought only in the state courts of the State of Delaware.

18. Entire Agreement. This Agreement represents the entire agreement between the parties hereto, and there are no other agreements, contracts or understandings between the parties hereto with respect to the subject matter of this Agreement, except as specifically referred to herein or as provided in Section 12 hereof.

19. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement.

VICAL INCORPORATED

By _____
Name: _____
Title: _____

[NAME OF INDEMNITEE]

**Amendment # 5
to the Research, Option and License Agreement
dated September 29, 1994**

This Amendment, dated this 23rd day of September, 2002, is by and between **VICAL INCORPORATED**, a Delaware Corporation (“VICAL”), having a place of business located at 9373 Towne Centre Drive, Suite 100, San Diego, California 91212, USA, **AVENTIS PASTEUR**, a French *Société Anonyme* (“AvP”), having a registered head office located at 2 avenue Pont Pasteur, 69007 Lyon, France, and **AVENTIS PASTEUR Limited**, a company organized and existing under the laws of the Province of Ontario, Canada (“AvP-Canada”) and having its principal place of business at Connaught Campus, 1755 Steeles Avenue West, Toronto, Ontario, Canada M2R 3T4.

WHEREAS, VICAL and AvP entered into a Research, Option and License Agreement (“the Agreement”) as of September 29, 1994, as amended by Amendment #1 dated as of September 29, 1994, by Amendment # 2 dated January 26, 1996, by Amendment # 3 dated as of April 15, 1996, and by Amendment # 4 dated December 7, 2001 (“Amendment # 4”) under which AvP was granted Options in the Field of *Immunotherapeutic vaccines against cancer in humans containing the [***]* and to obtain an exclusive license under certain Patent Rights and certain associated technologies owned by or licensed to VICAL; and

WHEREAS, VICAL informed AvP of its interest in reacquiring the rights related to [***]; and

WHEREAS, according to Amendment # 4, AvP’s Option Period will not expire before [***]; and

WHEREAS, AvP agrees to return its rights to [***] to VICAL;

NOW, THEREFORE, the parties agree to amend the Agreement as follows :

1. VICAL hereby requests that AvP abandons its rights to [***] before the end of the Option Period (as defined in Amendment # 4).
2. AvP hereby agrees to abandon the Option rights with respect to [***] (as described in point 3. of Amendment # 4), effective immediately.
3. In consideration of the reversion of rights, as soon as practicable upon execution of this Amendment # 5, VICAL will:
 - Refund to AvP-Canada the USD [***] paid after execution of Amendment # 4; and

[***] Confidential material redacted and separately filed with the Commission.

- Pay to AvP an additional USD [***] for AvP’s administrative efforts since execution of Amendment # 4.

4. Additionally, VICAL hereby offers to AvP an Option to obtain an exclusive, worldwide, royalty bearing license to an available cancer specific antigen (antigen to be identified by a GenBank accession number) under the same terms and conditions as Amendment #4. Such Option shall expire [***] following execution of the present Amendment #5. For the purpose of this Amendment #5, “available cancer specific antigen” shall mean a cancer specific antigen that:

- (i) VICAL is not pursuing either alone or with a Third Party; OR
- (ii) VICAL has not granted rights to a Third Party.

5. Any provision of the Agreement not modified by this Amendment # 5 shall remain unchanged. Capitalized terms in this Amendment # 5 shall have the meaning set forth in the Agreement unless otherwise specified.

IN WITNESS WHEREOF, the parties hereto have had this Amendment # 5 executed by their authorized representatives as set forth below.

VICAL INCORPORATED

AVENTIS PASTEUR Limited

By : /s/ VIJAY SAMANT

Vijay SAMANT
President and C.E.O.

Date : 9/23/02

By : /s/ MARK LIEVONEN

Mark LIEVONEN
President

Date : 10/18/02

AVENTIS PASTEUR S.A.

By : /s/ DAVE WILLIAMS

Dave WILLIAMS
President and CEO

Date : 10/7/02

By : /s/ JIM TARTAGLIA

Jim TARTAGLIA
Vice-President Research

Date : 10/21/02

[***] Confidential material redacted and separately filed with the Commission.

VICAL INCORPORATED
9373 Towne Centre Drive
Suite 100
San Diego, CA 92121

March 10, 2003

Mr. Vijay B. Samant

Re: Amendment to November 28, 2000 Letter Regarding Employment Terms

Dear Vijay:

This Amendment (the "*Amendment*") to your Letter Agreement with Vical Incorporated (the "*Company*") dated November 28, 2000 (the "*Agreement*") will amend the terms and conditions of the Agreement to the extent provided herein and supercedes the Letter Agreement dated February 5, 2002. Except as specifically amended by this Amendment, the terms and conditions of the Agreement shall remain in full force and effect.

Paragraph 6 of the Agreement is hereby deleted in its entirety and replaced with the following:

"6. Relocation. To assist you in moving to the San Diego area, we are prepared to pay the reasonable and customary expenses of relocating you and your family, not to exceed \$60,000 in the aggregate over the term of this Letter Agreement (the aggregate amount of relocation expenses for which you are entitled to reimbursement hereunder shall be referred to herein as the "Relocation Expense Amount"). In addition, in the event your residence in Pennsylvania is prepared and maintained (including customary insurance coverage) for sale in reasonable condition and listed for sale by September 1, 2003, the Company will reimburse you up to \$100,000 of any loss you incur on its sale; *provided that*, in the event such a loss is anticipated, the Company or its designees may, at the Company's sole discretion, purchase that residence for an amount equal to its cost to you (estimated to be approximately \$550,000). Once you and your family have relocated to the San Diego area, the Company will provide to you for a period not to exceed 24 months, a monthly housing cost-of-living differential payment of up to \$2,500 per month. Further, the Company will either pay the costs, not to exceed \$3,500 per month, of temporary housing for you in San Diego or, at the Company's option, provide temporary housing to you until the earlier of your purchase of a San Diego residence or December 31, 2003. The Company will also reimburse you for the reasonable costs of one trip per month in connection with your commuting to San Diego from your home in Pennsylvania, until the earlier of your purchase of a San Diego residence or December 31, 2003. You will be responsible for any personal taxes (income, employment or otherwise) arising from any of the payments described herein, except that the Company will reimburse you for the following: (i) the income, employment and any other taxes

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you incur arising from the Relocation Expense Amount and the actual monthly temporary housing payments received by you (or, if the Company provides temporary housing to you, the amount of income imputed to you with respect thereto); and (ii) the income, employment and any other taxes you incur arising from the payments made by the Company pursuant to Section 6(i) above and this Section 6(ii) so that you shall be fully reimbursed for any income, employment and any other taxes you incur associated with the payments to reimburse you for such income, employment and other taxes on such amounts."

This Amendment shall be governed by and construed in accordance with the laws of the State of California, without regard to conflicts of law principles.

Please sign and date this Amendment and return it to me at your earliest convenience.

Sincerely,

VICAL INCORPORATED

By: /s/ MARTHA J. DEMSKI
Martha J. Demski
Vice President & Chief Financial Officer

ACCEPTED AND AGREED:

/s/ VIJAY B. SAMANT
Vijay B. Samant

March 10, 2003

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Independent Auditors' Consent

The Board of Directors
Vical Incorporated

We consent to the incorporation by reference in the previously filed Registration Statements (No. 33-60826, No. 33-60824, No. 33-81602, No. 33-81600, No. 33-87972, No. 333-30181, No. 333-80681, No. 333-60293, No. 333-66254 and No. 333-97019) on Form S-8 of Vical Incorporated of our report dated February 6, 2003, with respect to the balance sheets of Vical Incorporated as of December 31, 2002 and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2002, which report appears in the December 31, 2002, annual report on Form 10-K of Vical Incorporated.

KPMG LLP
San Diego, California
March 28, 2003

CONSENT OF ARTHUR ANDERSEN

INFORMATION REGARDING CONSENT OF ARTHUR ANDERSEN LLP

AS PREVIOUSLY DISCLOSED IN THE COMPANY'S FORMS 8-K FILED ON APRIL 23, 2002, AND MAY 3, 2002. THE COMPANY DISMISSED ARTHUR ANDERSEN LLP AS ITS INDEPENDENT PUBLIC ACCOUNTANTS EFFECTIVE APRIL 16, 2002 AND ANNOUNCED THAT THE COMPANY HAD APPOINTED KPMG LLP TO REPLACE ARTHUR ANDERSEN LLP AS ITS INDEPENDENT PUBLIC ACCOUNTANTS EFFECTIVE APRIL 30, 2002.

AFTER REASONABLE EFFORTS, THE COMPANY WAS UNABLE TO OBTAIN THE WRITTEN CONSENT OF ARTHUR ANDERSEN LLP TO INCORPORATE BY REFERENCE ITS REPORT DATED FEBRUARY 1, 2002.

THE ABSENCE OF THIS CONSENT MAY LIMIT RECOVERY AGAINST ARTHUR ANDERSEN LLP UNDER SECTION 11 OF THE SECURITIES ACT OF 1933. IN ADDITION, AS A PRACTICAL MATTER, THE ABILITY OF ARTHUR ANDERSEN LLP TO SATISFY ANY CLAIMS (INCLUDING CLAIMS ARISING FROM ARTHUR ANDERSEN LLP'S PROVISION OF AUDITING AND OTHER SERVICES TO THE COMPANY AND ARTHUR ANDERSEN LLP'S OTHER CLIENTS) MAY BE LIMITED DUE TO RECENT EVENTS REGARDING ARTHUR ANDERSEN LLP, INCLUDING WITHOUT LIMITATION ITS CONVICTION ON FEDERAL OBSTRUCTION OF JUSTICE CHARGES ARISING FROM THE FEDERAL GOVERNMENT'S INVESTIGATION OF ENRON CORP.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Vijay B. Samant, the President and Chief Executive Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2002, to which this Certification is attached as Exhibit 99.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: March 31, 2003

/s/ VIJAY B. SAMANT

Vijay B. Samant
President and Chief Executive Officer

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-K TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-K), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Martha J. Demski, the Vice President, Chief Financial Officer, Treasurer and Secretary of Vical Incorporated (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2002, to which this Certification is attached as Exhibit 99.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: March 31, 2003

/s/ MARTHA J. DEMSKI

Martha J. Demski

Vice President, Chief Financial Officer, Treasurer and Secretary

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-K TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-K), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.
