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, 2003.**

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: 000-21088

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 30, 2003, was approximately $78,930,202. 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 1, 2004, was 20,095,244.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the solicitation of proxies for our 2004 Annual Meeting of Stockholders to be held on May 10, 2004, are hereby incorporated by reference into 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, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Our actual results may differ materially from those expressed in forward-looking statements made or incorporated by reference in this report. Forward-looking statements that express 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 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 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 and defense 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 the following documents:

- 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 SEC.

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 Pharma S.A.,
- Merial,
- Aqua Health Ltd., an affiliate of Novartis Animal Health Inc.
- Invitrogen Corporation,
- Human Genome Sciences, Inc., and
- Corautus Genetics Inc., formerly Vascular Genetics Inc.

We have also licensed complementary technologies from:

- The University of Michigan,
- CytRx Corporation,
- Genetronics Biomedical Corporation,

- The National Institutes of Health,
- The U.S. Centers for Disease Control and Prevention,
- The Ohio State University, and
- The City of Hope National Medical Center.

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 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 clinical development, but we are exploring additional opportunities.

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 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 currently have contract manufacturing agreements with 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, collaborative and out-licensed product development programs.

Product Area	Project Target and Indication(s)	Development Status(1)	Development Rights(3)
INFECTIOUS DISEASES			
Infectious disease vaccines	*Plasmodium falciparum* (malaria)	Phase 1/2	Vical
	Cytomegalovirus	Preclinical	Vical
	Bacillus anthracis (anthrax)	Preclinical	Vical
	Ebola	Phase 1	Vical/NIH
	West Nile Virus	Preclinical	Vical/NIH
	HIV – preventive	Phase 1	Merck & Co., Inc.
	HIV – therapeutic	Phase 1	Merck & Co., Inc.
	Hepatitis B virus – preventive	Research	Merck & Co., Inc.
	Hepatitis B virus – therapeutic	Research	Merck & Co., Inc.
	Hepatitis C virus – preventive	Research	Merck & Co., Inc.
CANCER			
Immunotherapeutic vaccine	High–dose Allovectin–7® for metastatic melanoma	Phase 2	Vical
Tumor-associated antigen	Unspecified cancer(2)	Research	Aventis Pasteur
therapeutic vaccines	Unspecified cancer(2)	Research	Merck & Co., Inc.
CARDIOVASCULAR			
Angiogenic growth factors	VEGF-2	Phase 2	Corautus Genetics Inc.
	FGF-1	Phase 2	Gencell S.A., a subsidiary of Aventis Pharma S.A.
VETERINARY			
Preventive vaccines	Various undisclosed(2)	Research-Clinical	Merial
	Undisclosed(2)	Clinical	Aqua Health Ltd.

(1) "Research" indicates exploration and/or evaluation of 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, or IND, application. "Phase 1" 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 2" clinical trials are conducted in order to determine preliminary effectiveness, or efficacy, optimal dosage, and to confirm the safety profile. 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 1/2" clinical trial. For non-human indications, "Clinical" indicates testing in the target species.

(2) Pursuant to our collaborative agreements, we are bound by confidentiality obligations to our collaborators that prevent us from publicly disclosing these targets and indications unless such information has been made generally available to the public. Additionally, some project targets and indications cannot currently be disclosed because they have not yet been selected by our collaborators.

(3) See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Other Matters" for costs associated with Vical independent product development programs.

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. 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 human studies, a very 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 plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and β2 microglobulin, which together form a Class I Major Histocompatibility Complex, or MHC-I antigen. Injection of Allovectin-7® directly into tumors, or intratumoral injection, may augment the immune response to both local and metastatic tumors by one or more mechanisms. In HLA-B7 negative recipients, a T-cell response may be initiated by the introduction of a foreign HLA, similar to that observed in tissue transplant rejections. In HLA-B7 positive recipients, enhanced HLA-B7 and b2 microglobulin surface expression by injected tumor cells could increase antigen presentation to tumor specific T-cells. In any recipient, a pro-inflammatory anti-tumor response may occur following intratumoral injection of the plasmid DNA/lipid complex, as demonstrated in preclinical animal tumor models.

Metastatic Melanoma. The American Cancer Society, estimates approximately 55,100 new diagnoses of, and 7,910 deaths from, melanoma in 2004 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 U.S. Food and Drug Administration, or FDA, approved treatments such as IL-2 or IFN-α is often significant, resulting in serious or life-threatening side effects in many of the patients treated.

In February 2001, we began a high-dose Phase 2 trial evaluating the Allovectin-7® gene-based immunotherapeutic for patients with Stage III or IV melanoma, who have few other treatment options. We presented unaudited data at the annual meeting of the American Society of Clinical Oncology, or ASCO, in May 2003 from interim analyses performed in early March 2003 for the first 91 patients in the high-dose cohort, indicating an objective response rate of 13 percent with continued excellent safety and tolerability. An update in July 2003 yielded an estimated median duration of response of at least 6.4 months. Patient enrollment was completed in July 2003 with a total of 133 patients, including 6 in an initial dose-escalation cohort and 127 in the high-dose cohort.

We continue to be encouraged by the results in our high-dose Allovectin-7® program. We assembled a panel of leading melanoma experts with both clinical and regulatory expertise to provide guidance on the Allovectin-7® program. This panel reviewed the safety and efficacy data from our high-dose and low-dose trials, including individual patient histories of the responding high-dose patients. Based on this review, we decided to seek FDA guidance on the potential for accelerated approval of Allovectin-7®.

We have initiated discussions with the FDA regarding whether the results from our high-dose Phase 2 trial could potentially support accelerated approval for marketing Allovectin-7® for use in certain patients with recurrent and/or otherwise treatment-intolerant metastatic melanoma. We expect these discussions will lead to two formal End-of-Phase 2, or EOP2, meetings shortly, but in any event within the next 60 days. The Product EOP2 meeting would focus on manufacturing and other product-related topics. The Clinical EOP2 meeting would focus on clinical and non-clinical data supporting claims of efficacy and safety. In preparation for the Clinical EOP2 meeting, we took a snapshot, in November 2003, of the efficacy data from the complete high-dose cohort after all enrolled patients had an opportunity to complete two cycles of Allovectin-7® therapy.

Based on the outcome of these two meetings, by the end of the second quarter of 2004, we expect to finalize our approach to seeking market approval of Allovectin-7®. Key clinical data on the full high-dose cohort are expected to be presented in a scientific meeting in June 2004.

Out-licensing of Cancer Targets

Details of our collaborations regarding cancer targets with Aventis Pasteur and Merck & Co., Inc., or Merck, can be found in "Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing."

DNA Vaccines for Infectious Diseases

DNA vaccines use portions of the genetic code of a pathogen to cause the host to produce proteins 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, avian or insect 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 our first independent development program focused on infectious diseases, a DNA-based immunotherapeutic vaccine against

cytomegalovirus, or CMV. Currently, there is no approved vaccine or even a late-stage vaccine development program for CMV.

The Institute of Medicine, or IOM, of the National Academy of Sciences estimated the cost of treating the consequences of CMV infection in the United States at more than $4 billion per year in a 1999 report, 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 groups such as immunocompromised individuals and women of reproductive age.

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

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

The initial clinical development plan includes vaccination of both donors and recipients in hematopoietic cell transplants, including bone marrow transplants. We made significant preclinical progress in 2003 with our CMV vaccine and expect to begin clinical testing in the next few months in support of an initial application in hematopoietic cell transplant patients. The majority of the required preclinical testing has been completed; a bivalent vaccine encoding two known immunogenic CMV proteins has been formulated with a poloxamer; and clinical supplies have been manufactured. We have established working relationships with some of the country's leading transplant centers, which have contributed to trial design and may participate in upcoming CMV vaccine trials. We also have secured intellectual property rights to the selected gene sequences.

Our lead vaccine configuration consists of two plasmid constructs, one encoding the surface antigen, glycoprotein B, and the other a potent T-cell target, phosphoprotein 65, or pp65. These constructs have been tested individually and in combination in our own laboratories. We have verified in preclinical studies that these immunogens elicit potent immune responses, generating both antibodies and T-cell responses.

Recently we identified a third viable immunogen that can be manufactured and that elicits a potent T-cell response. We are evaluating the benefit of incorporating this third plasmid into a trivalent vaccine to determine how this might further increase the likelihood of success of our CMV immunotherapeutic product, and are exploring the best way to integrate this discovery into our CMV immunotherapeutic program.

In addition, we have received notification of funding of approximately $1 million for research and development related to our CMV vaccine program under two grants from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID. A six-month Phase I Small Business Innovation Research, or SBIR, grant of approximately $300,000 will partially fund preclinical safety and toxicity evaluation of the CMV vaccine in support of our planned Phase 1 human trial. An 18-month research grant of approximately $700,000 will partially fund novel assays to measure and characterize immune responses in volunteers participating in the trial. The trial and immunological assays will be conducted in collaboration with the Fred Hutchinson Cancer Research Center in Seattle, Washington.

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 rarely rids 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 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. Relatively toxic 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, a next-generation vaccine designed to provide broader protection than any of the other anthrax vaccines either on the market or in development. Where the others target the single anthrax protein called Protective Antigen, or PA, our vaccine also targets

the anthrax protein called Lethal Factor, or LF. This second-generation, bivalent, cationic-lipid formulated vaccine is designed to provide broader protection against weaponized forms of anthrax than the currently approved anthrax vaccine.

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 nucleotide sequences encoding certain of these immunogens can be delivered effectively by formulated DNA, resulting in protective immune responses. Our technology allows us to readily produce detoxified forms of PA and LF that together may provide broader protection against weaponized forms of anthrax 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 can interact with the negatively charged DNA molecules, 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;

- DNA vaccines may 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 FDA in December 2002.

Encouraging results with multiple formulations of the vaccine in mouse and rabbit immunogenicity and challenge models were presented at an American Society for Microbiology meeting in March 2003. At several scientific conferences during the third quarter of 2003, we presented preclinical data from our anthrax vaccine program, including rabbit data which demonstrated protection against an aerosolized spore inhalation challenge at 7.5 months post-vaccination.

This research has been supported, in part, by a one-year Small Business Technology Transfer Research, or STTR, grant from the NIAID, as announced in July 2002. In July 2003, we were awarded a three-year, $5.7 million Phase II SBIR grant from the NIAID. The grant is partially funding the development of our DNA vaccine against anthrax.

In October 2003, we secured an exclusive license from The Ohio State University to allow use of proprietary technology in our anthrax vaccine.

The human clinical testing that was originally expected to start by the end of 2003 has not yet begun for two reasons. First, we are still completing some required preclinical work, which is being supported, in part, under the SBIR grant from the NIAID. An advisory committee meeting may be required before the FDA would allow Phase 1 human clinical testing of our anthrax vaccine to begin. Second, we have not received a commitment for additional government funding to support human studies, and that funding directly depends on the priorities and appropriations for biodefense research and Project BioShield, a biodefense vaccine project adopted by the U.S. government in 2003. Nevertheless, we remain excited about the potential for this vaccine and are continuing to work on non-clinical development supported under our existing grant.

We believe that the Animal Rule, which allows demonstration of effectiveness in two animal species in addition to safety in humans, would apply to the FDA's review of this vaccine.

About Anthrax. Anthrax is a serious infectious disease most frequently occurring in hoofed 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 who develop disease, 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.

NIH Vaccine Research Center

We have an agreement to manufacture HIV, Ebola, West Nile Virus and severe acute respiratory syndrome, or SARS, DNA vaccines for the VRC in our existing Eastgate manufacturing facility under a subcontract awarded in July 2002 and amended most recently in January 2004 for additional production of one of these vaccines. In November 2003, the VRC began testing an investigational DNA vaccine against Ebola, using clinical supplies provided by us under this agreement, in healthy human volunteers.

In May 2003, we announced a separate subcontract to manufacture bulk DNA vaccines for the VRC, which will be produced in a 500-liter fermenter and related purification equipment being furnished as government equipment, or GFE, in our new Pacific Center Court, or PCC, manufacturing facility. Under this agreement, we are guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement. In October 2003, the VRC formally notified us of its intention to place production orders under the bulk DNA vaccine manufacturing agreement, using the equipment being furnished by the VRC, beginning in mid-2004.

In February 2004, we received orders under the two subcontracts totaling approximately $6 million. Production will begin in the first half of 2004 in our Eastgate manufacturing facility, but the majority will be completed beginning in the second half of 2004 in our PCC facility. Additional orders may be placed under both subcontracts. Revenue from these orders will be recognized as product is shipped. This should substantially increase our contract revenues to more than $10 million in future years, subject to annual renewal. We are on track to begin production as scheduled and we fully intend to meet the VRC's requirements, including vaccines for HIV, Ebola, West Nile Virus and SARS. Under Federal Acquisition Regulations, the government has the right to terminate these agreements for convenience.

If we fail to satisfy our contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or government property in our possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on our financial results in the period or periods affected.

These contracts are issued and managed on behalf of the VRC by SAIC-Frederick, Inc. under the umbrella of a federally funded prime contract with the NIH.

In October 2003, we obtained an option to secure exclusive commercialization rights for a West Nile Virus vaccine being developed in collaboration with the VRC under a Cooperative Research and Development Agreement, or CRADA. In January 2004, we secured a license from the CDC for technology used in a similar DNA vaccine, which was shown in independent tests at the CDC to protect horses from West Nile Virus after a single injection.

International AIDS Vaccine Initiative

In January 2002, we signed a contract with the IAVI, a not-for-profit entity, to provide clinical trial supplies. The initial term of this contract extended to December 31, 2002, but was renewed through December 31, 2004. 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 December 2003, the IAVI began testing an investigational DNA vaccine against HIV, using clinical supplies provided by us, in healthy human volunteers. In 2003, we recognized $0.9 million of revenue from the IAVI. Dr. Douglas, our Chairman, served on the Board of Directors of the IAVI until June

30,2003. Our President and Chief Executive Officer, Vijay B. Samant, serves on the Project Management Subcommittee of the IAVI.

Other Infectious Diseases

To supplement our independent vaccine development programs, we have licensed our technology to Merck for the development of vaccines against certain infectious disease targets. 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 the VRC and the 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."

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 localized and 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 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 certain rights to utilize our DNA delivery technology for development and commercialization for specific vaccine candidates to Merial and Aqua Health Ltd. See "—Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing."

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, 2003, we had received approximately $7.1 million in royalty revenues under the Invitrogen/Life Technologies agreement.

Merck & Co., Inc. We are a party to an agreement with Merck which provides Merck with certain exclusive rights to develop and commercialize vaccines using our DNA delivery technology for certain human diseases. Under the original and amended agreement, Merck licensed preventive and therapeutic human infectious disease vaccines using our DNA delivery technology. In August 2003, under an additional amendment to the agreement, Merck obtained options for rights to use our DNA delivery technology for three cancer targets. Exercise of the option for each cancer target would result in a license fee payment to us, and further development may lead to milestone and royalty payments to us. In addition, Merck returned rights to us for certain preventive vaccines. Merck has retained rights to use the technology for HIV, hepatitis C virus, and hepatitis B virus.

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, 2003. 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 has the right to terminate this agreement without cause on 90 days written notice.

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.

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 certain infectious disease DNA vaccines 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 Pharma began testing the DNA delivery of a gene encoding FGF-1, 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 Pharma licensed the rights to our DNA delivery technology for cardiovascular applications using FGF-1 in June 2000. The angiogenic growth factor agreement could generate milestone payments plus royalties if products advance through commercialization. Aventis Pharma has the right to terminate this agreement without cause on 60 days written notice.

Through December 31, 2003, 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 livestock and companion animals. Through December 31, 2003, 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, 2003, 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 1 and Phase 2 clinical trials using DNA delivery of the VEGF-2 gene to promote the growth of blood vessels in patients with coronary artery disease. Corautus has announced that it is planning to start a Phase 2b trial.

Aqua Health Ltd. In October 2003, we granted a non-exclusive license for Canada to Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of the Swiss-based company Novartis Animal Health Inc., for use of our patented DNA delivery technology in a vaccine against an undisclosed target. Aqua Health is investigating a vaccine based on our DNA technology to combat a disease that affects both wild and farm-raised fish.

Centocor, Inc. In February 1998, we entered into an exclusive license and option agreement allowing Centocor, Inc., a company subsequently acquired by Johnson & Johnson, to use our DNA delivery technology to develop and commercialize certain DNA vaccines for the potential treatment of some types of cancer. During the third quarter of 2003, Centocor provided us with notice of termination of the agreement effective February 9, 2004, at which time all rights granted to Centocor under the agreement reverted to us.

Corporate Collaborators—In-licensing

Genetronics Biomedical Corporation. In October 2003, we entered into an agreement with Genetronics Biomedical Corporation giving us an option to a worldwide exclusive license to use Genetronics' proprietary electroporation technology in combination with our DNA delivery technology for undisclosed targets. We are preparing to advance into clinical testing with a new program involving solid tumors. We intend to announce a new product development program in solid tumors as an initial application of electroporation technology by year-end 2004.

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

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.

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, 2003, we had recognized revenue of $5.5 million under the agreement. In 2003, we signed an agreement with the ONR under which the ONR agreed to provide funding to us if we performed further research and development on a malaria vaccine. No significant work was performed under this agreement in 2003 or to date in 2004. Both parties are discussing future work, if any, under this agreement. We do not plan to pursue this program independently.

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 the Wisconsin Alumni Research Foundation, or WARF, its interest in that technology. We paid the WARF an initial license fee and agreed to pay the WARF a percentage of certain initial upfront monetary payments and a small percentage of some royalty payments received from third parties under sublicense agreements. A lawsuit was filed against us in July 2003 by the WARF in the United States District Court for the Western District of Wisconsin. This lawsuit concerns the interpretation of payment provisions of a license agreement that we entered into with the WARF in 1991, and payments made under this agreement. The WARF seeks a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and additional compensation from us, the amount of which is unspecified in the WARF's complaint. We have counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and a return of amounts overpaid to the WARF under this agreement in excess of $1.5 million.

Payments to Others

Under the Merck, Aventis Pasteur, Merial, Aventis Pharma, HGS, Corautus and Aqua Health agreements, we would be required to pay up to 10 percent of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the WARF. The CytRx agreement would require us to make payments to CytRx if we or our sublicensees advance products through clinical development. 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.

CRADAs

We have entered into several CRADAs with the NIH and the Naval Medical Research Center to promote the development and use of our technology in DNA vaccine candidates. Specific disease targets for which we currently support

DNA vaccine development under one or more CRADAs include HIV, West Nile Virus, malaria, anthrax, and Ebola. Our general responsibility under each CRADA includes providing materials and/or expertise to the government agency in return for an option to obtain an exclusive license for rights to any intellectual property that results from the CRADA.

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 we have a comprehensive patent portfolio. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We are the assignee of 31 issued U.S. and foreign patents having remaining lives of 5 to 15 years, which are listed below:

Patent No.	Description
U.S. PATENTS	
6,696,424	Cytofectin dimers and methods of use therof
6,673,776	Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human
6,670,322	Complex cationic lipids having quaternary nitrogens therein
6,586,409	Adjuvant compositions and methods for enhancing immune responses to polynucleotide-based vaccines
6,413,942	Methods of delivering a physiologically active polypeptide to a mammal
6,399,588	Cancer treatment method utilizing plasmids suitable for IL-2 expression
6,228,844	Stimulating vascular growth by administration of DNA sequences encoding VEGF
6,214,804	Induction of a protective immune response in a mammal by injecting a DNA sequence
6,147,055	Cancer treatment method utilizing plasmids suitable for IL-2 expression
6,022,874	Piperazine based cytofectins
5,994,317	Quaternary cytofectins
5,910,488	Plasmids suitable for gene therapy
5,891,718	Tetracycline inducible/repressible systems
5,861,397	Piperazine based cytofectins
5,707,812	Purification of plasmid DNA during column chromatography
5,703,055	Generation of antibodies through lipid mediated DNA delivery
5,693,622	Expression of exogenous polynucleotide sequences cardiac muscle of a mammal
5,641,665	Plasmids suitable for IL-2 expression
5,589,466	Induction of a protective immune response in a mammal by injecting a DNA sequence
5,580,859	Delivery of exogenous DNA sequences in a mammal
5,576,196	Process for reducing RNA concentration in a mixture of biological material using diatomaceous earth
5,561,064	Production of pharmaceutical-grade plasmid DNA
5,459,127	Cationic lipids for intracellular delivery of biologically active molecules
5,264,618	Cationic lipids for intracellular delivery of biologically active molecules
FOREIGN PATENTS	
EP0523189	Cationic lipids for intracellular delivery of biologically active molecules
EP0737750	Expression of exogenous polynucleotide sequences in a vertebrate
EP0742820	Production of pharmaceutical-grade plasmid DNA
EP0802975	Process for reducing RNA concentration in a mixture of biological material using diatomaceous earth
EP0902780	Quaternary cytofectins
EP1032428	Treatment of cancer using cytokine-expressing polynucleotides and compositions therefor
JP2538474	Cationic lipids for intracellular delivery of biologically active molecules

We are also co-assignee, together with Pasteur Mérieux Sérums et Vaccins, subsequently Aventis Pasteur, and the University of Texas Health Science Center of two issued U.S. patents related to vaccines against Lyme disease. In addition, we have been granted a Japanese patent related to our core gene delivery technology that was maintained after an opposition proceeding but is subject to requests for four Trials for Invalidation, or TFIs, and a patent in Europe related to our core gene delivery technology that was revoked as a result of an opposition and is currently under appeal.

We are also prosecuting 70 pending patent applications in the U.S. and in foreign countries that cover various aspects of our proprietary technology, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners. Four of the pending foreign patent applications are international patent applications under the Patent Cooperation Treaty, or PCT, each of which preserves our right to pursue national-phase patent applications in a large number of foreign countries. In addition, we are co-assignee, together with Merck, of foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

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. We are also an exclusive licensee 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 Pharma 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, or EPO. 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 allowed and then withdrawn 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;

  - 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 filed a rebuttal response to the revocation in a timely manner and the patent was maintained. In addition to the opposition proceedings, we received notice that four TFI requests

against the patent were filed in the JPO by two companies alleging both substantive and formal grounds for invalidation. We filed responses to the TFI requests in a timely manner and are awaiting further action by the JPO;

- *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 other patents related to gene delivery to the heart, including delivery of a vascular endothelial growth factor, or VEGF, and 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®. 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 EPO 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 filed a rebuttal response in a timely manner and are awaiting further action by the EPO.

During 2003 and early 2004, we announced the issuance of five European patents and three U.S. patents related to our core DNA delivery technology, enhancements of that technology, and applications of that technology:

- European Patent EP0737750, entitled "Expression of Exogenous Polynucleotide Sequences in a Vertebrate," is part of a family of patents based on our discovery that tissues can take up polynucleotides, such as DNA or RNA, without the use of viral delivery vehicles, and subsequently express the proteins encoded by the polynucleotides. The new patent claims medicinal compositions which contain cationic lipids and polynucleotides and which elicit an immune response against the proteins encoded by the polynucleotides. The new patent covers a range of applications of our core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as our clinical-stage Allovectin-7® treatment for melanoma, cationic lipid-formulated DNA vaccines such as our investigational anthrax vaccine, and similar pharmaceutical products under development by others. Through the EPO web site, we understand that this patent has been opposed, although we are awaiting formal notification by the EPO. We intend to respond in a timely manner.

- European Patent EP1032428, "Treatment of Cancer Using Cytokine-Expressing Polynucleotides and Compositions Therefor," broadly claims gene-based, extra-tumoral delivery of any cytokines for the treatment of cancer. Delivery can be either free from or formulated with transfection-facilitating materials such as cationic lipids or polymers. Cytokines are proteins such as interleukins and interferons which regulate specific cell functions, and typically are used to stimulate an immune response against cancer cells.

- European Patent EP0795015, "Plasmids Suitable for IL-2 Expression," specifically claims the composition, manufacture and application of gene-based cancer treatments delivering the cytokine interleukin-2.

- European Patents EP0742820, "Production of Pharmaceutical-Grade Plasmid DNA," and EP0802975, "Process for Reducing RNA Concentration in a Mixture of Biological Material Using Diatomaceous Earth," claim specific processes developed by us for the manufacture and purification of DNA.

- U.S. Patent No. 6,586,409 covers DNA vaccination with a novel adjuvant, Vaxfectin™. Specific claims include compositions and methods for gene-based vaccination using immunogen-encoding polynucleotides plus the Vaxfectin™ cationic lipid/co-lipid formulation.

- U.S. Patent No. 6,673,776 covers novel methods of using DNA to deliver biologically active proteins in any tissue. Examples of biologically active proteins of medical importance include angiogenic growth factors such as VEGFs or FGFs, growth hormones such as hGH or bGH, other regulatory hormones such as insulin or erythropoeitin, and cytokines such as GM-CSF or interferon alpha, among others.

- U.S. Patent No. 6,670,332 and U.S. Patent No. 6,696,424 cover new classes of cationic lipids useful in gene delivery applications. This patent expands on our existing coverage within a broad structural class of cationic lipids which can be used in formulations with DNA to improve gene delivery efficiency and cell targeting.

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 the PCC facility that we believe will be sufficient for foreseeable commercial manufacturing requirements. Construction was completed, and we have begun the validation process. We expect the PCC facility to begin production in the second half of 2004. We also engage in contract manufacturing of plasmid investigational products for selected clients. If we become capacity constrained, we may use outside organizations to manufacture our products.

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 infectious disease vaccine research and development. These include Acambis plc, Avant Immunotherapeutics, Aventis, Baxter International Inc., Chiron Corporation, Crucell N.V., DynPort Vaccine Company LLP, GlaxoSmithKline plc, ID Biomedical Corporation, MedImmune, Inc., Merck, Solvay S.A., VaxGen Inc., 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., Antigenics, Inc., CancerVax Corporation, Genta, Inc., Maxim Pharmaceuticals, Inc., Novartis A.G. and Transgene S.A., 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.

We will be impacted if the FDA-proposed rule on “Safety Reporting Requirements for Human Drug and Biological Products,” published March 23, 2003, in the Federal Register, is implemented. This rule would change the reporting requirements for drugs and biological products, such that any serious adverse event that cannot be definitely excluded as related to the product will be reported in an expedited manner. At present, sponsors of clinical research typically report on an annual basis all serious adverse event reports that have been deemed to be “unlikely” or “improbable.” The effect of this proposed rule will likely be to increase the number of expedited reports of serious adverse events reported to the FDA, which may create a perception of increased adverse events and higher risk profiles, despite no change in the actual severity or the actual number of adverse events that occur in the course of a product’s development.

To obtain FDA approval prior to marketing a pharmaceutical product in the United States typically 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 for therapeutic products are normally done in three phases. Phase 1 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 2 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 3 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 2 trials and are referred to as “Phase 1/2” 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 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 of clinical trials if an unwarranted risk is presented to patients. Human DNA vaccines and therapeutics are a new category of products and the clinical trial period may be lengthy or the number of patients or human volunteers 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 "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 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 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 cGMP, by FDA inspectors. The manufacturing facility must satisfy cGMP requirements prior to marketing clearance. In addition, after marketing clearance is secured, the manufacturing facility will be inspected periodically for cGMP 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 the 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.

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, 2004, we had 161 full-time employees, including 27 with doctorate degrees. Of these full-time employees, 129are 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.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available on our website at http://www.vical.com as soon as reasonably practicable after such reports and amendments are electronically filed with or furnished to the SEC.

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	51	President, Chief Executive Officer and Director
David C. Kaslow, M.D.	45	Chief Scientific Officer
Martha J. Demski	51	Vice President, Chief Financial Officer, Treasurer and Secretary
Alan E. Dow, J.D., Ph.D.	48	Vice President and General Counsel

(1)As of December 31, 2003.

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. Dr. Kaslow joined Merck in February 1999 as Senior Director, Vaccine Research, and was employed by Merck, most recently as Head of the Department of Vaccine Research and Technology, until he joined Vical. 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 from 2000 until he joined Vical. 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 consider carefully the risks described below, together with all of the other information included in this report, and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these 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, resulting in a loss of all or part of your investment.

None of our products has been approved for sale, and we have only one product candidate in Phase 2 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, in 2002 we announced that the efficacy data from our low-dose Phase 3 registration trial with Allovectin-7® in patients with metastatic melanoma would not support a registration submission with the FDA. We also announced in 2002 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, which is currently in Phase 2 clinical trials.

Additionally, we are in preclinical 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.

Our revenues partially depend on the development and commercialization of products by others to whom we have licensed our technology. If our collaborators or licensees are not successful or if we are unable to find collaborators or licensees in the future, we may not be able to derive revenues from these arrangements.

We have licensed our technology to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues partially depend upon the performance by these collaborators and licensees of their responsibilities under these arrangements. Some collaborators or licensees may not succeed in their product development efforts or devote sufficient time or resources to the programs covered by these arrangements, causing us to derive little or no revenue from these arrangements.

Our collaborators and licensees may breach or terminate their agreements with us, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technology.

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. We do not expect to sell any products for the next several years. Our net losses were approximately $24.4 million, $27.9 million and $9.2 million for 2003, 2002 and 2001, respectively. As of December 31, 2003, we have incurred cumulative net losses totaling approximately $114.8 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. For 2004, we have forecast a net loss of between $26 million and $29 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 marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. For example, we currently have on file an effective shelf registration statement with the SEC seeking to register an aggregate of up to $50 million of common stock or preferred stock. However, we may not be able to raise additional funds on favorable terms, or at all. In December 2003, we received a commitment letter from the leasing division of a bank to provide us with up to $8.5 million of financing for tenant improvements and equipment. We have accepted the terms of this commitment letter subject to completing final lease documentation. The financial covenants of the proposed agreement would require us to maintain cash collateral equal to the amount of outstanding borrowings. The bank would have a secured interest in any equipment financed under this agreement. Additionally, if unrestricted cash and marketable securities, as defined, are less than $45 million, we would be required to maintain a letter of credit issued by another financial institution equal to the amount of outstanding borrowings at that time. In the event this occurred, we would expect that our restricted cash deposits securing the lease would be returned to us, but we would have to make restricted cash deposits with another financial institution in order to obtain a letter of credit. 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.

We anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2005.

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 and licensees 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 therapeutic and vaccine products,
- The FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products, and
- Current regulations and guidances 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.

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. For example, an advisory committee meeting may be required before the FDA would allow Phase 1 human clinical testing of our anthrax vaccine to begin. 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 ongoing 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 Office of Biotechnology Activities. The NIH could restrict or delay the development of our product candidates.

We understand that both the FDA and the 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.

A rule published in 2002 by the FDA, known commonly as the "Animal Rule," attempts to establish requirements for demonstrating effectiveness of drugs and biological products in settings where human 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 up to two appropriate species of animal. We believe that with appropriate guidance from the FDA, we may seek and gain market approval under the Animal Rule for DNA-based products designed to treat or prevent a disease for which clinical efficacy trials in humans are neither feasible nor ethical, such as our DNA vaccine for anthrax. At the moment, however, we cannot guarantee that the Animal Rule will be applied to any of our products, or if applied, that its application would result in expedited development time or regulatory review.

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. In October 2002 and January 2003, 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, were diagnosed with leukemia that was caused by the integration of the viral delivery vehicle in or near a cancer-causing region of the children's genome. 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.

In March 2003, the FDA proposed a new rule on "Safety Reporting Requirements for Human Drug and Biological Products" that would change the reporting requirements for drugs and biological products, such that any serious adverse event that cannot be definitely excluded as related to the product will be reported in an expedited manner. At present, sponsors of clinical research typically report on an annual basis all serious adverse event reports that have been deemed to be "unlikely" or "improbable." The effect of this proposed rule will likely be to increase the number of expedited reports of serious adverse events reported to the FDA, which may create a perception of increased adverse events and higher risk profiles, despite no change in the actual severity or the actual number of adverse events that occur in the course of a product's development.

Some of our potential products may be administered to patients who are suffering from, or are 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 investigational CMV vaccine to patients who are at risk of CMV reactivation. Likewise, our investigational 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 are the assignee of 31 issued U.S. and foreign patents. We are also co-assignee, together with Pasteur Mérieux Sérums et Vaccins, subsequently Aventis Pasteur, and the University of Texas Health Science Center of two issued U.S. patents related to vaccines against Lyme disease. In addition, we have been granted a Japanese patent related to our core gene delivery technology that was maintained after an opposition proceeding but is subject to requests for four TFIs, and a patent in Europe related to our core gene delivery technology that was revoked as a result of an opposition and is currently under appeal.

We are also prosecuting 70 pending patent applications in the U.S. and in foreign countries that cover various aspects of our proprietary technology, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners. Four of the pending foreign patent applications are international patent applications under the PCT, each of which preserves our right to pursue national-phase patent applications in a large number of foreign countries. In addition, we are co-assignee, together with Merck, of foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

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.

Once issued, we maintain our patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated.

For example, our core DNA delivery technology is covered by a European patent that has been issued and revoked as a result of an opposition in Europe, and a Japanese patent that was originally revoked but subsequently reinstated in Japan. In addition, our core DNA delivery technology is covered by a patent that was allowed and then withdrawn as a result of a protest procedure in Canada. We are currently appealing the European revocation, have responded to TFI requests in Japan, and are continuing prosecution of the patent that was opposed in Canada, but if our actions do not succeed, 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 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. In addition, we could be required to pay money damages. 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 are not able to redesign our products or processes to avoid infringement.

We are currently involved in several legal proceedings involving our intellectual property rights. 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 EPO. In April 2002, we filed an appeal, which is still pending, seeking to overturn this initial ruling. Our core DNA delivery technology is also covered by a Canadian patent that was allowed and then withdrawn after protests against its issuance were filed on behalf of an undisclosed party or parties in August and December 2001. We have responded to the protests and are continuing prosecution of the application in the Canadian Patent Office.

In addition, our core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the JPO on formal and substantive grounds. We filed a rebuttal response to the revocation which resulted in the maintenance of the patent. Based on our arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. We also received notice that four TFI requests against this patent were filed in the JPO by two companies. We filed responses to the TFI requests in a timely manner and are awaiting further action by the JPO.

A European patent issued in 2003, covers a range of applications of our core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as our clinical-stage Allovectin-7® treatment for melanoma, cationic lipid-formulated DNA vaccines such as our investigational anthrax vaccine, and similar pharmaceutical products under development by others. Through the EPO web site, we understand that this patent has been opposed, although we are awaiting formal notification by the EPO. We intend to respond in a timely manner.

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 a European patent granted in March 2002. We have received notice from the EPO that one company filed an opposition in December 2002 alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible in February 2003. We filed a rebuttal response to the opposition in a timely manner and are awaiting further action by the EPO.

A lawsuit was filed against us in July 2003 by the WARF in the United States District Court for the Western District of Wisconsin. This lawsuit concerns the interpretation of payment provisions of a license agreement that we entered into with the WARF in 1991, and payments made under this agreement. The WARF seeks a

declaratory judgment as to the correct interpretation of the payment provisions of the agreement and additional compensation from us, the amount of which is unspecified in the WARF's complaint. We have counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and a return of amounts overpaid to the WARF under this agreement in excess of $1.5 million.

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 products may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our products 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 Allovectin-7®, attending physicians have punctured patients' lungs in less than one percent of procedures, requiring hospitalization. In addition, a physician administering Allovectin-7® 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.

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 our principal scientific, manufacturing, clinical, regulatory and management personnel, including Vijay B. Samant, our President and Chief Executive Officer, and David C. Kaslow, our Chief Scientific Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. We do not maintain "key person" life insurance on any of our personnel. 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 have not had any problem attracting and retaining key personnel and qualified staff in the recent past. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel.

A significant portion of our revenue is derived from agreements with government agencies, which are subject to termination and uncertain future funding.

We have entered into agreements with government agencies, such as the NIH, and we intend to continue entering into these agreements in the futureFor example, we have entered into an agreement to manufacture bulk DNA vaccines for the VRC. In connection with this agreement, the VRC has agreed to provide a 500-liter fermenter and related purification equipment being furnished as GFE in our PCC manufacturing facility. Our business is partially dependent on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time. If we fail to satisfy our contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or government property in our possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on our financial results in the period or periods affected. Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies In addition, we may fail to perform our responsibilities under these agreements. We may also be unsuccessful in entering into additional agreements with government agencies.

There are only a limited number of other contractors that could perform under the bulk DNA vaccines manufacturing contract in the unlikely event that we were unable to perform. The price they might charge could be more than what we would charge based on their capacity, utilization, size of order and other factors. Accordingly, we are unable to estimate a range of

potential cost that we could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that we were unable to meet.

We have limited experience in manufacturing our product candidates in commercial quantities. We may not be able to comply with applicable manufacturing regulations or produce sufficient product for contract or commercial purposes.

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's cGMP regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we must complete the installation and validation of a large-scale fermenter and related purification equipment in order to produce the quantities of product expected to be required under certain contract manufacturing agreements or for commercial purposes. We do not have any experience in manufacturing at this scale. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of our large-scale equipment, or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing arrangements.

We may initially depend on third parties to manufacture our product candidates commercially.

We may initially depend on collaborators, licensees or other third parties to manufacture our product candidates in commercial quantities. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

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. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, our business will be harmed.

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 how much, if any, 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, we could be prevented 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, became effective in 2003 and may complicate the process by 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 minor amounts of low-level radioactive compounds. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic 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. We have insurance that covers our use of hazardous materials with the following coverage limits: up to $25,000 per occurrence for losses related to the release of bio-contaminants, $1,000,000 per occurrence for losses from refrigerant contamination and $25,000 per occurrence for losses from radioactive contamination. Any liability could exceed the limits or fall outside the coverage of our insurance. 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. We also have potential liability for products manufactured by us on a contract basis for third parties. These risks are inherent in the development and manufacture of chemical and pharmaceutical products. Although we currently maintain product liability insurance in the amount of $10 million in the aggregate, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future 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, or our ability to manufacture products for third parties. To date, no product liability claims have been filed against us. However, if we are sued for any injury caused by our technology or products, or by third-party products that we manufacture, 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 pay 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. During the three-year period ended December 31, 2003, our stock price has ranged from $2.12 to $20.50. 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, licensees or competitors or for gene therapies in general,
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors,
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products,
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights,
- Other developments with our collaborators or licensees,
- 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,
- 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. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

The ability of our investors to seek remedies against Arthur Andersen LLP, who audited some of the financial statements included in our Annual Reports on Form 10-K for the years ended December 31, 2002 and 2001, and this Annual Report on Form 10-K, may be significantly limited.

Our annual financial statements for the year ended December 31, 2001, which were included in our Annual Reports on Form 10-K for the years ended December 31, 2002 and 2001, and are included in this Annual Report, were audited by Arthur Andersen LLP. We dismissed Arthur Andersen as our independent public accountants effective April 16, 2002. After reasonable efforts, we were unable to obtain Arthur Andersen's written consent to incorporate by reference its report dated February 1, 2002, with respect to these audited financial statements. The absence of this consent may limit the ability of investors to seek remedies against Arthur Andersen for any untrue statement of a material fact contained in these financial statements, or any omission of a material fact required to be stated in these financial statements. In addition, as a practical matter, any claims that may be available under federal securities laws against auditing firms may not be available against Arthur Andersen due to the diminished amount of assets of Arthur Andersen that are or in the future may be available for claims.

Anti-takeover provisions in our stockholder rights plan, our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Pursuant to the terms of our stockholder rights plan, we have distributed a dividend of one preferred stock purchase 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. Our certificate of incorporation and bylaws include other anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

The issuance of preferred stock could adversely affect our common stockholders.

In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

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 PCC, has approximately 68,400 square feet of manufacturing, research laboratory and office space. This site allowed us to consolidate most of our operations and offices while increasing our manufacturing capacity for both clinical and commercial production, with the addition of a 500-liter fermenter and associated processing equipment being furnished by the government as GFE. We began occupying PCC in March 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 currently hold three leases at three sites for our older manufacturing, research laboratories and offices, which do not terminate until the fourth quarter of 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 2003, we subleased the majority of the vacated space. We are negotiating to renew our lease on approximately 15,000 square feet in one facility for one year and approximately 10,000 square feet in another facility for five years. The lease on the third facility will not be renewed at termination.

We recognize level monthly rent expense over the entire lease period. 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 subleases, and excluding common area maintenance costs, is approximately $101,000.

Within our older facilities, we have manufactured sufficient quantities of pharmaceutical-grade product to supply our previous and ongoing clinical trials. In

addition, we have manufactured preclinical and clinical supplies of DNA for our corporate collaborators, government agencies and numerous academic researchers. We expect our new facility to begin production in the second half of 2004.

ITEM 3. LEGAL PROCEEDINGS

On July 29, 2003, the WARF filed a complaint against us in the United States District Court for the Western District of Wisconsin, seeking a declaratory judgment regarding the meaning of certain payment provisions in a license agreement we entered into with the WARF in 1991, as well as fees related to our sublicense of certain inventions jointly owned by us and the WARF, the amount of which is unspecified in the WARF's complaint. We intend to vigorously defend the suit and we have counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and a return of amounts overpaid to the WARF under this agreement in excess of $1.5 million. Based on the information presently available to us, we do not believe the WARF's claims are material to our business.

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 EPO. 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 issued patents and patent applications that are pending in Europe to protect our core DNA delivery technology.

Our core DNA delivery technology is also covered by a Canadian patent that was allowed and then withdrawn after protests against its issuance were filed on behalf of an undisclosed party or parties in August and December 2001. We have responded to the protests and are continuing prosecution of the application in the Canadian Patent Office.

In addition, our core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the JPO, on formal and substantive grounds. We filed a rebuttal response to the revocation. Based on our arguments and supporting evidence in that response, the JPO decided to reinstate the patent in

July 2003. We also received notice that four TFI requests against this patent were filed in the JPO by two companies. We filed responses to the TFI requests in a timely manner and are awaiting further action by the JPO.

A European patent issued in 2003, covers a range of applications of our core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as our clinical-stage Allovectin-7® treatment for melanoma, cationic lipid-formulated DNA vaccines such as our investigational anthrax vaccine, and similar pharmaceutical products under development by others. Through the EPO web site, we understand that this patent has been opposed, although we are awaiting formal notification by the EPO. We intend to respond in a timely manner.

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 a European patent granted in March 2002. We have received notice from the EPO that one company filed an opposition in December 2002 alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible in February 2003. We filed a rebuttal response to the opposition in a timely manner and are awaiting further action by the EPO.

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, except as noted above, and none of which, individually or in the aggregate, is deemed to be material to our financial condition.

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

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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, 2002.

	High	Low
2003		
First Quarter	$ 3.69	$ 2.12
Second Quarter	5.12	2.45
Third Quarter	7.80	4.07
Fourth Quarter	6.39	4.45
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

As of March 1, 2004, there were approximately 443 stockholders of record of our common stock with 20,095,244 shares outstanding. We have never declared or paid any dividends and do not expect to pay any dividends in the foreseeable future. We did not repurchase any securities of the Company in the fourth quarter of 2003.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2003 with respect to both of our equity compensation plans in effect on that date.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders (1)	3,333,693	$ 10.74	1,210,077

(1) Includes the Amended and Restated Stock Incentive Plan and the 1992 Directors Stock Option plan. As of December 31, 2003, we did not have any equity compensation plans that were not approved by our stockholders.

ITEM 6. SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data for each of the five years ended December 31, 2003. The information presented should be read in conjunction with the financial statements and notes included elsewhere in this report.

	Year ended December 31,				
	2003	2002	2001	2000	1999
	(in thousands, except per share amounts)				
Statements of Operations Data:					
Revenues(1):					
License and royalty revenue	$ 2,066	$ 3,999	$ 7,572	$ 5,027	$ 8,294
Contract revenue	6,012	3,008	3,794	2,593	2,417
	8,078	7,007	11,366	7,620	10,711
Operating expenses:					
Research and development	26,777	26,374	22,094	18,514	15,344
General and administrative	6,923	8,061	6,501	5,265	4,376
Write-down of investment(2)	482	4,200	—	—	—
Total operating expenses	34,182	38,635	28,595	23,779	19,720
Loss from operations	(26,104)	(31,628)	(17,229)	(16,159)	(9,009)
Investment income(3), (4)	2,067	3,984	8,286	9,357	2,229
Interest expense	(413)	(288)	(297)	(205)	(129)
Net loss before cumulative effect of accounting change	(24,450)	(27,932)	(9,240)	(7,007)	(6,909)
Cumulative effect of accounting change(1)	—	—	—	(1,510)	—
Net loss	$ (24,450)	$ (27,932)	$ (9,240)	$ (8,517)	$ (6,909)
Net loss per common share (basic and diluted)	$ (1.22)	$ (1.39)	$ (0.46)	$ (0.43)	$ (0.43)
Weighted average shares used in per share calculation(3)	20,091	20,079	20,032	19,689	16,136

	As of December 31,				
	2003	2002	2001	2000	1999
			(in thousands)		
Balance Sheets Data:					
Cash, cash equivalents and marketable securities, including restricted(3)	$ 84,517	$ 111,513	$ 134,087	$ 148,144	$ 37,675
Working capital(3)	77,681	106,608	130,933	145,569	35,996
Total assets(3)	110,707	129,426	154,495	162,903	45,059
Long-term obligations	8,662	4,319	4,545	5,121	740
Stockholders' equity(3)	89,822	114,307	142,159	150,794	38,669

(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, and reflected this change as a cumulative accounting change in the statement of operations.
(2) In the first quarter of 2003 and in the third quarter of 2002, we recorded write-downs of $0.5 million and $4.2 million, respectively, to our investment in Corautus/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 Pharma S.A.,

- Merial,
- Aqua Health Ltd., an affiliate of Novartis Animal Health Inc.
- Invitrogen Corporation,
- Human Genome Sciences, Inc., and
- Corautus Genetics Inc., formerly Vascular Genetics Inc.

We have also licensed complementary technologies from:

- The University of Michigan,
- CytRx Corporation,
- Genetronics Biomedical Corporation,
- The National Institutes of Health,
- The U.S. Centers for Disease Control and Prevention,
- The Ohio State University, and
- The City of Hope National Medical Center.

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 grants, 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, costs due to increased contract manufacturing activities, increased costs of our PCC facility, 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, 2003, our accumulated deficit was approximately $114.8 million. We expect our net loss for 2004 to be between $26 million and $29 million.

Results of Operations

Revenues were $8.1 million for the year ended December 31, 2003. License and royalty revenue for 2003 was $2.1 million and represented recognition of deferred license fees from Corautus, a license payment from Aqua Health Ltd. and royalty revenue. Contract revenue of $6.0 million for 2003, was from the NIH, the IAVI, the VRC and the ONR, and included $1.9 million of grant revenue for an anthrax SBIR grant.

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 and 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, the IAVI and the ONR. License and 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 our agreement with Pfizer as a result of applying a change in accounting principle to conform to the requirements of SEC Staff Accounting Bulletin No. 101, or SAB 101. 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 the NIH, and revenue from Pfizer and other agreements.

Our total operating expenses for the year ended December 31, 2003, were $34.2 million compared with $38.6 million for the same period in the prior year. Operating expenses for the years ended December 31, 2003 and 2002, included write-downs of investment of $0.5 million and $4.2 million, respectively, as more fully explained below.

Research and development expenses were $26.8 million for the year ended December 31, 2003, compared with $26.4 million in the comparable period in 2002. The increase in 2003 was due to higher facilities costs and personnel-related costs largely offset by lower clinical trial costs and the deferral of certain contract manufacturing costs which are not expensed until the related revenue is recognized upon product shipment. 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. Clinical trial costs were $0.5 million in 2003 compared with $1.7 million in 2002. The decrease was due to completion of enrollment of the high-dose Allovectin-7® trial in July 2003. Clinical trial costs decreased to $1.7 million in 2002 compared with $3.2 million in 2001 due to completion of the low dose Allovectin-7® registration trials in 2002 and discontinuing the Leuvectin® kidney cancer trial.

In 2004, we expect research and development expense to increase as we expand our preclinical and clinical 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 a full year of occupancy in PCC, increased contract manufacturing activities and possible preparation for commercialization activities associated with Allovectin-7®.

General and administrative expenses decreased to $6.9 million in 2003 compared with $8.1 million in 2002. The decrease in 2003 compared with 2002 was due to lower personnel-related costs, including lower incentive-based compensation expense, lower professional fees and lower facilities costs due to sublease loss accruals recorded in 2002. General and administrative expenses increased to $8.1 million in 2002 compared with $6.5 million in 2001. General and administrative expenses increased in 2002

compared with 2001 primarily due to increased personnel-related costs and increased facilities costs.

Operating expenses in 2003 and 2002 also included write-downs of our investment in VGI, now Corautus. In February 2000, we received shares of preferred stock in VGI in exchange for a license to our technology. The shares were recorded as an investment on the balance sheet at an estimated fair value of $5.0 million. No cash was received or paid by

either party to this transaction. In September 2002, we wrote down the investment in VGI to $0.8 million based on objective values established as a result of a proposed merger between VGI and GenStar, a public company listed on the AMEX. The VGI shares continued to be reflected as an investment on the balance sheet at December 31, 2002. Operating expenses for the year ended December 31, 2003, also included a write-down of investment of $0.5 million in March 2003. In February 2003, GenStar and VGI completed their merger and created a new entity, Corautus. In connection with the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on the AMEX. The value of our Corautus shares as measured by the quoted price on the AMEX on March 31, 2003, was $0.3 million compared with our recorded value of $0.8 million. Based on this market information, we wrote down our investment to $0.3 million in March 2003. The market value of our investment in Corautus at December 31, 2003, was approximately $1.0 million.

In the fourth quarter of 2002, we recorded an expense of $0.7 million for the expected loss on vacant leased space that was expected to be subleased at rental rates less than those incurred by us and on the unamortized balance of leasehold improvements. Of this amount, $0.5 million was reflected in general and administrative expense and $0.2 million was recorded in research and development expense. In 2003, we subleased the majority of the vacated space and recorded additional losses of $0.2 million, allocated equally between general and administrative and research and development expense, on subleases to provide for the loss on the sublease rentals and vacant space.

Investment income decreased to $2.1 million in 2003, compared with $4.0 million in 2002 and $8.3 million in 2001. Investment income included realized gains on sales of marketable securities of $0.2 million, $0.2 million and $1.1 million in 2003, 2002 and 2001, respectively. Investment income, excluding the gains on the sale of investments, decreased in these years primarily due to significantly lower investment rates of return. We expect lower investment income in 2004 compared with 2003 due to lower investment balances.

Interest expense was $0.4 million in 2003, compared with $0.3 million in 2002 and 2001. Indebtedness for capital leases was higher in each year compared to the prior year, however, in 2002 lower outstanding balances on bank debt and lower interest rates offset this increase compared with 2001. Interest expense is expected to increase in 2004 due to higher capital lease obligations incurred mostly in 2003 related to the increased capital spending principally for PCC.

For 2003, we reported a net loss of $24.4 million, or $1.22 per share, compared with a net loss of $27.9 million, or $1.39 per share, for 2002. Net loss for 2003 included a $0.5 million write-down of our investment in VGI, and net loss for 2002 included a $4.2 million write-down of this investment. Excluding the impact of these write-downs, the 2003 loss was higher primarily because the decline in investment income more than offset the increase in revenues in 2003. Net loss for 2001 was $9.2 million or $0.46 per share. 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.

Other Matters

Since inception, we estimate that we have spent approximately $183 million on research and development. Approximately $69 million of this amount was for our two cancer programs, Allovectin-7®, which is currently in a high-dose Phase 2 trial in melanoma, but for which we have elected not to proceed with a BLA filing for a low dose based on low-dose clinical trial results, and Leuvectin®, for which development was discontinued in September 2002 due to other priorities. We expect the high-dose Phase 2 trial to determine whether higher dosing will provide the level of efficacy needed to support further development. From inception, we have spent about $51 million in our Allovectin-7® program. If future trials are needed, this would add to the time and cost of development. From inception, we have spent approximately $18 million in our Leuvectin® program. From inception, we have spent approximately $4 million on our malaria program.

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.

Costs incurred by major program for each of the three years in the period ended December 31, 2003, were as follows (in thousands):

	2003	2002	2001
Allovectin-7®	$ 5,152	$ 8,704	$ 8,829
Leuvectin®	190	1,319	1,987
Anthrax	6,641	1,582	—
CMV	7,208	1,319	—
Malaria	308	527	1,324
Other research and development, and technology enhancements	7,278	12,923	9,954
Total R&D spending	$ 26,777	$ 26,374	$ 22,094

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, 2003, we had working capital of approximately $77.7 million, compared with $106.6 million at December 31, 2002. Cash and marketable securities, including restricted securities, totaled approximately $84.5 million at December 31, 2003, compared with $111.5 million at December 31, 2002.

Cash used in operating activities increased to $21.3 million for 2003, compared with $19.7 million in 2002 due to cash payments resulting in a decrease in the outstanding balance of accounts payable primarily related to construction payments, and increased prepayments on manufacturing contracts, partially offset by reimbursement of certain construction costs by our landlord and collection of interest receivable. Cash used to acquire other assets was lower in 2003 than in the corresponding period in 2002 because of the rent deposit we paid on our new facility in 2002. Net loss for both 2003 and 2002, also included noncash write-downs of our investment in VGI, now Corautus,

as more fully explained under “Results of Operations” above.

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 provided from investing activities was $8.5 million for 2003, compared with $10.3 million in 2002. In 2003, our net sales of marketable securities yielded $13.5 million of cash compared with net sales of $11.5 million in 2002. In 2003, we also sold restricted marketable securities and purchased restricted cash equivalents that are used as collateral to support a letter of credit. Capital expenditures for 2003 increased from the same period in the prior year due to capital purchases for, and improvements to, our new facility. Additionally, spending for licensed technology and patents increased from the same period in the prior year. 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 financing activities in 2003 was $3.2 million compared with $1.7 million for the same period in 2002. Payments on capital lease obligations for 2003 increased compared with 2002 due to higher balances of capital lease obligations. 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. This borrowing converted to a term loan payable over 42 months in June 2001. The term loan bears interest approximating the bank’s prime rate. At December 31, 2003, outstanding borrowings under the term loan were $0.3 million, at an interest rate of 4.0 percent.

In 2004, we expect that our total net cash used may differ from our projected net loss principally because of timing of cash receipts on certain contract work.

Capital equipment spending, including amounts financed under capital leases, is expected to be lower in 2004 compared with 2003 because we completed most of our capital improvements to the PCC facility in 2003. In December 2003, we received a commitment letter from the leasing division of a bank to provide us with up to $8.5 million of financing for tenant improvements and equipment. We have accepted the terms of this commitment letter subject to completing final lease documentation.

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 and clinical 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. In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. 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 2005.

We do not utilize “special purpose entities” for any transactions.

Contractual Obligations

The following table sets forth our contractual obligations, including all off-balance sheet arrangements, as of December 31, 2003 (in thousands):

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**After 5 years**
Long-Term Debt	$ 340	$ 340	$ —	$ —	$ —
Capital Lease Obligations	12,384	4,591	6,615	1,178	—
Operating Leases	44,213	4,349	5,460	5,740	28,664
Unconditional Purchase Obligations	889	889	—	—	—
Other Long-Term Obligations(1)	—	—	—	—	—
Total Contractual Cash Obligations	$ 57,826	$ 10,169	$ 12,075	$ 6,918	$ 28,664

(1) Certain long-term liabilities reflected on our balance sheet are not presented in this table because they are already reflected in operating lease commitments, or do not require cash settlement in the future.

In addition, we have undertaken certain commitments under agreements with collaborators, and our officers and directors. Under the license agreements with our collaborators, we have agreed to continue to maintain and defend the patent rights licensed to the collaborators. In addition, we have entered into indemnification agreements with each of our officers and directors which would indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

Under employment agreements with four of our officers, we are also obligated to pay salary continuation if we terminate an officer’s employment without “cause,” or if an officer resigns for “good reason,” as defined in the agreements. We would continue to pay at the current base compensation rate, or current base compensation rate plus the prior year’s cash bonus in the case of the CEO, for the period specified in each agreement, which ranges from six to twelve months. These agreements also specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from us. Total payments due under these employment agreements would have been $1.0 million at December 31, 2003.

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:

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, which is generally ten 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. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. If assets are to be disposed of, they are reported at the lower of the carrying amount or fair value less costs to sell. 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 accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the trial site and other external expenses 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 number of treatments for each patient. Treatment periods vary depending on the clinical trial. We make revisions to the clinical trial cost estimates as clinical trials progress. Clinical trial expense was $0.5 million, $1.7 million, and $3.2 million for 2003, 2002 and 2001, respectively. No material revisions to the estimates were made in the periods presented.

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, such as the NIH. We have established accruals of approximately $0.6 million at December 31, 2003, to provide for potential disallowed costs. In the event that the final costs allowed are different from what we have estimated, we may need to make a change in our estimated accrual, which could also affect our results of operations and cash flow. No material adjustments were made to the accruals in the periods presented.

Revenue recognition

We earn revenue from licensing our proprietary technology and by performing services under research and development contracts and grants, and service contracts. In general, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or 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 agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the passage of time, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured. Royalty revenue is recognized as the cash is received from the licensee.

Revenue under research and development contracts and grants, and manufacturing and regulatory service contracts, except for fixed-price contracts, is recognized as the research and development expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met. 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 highly probable that we will receive a signed modification, or if we have received a signed modification, increasing the funding under the contract which will allow us to recover the costs incurred. Otherwise, the costs are expensed as 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.

We also have entered into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used for preclinical and clinical research. Under these contracts, revenue is recognized when the product is shipped, and any deferred manufacturing costs are recognized as expense at that time.

Recent Accounting Pronouncements

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 different units delivered in particular to license, research and development and contract manufacturing agreements often entered into by companies in the biotechnology industry. We have entered into fixed price manufacturing contracts which we believe would qualify for multiple element accounting under EITF Issue No. 00-21. In certain cases, this might allow us to recognize a portion of the revenue before all of the multiple elements are delivered. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The provisions of EITF Issue No. 00-21 did not have a material effect on our financial position or results of operations for the year ended December 31, 2003.

In December 2003, the Staff of the SEC issued Staff Accounting Bulletin No. 104, or SAB 104, "Revenue Recognition", which superseded SAB 101, "Revenue Recognition in Financial Statements," and became effective upon issuance. SAB 104 rescinded the accounting guidance contained in SAB 101 related to multiple-element revenue arrangements that was superseded as a result of the issuance of the aforementioned EITF 00-21. SAB 104 also rescinded the SEC's related "Revenue Recognition in Financial Statements Frequently Asked Questions and Answers" issued with SAB 101 that had been codified in SEC Topic 13, "Revenue Recognition." SAB 104 incorporates the guidance on revenue recognition under EITF 00-21, however, the basic revenue recognition principles of SAB 101 remain substantially the same under SAB 104, which was effective upon issuance. Our adoption of SAB 104 did not have a material effect on our financial position or results of operations.

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 on our balance sheet any guarantees upon the issuance of such guarantees 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 January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51," or FIN 46. FIN 46 addresses the consolidation by business enterprises of variable interest entities as defined in the interpretation. FIN 46 applies immediately to variable interest in variable interest entities created after January 31, 2003, and to variable interest in variable interest entities obtained after January 21, 2003. FIN 46 requires certain disclosures in financial statements issued after January 31, 2003, if it is reasonably possible that the company will consolidate or disclose information about variable interest entities when FIN 46 becomes effective. The application of this interpretation did not have a material effect on our consolidated financial statements.

In December 2003, the FASB issued Interpretation No. 46R, "Consolidation of Variable Interest Entities," which supercedes FIN 46. The application of the revised interpretation is required in the financial statements of companies that have interests in special purpose entities for periods after December 15, 2003. The application of this interpretation did not have a material effect on our consolidated financial statements.

We have 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. We have provided the required disclosure in Note 1 of the Notes to Financial Statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES 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. Our investment portfolio consists of cash equivalents and marketable securities. The average maturity of our non-equity investments is approximately nine months. Our investments are all classified as available-for-sale securities.

Beginning March 31, 2003, marketable securities also included our investment in common stock of Corautus. Any subsequent change in the fair value of the Corautus shares we own, based on the market price of the listed shares, is reflected as an unrealized gain or loss in the stockholders' equity section of our balance sheet at the end of each quarter, provided any reduction in value is not due to impairment which is other than temporary. See Note 2 of the Notes to Financial Statements for further details.

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 12-month time horizon, a 9-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been $0.5 million lower than the reported fair value of our non-equity investments at December 31, 2003. At December 31, 2003, our unrealized gain on marketable securities was $0.8 million, including an unrealized gain of $0.7 million on our investment in Corautus. We expect lower investment income in 2004 compared with 2003 due to lower investment balances.

The fair market value of floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. Based on our market risk-sensitive instruments outstanding at December 31, 2003, and December 31, 2002, we believe that there were no material market risk exposures to our financial position, results of operations or cash flows as of such dates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The 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 the Audit Committee of our Board of

Directors. Andersen did not prepare a report on our financial statements for the fiscal years ended December 31, 2003 or 2002.

During 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 a report on our financial statements; and there were no reportable events, as listed in Item 304(a)(1)(v) of Regulation S-K.

Effective April 30, 2002, we engaged KPMG LLP, or KPMG, as our independent auditor for the fiscal year ended December 31, 2002. During the fiscal years ended December 31, 2003 and 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.

ITEM 9A. CONTROLS AND PROCEDURES

Prior to the filing of this report, we carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. 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 SEC's rules and forms. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report. There has been no change in our internal control over financial reporting during the three months ended December 31, 2003, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

Information required by this item regarding our directors is incorporated by reference from the information under the caption "Election of Directors" in our Proxy Statement. Information required by this item concerning compliance with Section 16(a) of the Securities Act is set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement, and is incorporated herein by reference. Additional required information concerning our executive officers is contained in Part I of this report.

The information required by this item concerning our Code of Business Conduct and Ethics is set forth under the caption "Code of Business Conduct and Ethics" in our Proxy Statement, and is incorporated herein by reference.

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 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 Proxy Statement.

The equity compensation plan information required by this item will be set forth under the caption "AMENDMENT OF THE STOCK INCENTIVE PLAN—Equity Compensation Plan Information" in our Proxy Statement, and is incorporated herein by reference.

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 2004 Definitive Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth under the caption "RATIFICATION OF SELECTION OF INDEPENDENT AUDITORS—Fees of Former and Current Principal Accounting Firm" in our Proxy Statement, and is incorporated herein by reference.

PART IV

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

(a) (1) Financial Statements

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

(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

On November 5, 2003, we filed a Current Report on Form 8-K to disclose a press release announcing our financial results for the three months and nine months ended September 30, 2003.

(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(19)(a)	Form of Indemnity Agreement between the Company and its directors and officers.
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.
10.28(18)(a)	Amendment dated February 5, 2002, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.29(17)(a)	Employment Agreement dated June 17, 2002, between the Company and Alain P. Rolland.
10.30(19)(b)	Amendment No. 5 dated September 23, 2002, to Research, Option and License Agreement between the Company and Aventis Pasteur (formerly Pasteur Mérieux Sérums & Vaccins).
10.31(19)(a)	Amendment dated March 10, 2003, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.32(20)(b)	Fourth Amendment dated August 20, 2003, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.33(c)	Agreement dated May 6, 2003, between the Company and SAIC-Frederick, Inc.
23.1	Consent of KPMG LLP.
23.2	Consent of Arthur Andersen LLP.
31.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Martha J. Demski, Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Martha J. Demski, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the Company's Registration Statement on Form S-1 (No. 33-56830) filed on January 7, 1993.
(2) Incorporated by reference to the exhibit of the same number to the Company's Report on Form 10-K for the fiscal year ended December 31, 1994 (No. 0-21088).
(3) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-1 (No. 33-56830) filed on January 7, 1993.

(4) Incorporated by reference to Exhibit 10.1 filed with the Company's Registration Statement on Form S-8 (file No. 333-97019) filed on July 24, 2002.
(5) Incorporated by reference to Exhibit 10.1 filed with the Company's Registration Statement on Form S-8 (No. 333-30181) filed on June 27, 1997.
(6) Incorporated by reference to Exhibit 10.9 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994 (No. 0-21088).
(7) Incorporated by reference to Exhibit A of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994.
(8) Incorporated by reference to Exhibit A of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994 (No. 0-21088).
(9) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.
(10) Incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 1997.
(11) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999.
(12) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999.
(13) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
(14) Incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
(15) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.
(16) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
(17) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
(18) Incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.
(19) Incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.
(20) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.

(a) Indicates management contract or compensatory plan or arrangement.
(b) The Company has received confidential treatment of certain portions of this agreement which have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.
(c) The Company has requested confidential treatment of certain portions of this agreement which have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

(d) Financial Statement Schedules

The financial statement schedules required by this item are set forth at the pages indicated in Item 15(a)(2) above.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 11, 2004.

VICAL INCORPORATED

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

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

/s/ VIJAY B. SAMANT Vijay B. Samant	President, Chief Executive Officer and Director	March 11, 2004
/s/ MARTHA J. DEMSKI Martha J. Demski	Vice President, Chief Financial Officer, Treasurer and Secretary	March 11, 2004
/s/ R. GORDON DOUGLAS, M.D. R. Gordon Douglas, M.D.	Chairman of the Board of Directors	March 11 2004
/s/ ROBERT H. CAMPBELL Robert H. Campbell	Director	March 11, 2004
/s/ M. BLAKE INGLE, PH.D. M. Blake Ingle, Ph.D.	Director	March 11, 2004
/s/ PATRICK F. LATTERELL Patrick F. Latterell	Director	March 11, 2004
/s/ GARY A. LYONS Gary A. Lyons	Director	March 11, 2004
/s/ ROBERT C. MERTON, PH.D. Robert C. Merton, Ph.D.	Director	March 11, 2004

INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders of
Vical Incorporated:

We have audited the accompanying balance sheets of Vical Incorporated as of December 31, 2003 and 2002 and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The accompanying statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2001, 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 audits 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 audits provide a reasonable basis for our opinion.

In our opinion, the 2003 and 2002 financial statements referred to above present fairly, in all material respects, the financial position of Vical Incorporated as of December 31, 2003 and 2002 and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

San Diego, California
February 6, 2004, except
as to the third paragraph
of Note 13, which is as
of March 4, 2004.

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, 2003. 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.

VICAL INCORPORATED
BALANCE SHEETS

	December 31, 2003	December 31, 2002
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 16,573,912	$ 32,608,954
Cash equivalents—restricted	2,355,700	—
Marketable securities—available-for-sale	65,588,091	76,606,286
Marketable security—restricted	—	2,298,240
Receivables and other	5,386,211	5,893,491
Total current assets	89,903,914	117,406,971
Investment	—	800,000
Property and Equipment:		
Equipment	17,922,355	10,180,279
Leasehold improvements	8,426,848	4,687,877
	26,349,203	14,868,156
Less—accumulated depreciation and amortization	(12,013,962)	(9,925,642)
	14,335,241	4,942,514
Intangible assets, net	5,870,123	5,642,372
Other assets	597,912	634,091
	$ 110,707,190	$ 129,425,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,626,914	$ 7,369,546
Current portion of capital lease obligations	3,918,118	1,267,974
Current portion of notes payable	340,476	633,333
Current portion of deferred revenue	2,337,019	1,528,409
Total current liabilities	12,222,527	10,799,262
Long-Term Obligations:		
Long-term obligations under capital leases	7,196,376	1,976,920
Notes payable	—	340,476
Deferred revenue	131,130	949,315
Deferred lease credits	1,334,880	1,052,726
Total long-term obligations	8,662,386	4,319,437
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— 20,092,594 and 20,091,344 shares issued and outstanding at December 31, 2003, and December 31, 2002, respectively	200,926	200,913
Additional paid-in capital	203,607,418	203,554,007
Accumulated other comprehensive income	798,223	887,068
Accumulated deficit	(114,784,290)	(90,334,739)
Total stockholders' equity	89,822,277	114,307,249
	$ 110,707,190	$ 129,425,948

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2003	2002	2001
Revenues:			
License and royalty revenue	$ 2,066,029	$ 3,999,363	$ 7,572,190
Contract revenue	6,012,400	3,007,848	3,793,900
	8,078,429	7,007,211	11,366,090
Operating expenses:			
Research and development	26,777,241	26,374,443	22,094,460
General and administrative	6,922,310	8,060,610	6,500,933
Write-down of investment	482,217	4,200,000	—
	34,181,768	38,635,053	28,595,393
Loss from operations	(26,103,339)	(31,627,842)	(17,229,303)
Other income (expense):			
Investment income	2,066,608	3,983,594	8,285,889
Interest expense	(412,820)	(288,246)	(296,577)
Net loss	$ (24,449,551)	$ (27,932,494)	$ (9,239,991)
Net loss per common share (basic and diluted)	$ (1.22)	$ (1.39)	$ (0.46)
Weighted average shares used in computing basic and diluted net loss per common share	20,091,436	20,078,591	20,032,360

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE YEARS ENDED DECEMBER 31, 2003

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity	Total Comprehensive Loss
	Shares	Amount					
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)
Stock option exercises	1,250	13	2,874	—	—	2,887	
Non-cash compensation expense related to grant of stock options	—	—	50,537	—	—	50,537	
Unrealized gain on marketable securities arising during holding period							$ 100,699
Reclassification of realized gain included in net loss							(189,544)
Unrealized loss on marketable securities	—	—	—	(88,845)	—	(88,845)	(88,845)
Net loss	—	—	—	—	(24,449,551)	(24,449,551)	(24,449,551)
BALANCE, December 31, 2003	20,092,594	$ 200,926	$ 203,607,418	$ 798,223	$ (114,784,290)	$ 89,822,277	$ (24,538,396)

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2003	**2002**	**2001**
OPERATING ACTIVITIES:			
Net loss	$ (24,449,551)	$ (27,932,494)	$ (9,239,991)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,542,821	2,736,305	1,882,877
Write-down of investment	482,217	4,200,000	—
Loss on sublease	249,140	720,000	—
Compensation expense related to grant of stock options	50,537	1,571	155,416
Deferred lease credits	282,154	1,052,726	—
Change in operating assets and liabilities:			
Receivables and other	507,280	(1,257,957)	(222,457)
Other assets	36,179	(328,746)	(135,043)
Accounts payable and accrued expenses	(1,991,772)	2,360,541	596,474
Deferred revenue	(9,575)	(1,272,059)	(1,412,692)
Net cash used in operating activities	(21,300,570)	(19,720,113)	(8,375,416)
INVESTING ACTIVITIES:			
Sales of marketable securities	123,371,186	101,610,544	188,382,838
Purchases of marketable securities	(109,825,814)	(90,093,258)	(146,903,472)
Purchase of restricted cash equivalents	(2,355,700)	—	—
Capital expenditures	(1,856,797)	(497,657)	(2,004,907)
Licensed technology expenditures	(80,000)	—	(3,750,000)
Patent expenditures	(744,443)	(762,562)	(188,140)
Net cash provided from investing activities	8,508,432	10,257,067	35,536,319
FINANCING ACTIVITIES:			
Issuance of common stock, net	2,887	8,801	282,340
Proceeds from notes payable	—	—	1,107,700
Payments on notes payable	(633,333)	(657,144)	(502,380)
Principal payments under capital lease obligations	(2,612,458)	(1,015,725)	(792,582)
Net cash (used in) provided from financing activities	(3,242,904)	(1,664,068)	95,078
Net (decrease) increase in cash and cash equivalents	(16,035,042)	(11,127,114)	27,255,981
Cash and cash equivalents at beginning of year	32,608,954	43,736,068	16,480,087
Cash and cash equivalents at end of year	$ 16,573,912	$ 32,608,954	$ 43,736,068
Supplemental Disclosure of Cash Flow Information:			
Cash paid during the year for interest	$ 458,630	$ 291,425	$ 326,704
Non-Cash Investing and Financing Activities:			
Investment accounted for on the cost method, subsequently reclassified to marketable securities available-for-sale, at quoted market value	$ 317,783	$ —	$ —
Property and equipment financed under capital lease financing	$ 10,482,059	$ 1,797,594	$ 1,230,230

See accompanying notes to financial statements.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2003

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, grants and manufacturing 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 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. Management of the Company must make estimates in assessing the recoverability and useful life of intangible assets, the valuation allowance of deferred tax assets, accruals for clinical trial expenses and accruals for potential disallowed costs on government contracts.

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 ten-year useful life of the technology. 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 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.

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. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the

amount by which the carrying amount of the assets exceeds the fair value of the assets. If assets are to be disposed of, they are reported at the lower of the carrying amount or fair value less costs to sell. 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.

Research and Development Costs

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 accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, 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 number of treatments that a patient receives. Treatment periods vary depending on the clinical trial. The company makes revisions to the clinical trial cost estimates as clinical trials progress.

Revenue Recognition

The Company earns revenue from licensing its proprietary technology and by performing services under research and development contracts and grants, and service contracts. In general, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or 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 agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the passage of time, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured. Royalty revenue is recognized as the cash is received from the licensee.

Revenue under research and development contracts and grants, and manufacturing and regulatory service contracts, except for fixed-price contracts, is recognized as the research and development expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met. The Company does not recognize revenue on contract change orders until the service is performed and it 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 highly probable that the Company will receive a signed modification, or if the Company has received a signed modification, increasing the funding under the contract which will allow it to recover the costs incurred. Otherwise, the costs are expensed as 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.

The Company also has entered into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used for preclinical and clinical research. Under these contracts revenue is recognized when the product is shipped.

Accruals for Potential Disallowed Costs on Government Contracts

The Company has contracts with agencies of the U.S. government under which it bills for direct and indirect costs incurred. These billed costs are subject to audit by government agencies, such as the NIH. The Company has established accruals of approximately $0.6 million at December 31, 2003 to provide for potential disallowed costs. In the event that the final costs allowed are different from what the Company has estimated, the Company may need to make a change in its estimated accrual, which could also affect its results of operations and cash flow. No material adjustments were made to the accruals in the periods presented.

Net Loss Per Common Share

Basic and diluted net loss per common share has been computed using the weighted average number of shares of common stock outstanding during each of the three years ended December 31, 2003, 2002 and 2001. 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 number of shares so excluded was 3,333,693, 2,910,347 and 2,638,069, for the years ended December 31, 2003, 2002 and 2001, respectively. See Note 9 for average exercise prices of options outstanding.

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 since the exercise price of the option is equal to the fair market value of a share of common stock on the date of grant. 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, "Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123." 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:

	2003	2002	2001
Net loss - as reported	$ (24,449,551)	$ (27,932,494)	$ (9,239,991)
Add stock-based compensation expense included in reported net loss	50,537	1,571	155,416
Less stock-based compensation expense determined under fair value based method for all awards	(3,570,033)	(4,848,193)	(6,362,333)
Net loss - pro forma	$ (27,969,047)	$ (32,779,116)	$ (15,446,908)
Net loss per common share (basic and diluted) - as reported	$ (1.22)	$ (1.39)	$ (0.46)
Net loss per common share (basic and diluted) - pro forma	$ (1.39)	$ (1.63)	$ (0.77)

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 2.55% for 2003, 3.86% for 2002 and 4.24% for 2001; and expected volatility of 80% for 2003, 82% for 2002 and 81% for 2001. 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, or SAB, 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 $0.1 million, $0.0 million and $0.2 million for the years ended December 31, 2003, 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.

In September 2003, the SAB was dissolved. The option agreements were amended to provide for continued vesting over the original four-year vesting period as it is expected that the advisors will continue to provide services to the Company on a periodic basis. The estimated fair value of the options continues to be remeasured at the end of each quarter 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 3 for fair value of cash equivalents and marketable securities. For each of the years 2003, 2002 and 2001, 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 preferred stock in Vascular Genetics Inc., or VGI, a privately held company, in exchange for a license to Vical technology. The shares were recorded as an investment on the balance sheet at an estimated fair value of $5.0 million. In September 2002, the Company wrote down the investment in VGI to $0.8 million based on objective values established as a result of a proposed merger between VGI and GenStar Therapeutics Corporation, or GenStar, a public company listed on the American Stock Exchange, or AMEX. The VGI shares continued to be reflected as an investment on the balance sheet at December 31, 2002.

In February 2003, the merger closed, resulting in the creation of a new entity, Corautus Genetics, Inc., or Corautus. In connection with the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on the AMEX. The Company is restricted in the number of Corautus shares it can sell over a period of time. The value of the Company's Corautus shares, as measured by the quoted price on the AMEX on March 31, 2003, was $0.3 million. Based on this market information, on March 31, 2003, the Company wrote down its investment to $0.3 million and reclassified the investment as an available-for-sale security.

3. 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 investment ratings, 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 at time of purchase of less than three months. Cash equivalents of $15.3 million and $29.3 million at December 31, 2003 and 2002, 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 cash equivalents in 2003 and the restricted marketable security in 2002 represent securities pledged as collateral for a standby letter of credit in the amount of $2.4 million. Unrealized holding gains or losses, net of related tax effect, 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 2003 and 2002. A decline in the market value below cost that is deemed to be other than temporary would result in a charge to earnings in the period the decline occurs. At December 31, 2003, marketable securities, with market value determined based on quoted market prices, consisted of the following:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. government obligations	$ 46,911,750	$ 123,554	$ (11,975)	$ 47,023,329
Corporate bonds	11,229,884	35,411	(2,806)	11,262,489
Corporate asset backed securities	5,564,371	10,927	(9,631)	5,565,667
International bond	766,080	—	(2,280)	763,800
Investment in common stock of Corautus	317,783	655,023	—	972,806
	$ 64,789,868	$ 824,915	$ (26,692)	$ 65,588,091

At December 31, 2003, approximately 69 percent of these securities mature within one year, an additional 18 percent mature within two years, an additional 9 percent mature within three years, and the remaining 4 percent mature thereafter.

At December 31, 2002, marketable securities consisted of the following:

	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. government obligations	$ 59,528,227	$ 775,282	$ —	$ 60,303,509
Corporate bonds	10,119,388	59,308	(1,879)	10,176,817
Corporate asset backed securities	7,368,710	51,883	(913)	7,419,680
International bond	1,001,133	3,387	—	1,004,520
	$ 78,017,458	$ 889,860	$ (2,792)	$ 78,904,526

4. Intangible Assets

At December 31 of each year shown, intangible assets consisted of the following:

	2003		2002	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents and patent applications	$ 3,660,337	$ 834,003	$ 2,915,894	$ 617,272
Licensed technology rights	3,830,000	786,211	3,750,000	406,250
	$ 7,490,337	$ 1,620,214	$ 6,665,894	$ 1,023,522

Certain accumulated costs related to patent applications are amortized over the estimated economic lives of the patents, which currently is 20 years from the date the patent application is filed. The cost of licensed technology rights is amortized to expense over the estimated useful life of the technology, 10 years.

Amortization expense for patents and technology rights is included in research and development expense in the accompanying statements of operations. Aggregate amortization expense was $0.6 million, $0.5 million and $0.2 million, for the years ended December 31, 2003, 2002 and 2001, 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, 2004 through 2008, to be approximately $0.6 million.

5. Significant Contracts and License Agreements

Merck & Co., Inc.

The Company is a party to an agreement with Merck & Co., Inc., or Merck, which provides Merck with certain exclusive rights to develop and commercialize vaccines using the Company's DNA delivery technology for certain human diseases. Under the original and amended agreement, Merck licensed preventive and therapeutic human infectious disease vaccines using the Company's DNA delivery technology. In August 2003, under an additional amendment to the agreement,

Merck obtained options for rights to use the Company's DNA delivery technology for three cancer targets. Exercise of the option for each cancer target would result in a license fee payment to the Company, and further development may lead to milestone and royalty payments to the Company. In addition, Merck returned rights to the Company for certain preventive vaccines. Merck has retained rights to use the technology for HIV, hepatitis C virus, and hepatitis B virus.

In November 2001, the Company received a $3.0 million payment from Merck in accordance with its licensing agreement. The payment extended 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. Through December 31, 2003, 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 2003 or 2002. 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.

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 livestock and companion animals. 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 2002. Through December 31, 2003, the Company had received a total of $7.0 million under this agreement. License revenue recognized under this agreement was $0.0 million, $1.5 million and $0.7 million in 2003, 2002 and 2001, respectively. If Merial markets these vaccines, cash payments and royalties on net product sales would be due to the Company.

Aventis Pharma

The Company and Aventis Pharma S.A., a division of Aventis S.A., have an agreement that originally granted Aventis Pharma 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 Pharma. In June 2000, the Company and Aventis Pharma entered into a license agreement granting Aventis Pharma rights to use the Company's technology to deliver a growth factor gene for which Aventis Pharma holds rights. Under this agreement the Company received $1.5 million, which was recognized as revenue in 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.

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 certain infectious disease DNA vaccines 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, 2003, 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.

Centocor, Inc.

In February 1998, the Company entered into an exclusive license and option agreement allowing Centocor, Inc., a company subsequently acquired by Johnson & Johnson, to use the Company's DNA delivery technology to develop and commercialize certain DNA vaccines for the potential treatment of some 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 2002. Through December 31, 2003, the Company had received $3.7 million under this agreement. During the third quarter of 2003, Centocor provided the Company with notice of termination of the agreement effective February 9, 2004, at which time all rights granted to Centocor under the agreement reverted to the Company.

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, 2003, the Company had received approximately $7.1 million in royalty revenues under the Invitrogen/Life Technologies agreement and had recognized royalty revenue of $0.9 million in 2003 and $1.0 million in each of the years 2002 and 2001.

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, 2003, neither party had selected a gene for an initial option exercise.

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 was exchanged for common stock of Corautus. 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, 2003, of $0.8 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 each of the years 2003, 2002 and 2001.

SBIR Grant

In July 2003, the Company was awarded a three-year, $5.7 million Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases, or NIAID, for the development of a DNA vaccine against anthrax. Through December 31, 2003, the Company had recognized $1.9 million of revenue under this grant.

Aqua Health Ltd.

In October 2003, the Company granted a non-exclusive license for Canada to Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of the Swiss-based company Novartis Animal Health Inc., for use of the Company's patented DNA delivery technology in a vaccine against an undisclosed target. Aqua Health is investigating a vaccine based on the Company's DNA technology to combat diseases that affect both wild and farm-raised fish. The Company recognized license fees of $50,000 related to this agreement in 2003.

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 $5.5 million of funding to the Company, of which $0.2 million, $0.3 million and $1.5 million of contract revenue was recognized in 2003, 2002 and 2001, respectively. In 2003, Vical and ONR signed an agreement under which ONR agreed to provide funding to the Company if it performed further research and development on a malaria vaccine. No significant work was performed under this agreement in 2003 or to date in 2004. Both parties are discussing future work, if any, under this agreement. The Company does not plan to pursue this program independently.

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 funded $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 $3.9 million, $2.7 million and $1.8 million was recognized as revenue in 2003, 2002 and 2001, respectively. 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. See also Note 10 for related party agreements.

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 that had been 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 is required to pay the WARF up to 10 percent of certain initial upfront monetary payments and a small percentage of some royalty payments received under the Merck, Aventis Pasteur, Merial, Aventis Pharma, HGS, Corautus and Aqua Health agreements. The CytRx agreement would require the Company to make payments to CytRx if it or its sublicensees advance products through clinical development. Royalty expense for these agreements was $0.0 million, $0.2 and $0.4 million in 2003, 2002 and 2001, respectively. See also Note 8.

Potential Future Milestone Payments

The Company may be entitled to receive future payments from its collaborators based on the achievement of milestones set forth in the various collaborative agreements. In some cases, the triggering event for the milestone payments is the earlier to occur of the actual achievement of the milestones or the elapse of a certain amount of time under the agreements. In other cases, the milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to develop specific disease targets, commencement of various phases of clinical trials, filing of product license applications and approval of product licenses from the FDA or a foreign regulatory agency. In the case of veterinary applications, milestone payments are tied to the approval of field trials or product licenses by the United States Department of Agriculture. Receipt of any future milestone payments under the collaborative agreements is highly speculative and subject to a number of contingencies. In addition, for each of the collaborative agreements the rights to develop the indications covered by the agreements have been assigned to the Company's collaborators who may not be successful in their development efforts or in obtaining required regulatory approval. Additionally, a collaborator may exercise its right to terminate an agreement or alternatively seek to renegotiate the agreement milestones or the amount of milestone payments.

The aggregate amount of additional milestone payments that the Company could receive under all of its collaborative agreements in place at December 31, 2003, is approximately $78.3 million. This amount assumes that all remaining milestones contained in these agreements are met. In the event that product license approval for any of the collaborators' products is obtained, the Company may be entitled to receive royalty payments in addition to these milestone payments. Although the Company believes that some of the milestones contained in its collaborative agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are highly contingent and the Company has such limited control over whether the development and regulatory milestones will be achieved, the Company is not in a position to accurately estimate how much, if any, of the potential milestone payments will ultimately be realized. Additionally, under the collaborative agreements, many of the milestone events cannot occur for several years. The Company has not relied on prior milestone payments received under its collaborative agreements to finance its operations in the past and does not anticipate that these payments will constitute a material source of its financing in the near future.

6. Accounts Payable and Accrued Expenses

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

	2003	2002
Employee compensation	$ 1,740,893	$ 1,843,404
Accrued contract liabilities	642,318	630,720
Accrued construction liabilities	555,539	1,696,332
Accounts payable	406,289	393,333
Accrued sub-lease liabilities	275,245	517,000
Accrued clinical trials cost	241,463	776,273
Other accrued liabilities	1,765,167	1,512,484
	$ 5,626,914	$ 7,369,546

7. Leases and Notes Payable

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 also specified in the lease. The Company is also required to pay taxes, insurance and operating costs under the facilities leases. The Company recognizes level monthly rent for all facility leases 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 $1.3 million through December 31, 2003, is recorded as "deferred lease credits" in the balance sheet.

In January 2002, the Company signed a 15-year lease for a new building in northernSan 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 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 three leases, which terminate in late 2004, at three sites for manufacturing, research and office space. In March 2003, the Company relocated most of its employees to the new PCC facility. In March 2003, the Company subleased to a third party all of the vacated research space. In May 2003 and September 2003, the Company subleased portions of the vacated office space. The Company adjusted its accrual for estimated loss on the leases after each sublease

transaction. The Company is negotiating to renew its lease on approximately 15,000 square feet in one facility for one year and approximately 10,000 square feet in another facility for five years. The lease on the third facility will not be renewed at termination.

The equipment capital leases are secured by substantially all equipment of the Company. Information about operating and capital leases at December 31, 2003, is set forth below.

	Operating Leases	Capital Leases
Years ending December 31,		
2004	$ 4,348,586	$ 4,591,326
2005	2,700,341	4,018,698
2006	2,759,905	2,596,403
2007	2,827,695	1,177,619
2008	2,912,526	—
Thereafter	28,664,267	—
Total minimum lease payments	$ 44,213,320	12,384,046
Less amount representing interest		(1,269,552)
Present value of capital lease payments		11,114,494
Less current portion		(3,918,118)
Long-term obligations under capital leases		$ 7,196,376

Rent expense for the years ended December 31, 2003, 2002 and 2001, was $4.0 million, $3.7 million and $1.6 million, respectively. Rent expense for 2003 and 2002 included $0.2 million and $0.5 million, respectively, for the expected loss on space in the Company's older facilities that is vacant or sublet at rental rates less than those incurred by the Company. See also Note 6. In 2002 the Company also recorded a $0.2 million write-down of the unamortized balance of leasehold improvements at the Company's older facilities. Income from subleases expected to be recognized in 2004 is approximately $0.4 million. Total sublease rental income was approximately $0.2 million in 2003.

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

	Cost	Accumulated Depreciation	Net
December 31, 2003	$ 14,785,783	$ 3,158,572	$ 11,627,211
December 31, 2002	$ 5,163,418	$ 2,216,340	$ 2,947,078

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 lease line included approximately $8.0 million of credit for tenant improvements and equipment for the new leased facility. At December 31, 2003, $10.8 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.

Notes payable consisted of the following at December 31:

	2003	2002
Note payable to bank, payable in monthly installments of $30,952 through 2004, plus interest at the bank's prime rate (4.0% and 4.25% at December 31, 2003 and 2002, respectively)	$ 340,476	$ 711,904
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% at December 31, 2002)	—	261,905
	340,476	973,809
Less current portion	(340,476)	(633,333)
Notes payable, long-term	$ —	$ 340,476

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 from other lenders to $13 million.

8. Commitments and Contingencies

On July 29, 2003, the WARF filed a complaint against the Company in the United States District Court for the Western District of Wisconsin, seeking a declaratory judgment regarding the meaning of certain payment provisions in a license agreement the Company entered into with the WARF in 1991, as well as fees related to the Company's sublicense of certain inventions jointly owned by the Company and the WARF, the amount of which is unspecified in the WARF's complaint. The Company intends to vigorously defend the suit and has counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and a return of amounts overpaid to the WARF under this agreement in excess of $1.5 million. Based on the information presently available, the Company does not believe the WARF's claims are material to its business.

Vical's 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, or EPO. In April 2002, the Company filed an appeal, which is still pending, seeking to overturn this initial ruling.

The Company's core DNA delivery technology is also covered by a Canadian patent that was allowed and then withdrawn after protests against its issuance were filed on behalf of an undisclosed party or parties in August and December 2001. The Company has responded to the protests and is continuing prosecution of the application in the Canadian Patent Office.

In addition, the Company's core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the Japanese Patent Office, or JPO, on formal and substantive grounds. The Company filed a rebuttal response to the revocation. Based on the Company's arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. The Company also has received notice that four Trial for Invalidation, or TFI, requests against this patent were filed in the JPO by two companies. The Company filed responses to the TFI requests in a timely manner and is awaiting further action by the JPO.

A European patent issued in 2003, covers a range of applications of the Company's core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as its clinical-stage Allovectin-7® treatment for melanoma, cationic lipid-formulated DNA vaccines such as its investigational anthrax vaccine, and similar pharmaceutical products under development by others. Through the EPO web site, the Company understands that this patent has been opposed, although it is awaiting formal notification by the EPO. The Company intends to respond in a timely manner.

The Company has 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 a European patent granted in March 2002. The Company has received notice from the EPO that one company filed an opposition in December 2002 alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible in February 2003. The Company has submitted a rebuttal response to the opposition in a timely manner and is awaiting further action by the EPO.

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 it, except as noted above, and none of which, individually or in the aggregate, is deemed to be material to the financial condition of the Company.

In addition, the Company has undertaken certain commitments under agreements with its collaborators, and its officers and directors. Under license agreements with its collaborators, the Company has agreed to continue to maintain and defend the patent rights licensed to the collaborators. In addition, the Company has entered into indemnification agreements with each officer and director of the Company which would indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding. The Company is also obligated to pay salary continuation to four officers under certain circumstances as more fully explained in Note 10.

9. 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, 2003 or 2002.

Common Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 40,000,000 shares of common stock.

In December 2003, a shelf registration statement that the Company filed with the SEC was declared effective, which will allow the Company to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. The shelf registration is intended to provide flexibility in financing the Company's business needs. Specific terms of any offering under the shelf registration and the securities involved would be established at the time of sale.

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, 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, including restricted stock. 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, 2003. 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, 2003, 2002 and 2001:

	Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Grants
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	
Granted	929,508	$ 3.44	$ 2.45
Exercised	(1,250)	$ 2.31	
Forfeited	(504,912)	$ 13.47	
Outstanding December 31, 2003	3,333,693	$ 10.74	

The following table summarizes information about stock options outstanding under the Company's stock option plans at December 31, 2003:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 2.31 - $3.59	773,333	9.1	$ 3.13	7,238	$ 3.17
$ 3.65 - $9.40	844,015	8.1	$ 7.60	347,253	$ 8.20
$ 9.60 - $15.19	801,619	6.0	$ 12.51	628,342	$ 12.91
$ 15.25 - $20.69	682,076	6.0	$ 17.39	582,055	$ 17.31
$ 20.75 - $39.25	232,650	6.1	$ 21.89	229,829	$ 21.84
$ 2.31 - $39.25	3,333,693	7.3	$ 10.74	1,794,717	$ 14.53

The number of shares and weighted average price of options exercisable at December 31, 2003, 2002 and 2001, were 1,794,717 shares at $14.53, 1,594,837 shares at $15.71 and 1,440,071 shares at $15.79, respectively. At December 31, 2003, shares available for grant under the Company's stock option plans were 1,210,077.

10. Related Parties

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, is also the Director of Strategic Planning at the NIH Dale and Betty Bumpers Vaccine Research Center, or VRC. For varying periods beginning from November 2000, the VRC has contracted with Vical for providing regulatory support, manufacturing services, and the production of research and clinical trial supplies. Revenue recognized under these contracts was $3.0 million, $1.9 million and $1.3 million, for the years ended December 31, 2003, 2002 and 2001, respectively. In May 2003, the Company announced a contract to manufacture bulk DNA vaccines for the VRC. In support of this contract, the VRC has agreed to provide a 500-liter fermenter and related purification equipment in the Company's new manufacturing facility during the term

of the contract. Under this agreement, the Company is guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement.

If the Company fails to satisfy its contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and the Company may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or government property in its possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected. There are only a limited number of other contractors that could perform under this contract in the unlikely event that Vical was unable to perform. The price they might charge could be more than what Vical would charge based on their capacity, utilization, size of order and other factors. Accordingly, the Company is unable to estimate a range of potential cost it could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that the Company was unable to meet.

No revenue was recognized under this agreement in 2003. Included in "receivables and other" at December 31, 2003, is a receivable from the VRC in the amount of $0.9 million, of which $0.6 million pertains to equipment reimbursements.

Dr. Douglas was on the board of directors of the International AIDS Vaccine Initiative, or IAVI, a not-for-profit entity, until June 30, 2003. Vijay B. Samant, President and CEO of the Company, serves on the Project Management Subcommittee of the IAVI. In 2002, the Company signed an agreement with the IAVI to provide clinical trial supplies. Revenue recognized under this agreement for the years ended December 31, 2003 and 2002, was $0.9 million and $0.2 million, respectively.

The above related-party agreements 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, 2003 and 2002, 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 was $0.3 million and $0.4 million at December 31, 2003 and 2002, respectively. The current portion, included in "receivables and other," was $0.2 million and $0.1 million at December 31, 2003 and 2002, respectively.

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 at the current base compensation rate, or current base compensation rate plus the prior year's cash bonus in the case of the CEO, for the period specified in each agreement, which ranges from six to twelve months. These agreements also specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from the Company.

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 $0.1 million in 2003 and $0.3 million in 2002, including payroll taxes paid by the Company on the officers' behalf. In August 2002 the Company purchased and resold an officer's home and incurred a loss of $0.1 million. In 2001, the Company made a $0.3 million, interest free loan to one of the 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 the 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.

11. Income Taxes

The differences 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:

	2003	2002	2001
Computed "expected" tax benefit	$ (8,312,847)	$ (9,496,776)	$ (3,141,324)
State income taxes, net of federal benefit	(2,161,340)	(1,675,902)	(554,351)
Tax effect of:			
Change in valuation allowance	12,864,852	15,421,675	12,640,270
Adjustment to prior year credits and deferred taxes	(1,404,623)	(3,031,156)	(8,973,449)
Various tax credits	(1,048,500)	(1,234,474)	—

Other	62,458	16,633	28,854
Provision for income taxes	$ —	$ —	$ —

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

	2003	2002	2001
Deferred Tax Assets			
Net operating losses	$ 37,440,700	$ 29,168,043	$ 21,021,654
Various tax credits	14,626,050	12,166,687	6,768,613
Depreciation and amortization	8,304,834	5,557,016	5,509,838
Other	2,025,616	1,913,665	—
Accruals and reserves	1,151,705	2,146,884	531,511
Deferred revenue	1,057,355	789,113	2,492,049
Total gross deferred tax assets	64,606,260	51,741,408	36,323,665
Less valuation allowance	(64,606,260)	(51,741,408)	(36,323,665)
Net deferred tax assets	$ —	$ —	$ —

As of December 31, 2003 and 2002, the Company had available federal net operating loss carryforwards of approximately $107.2 million and $82.8 million, respectively. In addition, the Company had research and development credit and orphan drug credit carryforwards of $10.6 million as of December 31, 2003, and $8.9 million as of December 31, 2002, to reduce future federal income taxes, if any. These carryforwards expire from 2004 through 2023 and are subject to review and possible adjustment by the Internal Revenue Service. The Company also has available California state net operating loss carryforwards of approximately $11.1 million which expire from 2010 to 2013.

The Company had deferred tax assets of approximately $64.6 million and $51.7 million as of December 31, 2003 and 2002, 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.

The tax benefit associated with the Company's stock incentive plan was $5.0 million as of December 31, 2003 and 2002, which benefit will be reflected in additional paid-in capital, if realized.

The Tax Reform Act of 1986 limits a company's ability to utilize certain net operating loss and tax credit 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 amount of these limitations, if any, is unknown, and net operating and tax credit carryforwards may expire unused.

In 1999, one of the Company's product candidates, Allovectin-7â, 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 is continuing development of high-dose Allovectin-7â for melanoma, but discontinued development of Leuvectin® for kidney cancer and prostate cancer and low-dose applications of Allovectin-7®.

12. 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 2003 and 2002, and $0.1 million in 2001.

13. Subsequent Events

In December 2003, the Company received a commitment letter from the leasing division of a bank to provide the Company with up to $8.5 million of financing for tenant improvements and equipment. The Company has accepted the terms of this commitment letter subject to completing final lease documentation. The financial covenants of the proposed agreement would require the Company to maintain cash collateral equal to the amount of outstanding borrowings. The bank would have a secured interest in any equipment financed under this agreement. Additionally, if unrestricted cash and marketable securities, as defined, are less than $45 million, the Company would be required to maintain a letter of credit issued by another financial institution equal to the amount of outstanding borrowings at that time. In the event this occurred, the Company would expect that its restricted cash deposits securing the lease would be returned, but the Company would have to make restricted cash deposits with another financial institution in order to obtain a letter of credit.

In January 2004, the Company secured a license from the U.S. Centers for Disease Control and Prevention, or CDC, for technology used in a DNA vaccine, which was shown in independent tests at the CDC to protect horses from West Nile Virus after a single injection.

In addition, we have received notification of funding of approximately $1 million for research and development related to our CMV vaccine program under two grants from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID. A six-month Phase I Small Business Innovation Research, or SBIR, grant of approximately $0.3 million will partially fund preclinical safety and toxicity evaluation of the CMV vaccine in support of the company's planned Phase I human trial. An 18-month research grant of approximately $0.7 million will partially fund novel assays to measure and characterize immune responses in volunteers participating in the trial. The trial and immunological assays will be conducted in collaboration with the Fred Hutchinson Cancer Research Center in Seattle, Washington.

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, 2003 and 2002 (in thousands, except per share amounts):

2003	March 31,	June 30,	September 30,	December 31,
Revenues	$ 908	$ 602	$ 4,873	$ 1,695
Research and development costs	6,584	6,318	6,923	6,952
Total operating expenses	8,606	8,069	8,661	8,846

Net loss	$ (7,025)	$ (6,922)	$ (3,557)	$ (6,946)
Net loss per common share (basic and diluted)	$ (.35)	$ (.34)	$ (.18)	$ (.35)
Weighted average shares used in per share calculation	20,091	20,091	20,091	20,092

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

As more fully explained in Note 2, the results of operations for the three months ended March 31, 2003, and September 30, 2002, included $0.5 million and $4.2 million write-downs, respectively, of the Company's investment in VGI, now Corautus Genetics, Inc. Also, in the fourth quarter of 2002, the Company recorded a loss of $0.7 million for the expected loss on vacant leased space that was subleased at rental rates less than those incurred by the Company, and on the unamortized balance of leasehold improvements when the Company vacated its older facilities.

*** Text Omitted and Filed Separately Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2

SAIC FREDERICK SOLICITATION, OFFER AND AWARD

1. Maryland Sales and Use Tax Direct Pay Permit No. 3

2. Subcontract No.
23XS003

3. Solicitation No.
S03-003

4. ☐ Sealed Bid (IFB)
☒ Negotiated (RFP)

5. Date Issued
4/01/03

6. Requisition/Purchase No.
DD1069

7. Issued By: Address Offer To:
SAIC-Frederick, Inc.
NCI-Frederick Cancer Research & Development Center
P.O. Box B
Attn: Bldg. 244, Rm. 227, Miller Drive, Fort Detrick
Frederick, Maryland 21702-1201

8. Delivery Date: Specified in resulting Delivery Orders

8A. Place of Delivery: N/A

8B. ☐ FOB Destination ☒ FOB Origin

NOTE: In sealed bid solicitation *"offer"* and *"offeror"* mean *"bid"* and *"bidder"*.

SOLICITATION

9. To be timely sealed offers in original and copies must be received at the room specified in Item 7 by local time .
Envelopes shall be marked to show solicitation number and time. (hour) (date)

10. FOR INFORMATIONCALL:

A. NAME Jean LaPadula
B. Telephone No. *(Include area code)* (NO COLLECT CALLS)
(301) 644-2045

OFFER/SUBCONTRACT CONSISTS OF:

Part 1 - The Schedule

A. Solicitation/Contract Form
B. Supplies or Services and Prices/Costs
C. Description/Specs./Statement of Work
D. Packaging and Marking
E. Inspection and Acceptance
F. Deliveries or Performance
H. Special Contract Requirements

Part II - Contract Clauses

I. Contract Clauses

Part III - List Of Documents, Exhibits and Other Attachments

J. List of Attachments

Part IV - Representations and Instructions

K. Representations, Certifications and Other Statements of Offerors

SCHEDULE

ITEM NO.	SUPPLIES/SERVICES	QTY.	UNIT	UNIT PRICE	AMOUNT
	SEE STATEMENT OF WORK IN SECTION C.				[…***…]

12. In compliance with the above, if this offer is accepted within calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item in accordance with the terms of the offer.
Note: Sealed bids providing less than calendar days for acceptance will be considered non-responsive and rejected.

10 Calendar Days	20 Calendar Days	30 Calendar Days	Calendar Days

13. DISCOUNT FOR PROMPT PAYMENT (See Section D, Clause No. 52.232-8)	0 %	0 %	0 %	0 %

14. ACKNOWLEDGMENT OF AMENDMENTS

The offeror acknowledges receipt of amendments to the solicitation for offerors and related documents numbered and dated:

AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. Name and Address of Offeror

Vical, Inc.
10390 Pacific Centre Court
San Diego, CA 92121

15B. Telephone No. *(Include Area Code):* 858-646-1100

15C. ☐ Check if remittance address is different from above. Enter such address in schedule.

16. Name and Title of Person Authorized to Sign Offer *(Type or print)*

Vijay B. Samant
President and CEO

17. Signature
/s/ Vijay B. Samant

18. Offer Date April 4, 2003

AWARD *(On this form or by other written notice)*

19. Accepted As To Items Numbered:

20. IDIQ – Minimum obligation is **[**…***…**]**

21. Accounting Data:

22. Submit Invoices to Address, Item 7, Attn.: Accounts Payable *(3 copies unless other specified)*

23. Name/Title of Person Authorized to Sign – SAIC
Dennis Dougherty
Manager, Research Contracts

24. Signature of Person Authorized to Sign – SAIC

/s/ Dennis J. Dougherty

28. Award Date

5/6/03

*** CONFIDENTIAL TREATMENT REQUESTED**

CONTRACT NO.
23XS003

SPECIAL PROVISIONS

PART I

SECTION A - SOLICITATION, OFFER AND AWARD FORM

TABLE OF CONTRACT CONTENTS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COST

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

A. SAIC Frederick, Inc. (hereafter "SAIC" or "Government") under its Operations and Technical Support (OTS) contract with the National Cancer Institute – Frederick ("NCI") requests Vical, Inc. ("Contractor") to produce DNA plasmids on a delivery order basis for the Vaccine Research Center (VRC).

B. This is an Indefinite Delivery/Indefinite Quantity Contract for the supplies or services specified in Section C, Description/Specifications/Statement of Work. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract. Work shall proceed upon the issuance of a Delivery Order issued by the SAIC Contracting Officer. The Delivery Order issued shall be on a fixed price basis. Payment shall be made at the unit contract price(s) established for the initial period of performance and each option period specified in Article B.2. The period of performance is for (1) year after date of award with four (4) additional one-year option years to be unilaterally exercised by the Government. The total duration of this contract shall be for five years if all option years are exercised.

C. Independently, and not as an agent of the Government, the Contractor shall furnish services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this Indefinite Delivery/Indefinite Quantity Contract, as needed to produce DNA plasmids, or to otherwise perform the Statement of Work (SOW) specified in Section C herein.

ARTICLE B.2. PRICES/COSTS

Delivery Orders will be placed utilizing the following pricing for each corresponding year of performance:

001 – 100-Liter Small-Scale Production

Description	Base Year	Option Year 1	Option Year 2	Option Year 3	Option Year 4
Price per week	[…***…]	[…***…]	[…***…]	[…***…]	[…***…]

Note: The Contractor is responsible for vialing, labeling, and packaging of material produced with the 100-Liter manufacturing train.All vials […***…] will be filled up to a concentration of […***…] / mL and to a volume of […***…] unless otherwise specified in resulting Delivery Orders. The maximum number of vials to be filled by the Contractor cannot exceed […***…] per two fermentation runs.

002 – 500-Liter Large-Scale Production

Description	Base Year	Option Year 1	Option Year 2	Option Year 3	Option Year 4
Price per week	[…***…]	[…***…]	[…***…]	[…***…]	[…***…]

Note: The Contractor is not responsible for formulating, vialing, labeling, or packaging material produced with the 500-Liter manufacturingtrain.

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003 – Preparation of Master Cell Bank

Description	Base Year	Option Year 1	Option Year 2	Option Year 3	Option Year 4
Price per Master Cell Bank	[…***…]	[…**…]	[…***…]	[…***…]	[…***…]

Note: Government is responsible for costs associated with the procurement of adventitious agent testing and DNA sequencing.

004 – Document Preparation and Shipping

Description	Base Year	Option Year 1	Option Year 2	Option Year 3	Option Year 4
Document preparation and shipping preparation per shipment.	[…***…]	[…**…]	[…**…]	[…**…]	[…**…]

005 – Stability Testing

Description	Base Year	Option Year 1	Option Year 2	Option Year 3	Option Year 4
Stability Testing per test	[…**…]	[…**…]	[…**…]	[…**…]	[…**…]

Note: The following costs are not included in the fixed prices listed in Line Items 001-005:

1. Sequencing of new plasmids;
2. Post-bulk expression testing;
3. Adventitious agent testing of Master Cell Bank; and
4. DNA sequencing of Master Cell Bank.

General Assumptions:

1. Plasmid size is no larger than 10,000 base pairs

ARTICLE B.3. ITEMS TO BE FURNISHED TO THE CONTRACTOR

A. The Government will provide the Contractor with equipment consisting of a 500-Liter manufacturing train (Article G.3.B). The equipment is Government property and shall be used for this project only and shall not be used subsequently by the Contractor for any for-profit or non-for-profit venture without explicit written permission of SAIC-Frederick, Inc. Following the receipt of authorization to use the equipment, the Contractor may use the equipment for the approved dates for a fee (Note: fee is a percentage of purchase price calculated in accordance with FAR 52.245-9 (c)(i)). The Government will evaluate in good faith specific requests made by Contractor for waiver of the rental fee on a case-by-case basis. The Government shall not unreasonably deny requests from the Contractor for commercial use of the equipment.

In addition to providing equipment, the Government will pay to install and validate the equipment in the Contractor's facility. Contractor is responsible for all costs related to facility improvements, including but not limited to upsizing utilities, and proper maintenance and repair of the equipment. Contractor shall provide equipment maintenance records to the Government on an annual basis for all Government-

*** CONFIDENTIAL TREATMENT REQUESTED**

owned equipment.

At contract termination, the Government and the Contractor will mutually select and pay for an independent appraiser to appraise the current fair market value(1) of the equipment which appraisal shall assess only the fair market value of the equipment excluding the facilities and any facility improvements. The government and Contractor will negotiate a fair and reasonable price for the equipment based on the appraised value.

B. The Government shall provide the Contractor plasmids suitably developed (i.e. reasonably optimized for growth, plasmid yield and plasmid stability) for clinical trial production (as identified in resulting Delivery Orders). All materials and products, provided by the Government shall be used for this project only and shall not be used subsequently by the Contractor for any for-profit or not-for-profit venture without explicit written permission of SAIC-Frederick, Inc. Following contract completion, the DNA plasmids should be returned or disposed of as directed by the COTR.

C. In the event items are not furnished by the date specified, the Delivery Order will be modified, as necessary, to accommodate the delay (FAR 52.242-17, Government Delay of Work, April 1984).

D. The Contractor is responsible for the Contractor's loss or damage of Government furnished equipment, tools and supplies.

(1) Definition of fair market value: "The price a willing and knowledgeable buyer would pay to a willing and knowledgeable seller, both free from mistake or coercion, without regard to increases or decreases attributable to the project for which the property is being acquired." Source: GAO; "Principles of Federal Appropriations Law;" Second Addition; Volume IV; March 2001.

SECTION C - DESCRIPTION/SPECIFICATION/STATEMENT OF WORK

ARTICLE C.1. STATEMENT OF WORK

A. Background

The Vaccine Research Center (VRC) has an on-going need for DNA plasmids to support clinical trials of different vaccine products. The purpose of this contract is to enable the VRC to quickly fulfill requirements for DNA plasmids through the issuance of Delivery Orders.

B. Scope

The scope of this contract is the cGMP production of DNA plasmids for use in Phase I or Phase II human clinical trials for the specified disease targets (see below). Production of plasmids at the 100 liter scale shall include production, formulation in saline, vialing, labeling, packaging and storage of product. Production of plasmids at the 500 liter scale shall include only the production of bulk product.

The Contractor shall manufacture DNA plasmids for the following disease targets for the base year and all option years:

[…*…]**

The Contractor shall manufacture DNA plasmids for the following disease targets during the base year of this contract (written agreement from the Contractor is required for the manufacture of these plasmids for each option year):

[…***…**]**

C. Tasks

The Contractor shall manufacture products as specified in resulting Delivery Orders. The Contractor will develop and produce specified amounts (defined in resulting delivery orders) of clinical grade lots (cGMP) of DNA plasmids in suitable packaging and purity for clinical human vaccine trials. In addition, the Contractor shall provide storage required for stability testing of the plasmids. Stability testing shall be performed in accordance with cGMP guidelines and all of the relevant Points to Consider at the Contractor's facility for a maximum of two (2) years following each production or at the first time point following last clinical use.

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1. The Contractor shall complete the following tasks to produce the specified vaccine products as directed by the COTR:

   a. Where applicable, obtain starting materials from product inventor/supplier. Complete a material transfer agreement, if needed.

   b. As applicable and as requested by the Government, prepare a Master Cell Bank including the preparation of approximately 50 glycerol stock tubes, to be stored in liquid nitrogen. The Contractor will manage the administration of adventitious agent testing and DNA sequencing of the Master Cell Bank. Costs associated with the procurement of adventitious agent testing and DNA sequencing shall be borne by the Government.

   c. Develop detailed production plan and timeline for manufacture of lots of candidate vaccine products.

   d. Where applicable, purchase or otherwise acquire products and materials necessary for production of stated vaccine product.

   e. Produce vaccine product in a form suitable for use in human clinical studies. These products shall be prepared under cGMP conditions (Article C.1.3).

   f. Prepare vaccine product for shipment as specified in Article D.1.

   g. The Contractor shall provide notification of all deviations, Out of Specifications (OOS), and failure investigations to the COTR (Article G.1.B) and Program Manager (Article G.1.C) within 5 business days.

2. The Contractor shall provide the necessary facilities, equipment and resources including:

   a. Provide facilities and equipment suitable for cGMP production of vaccine product. All equipment and room identification must be traceable to batch records.

   b. Maintain and operate controlled storage of samples at appropriate temperatures with appropriate monitoring for failure (Room temperature through -70°C. Liquid nitrogen storage may be required for some products.)

   c. If necessary, receive, store and manipulate biohazardous materials (Biosafety Level 1 Containment) and maintain their viability in facilities, which provide aseptic and/or sterile conditions as appropriate.

   d. If necessary, provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, employed by Contractor, for the safety and protection of workers.

   e. Conduct work under the contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions.

3. Other than Potency Testing, the Contractor shall perform or manage as applicable the subcontracting of vaccine lot characterization tests.

   At various steps during the manufacture of a vaccine the product must be characterized. Prior to use of a vaccine in clinical studies the manufactured vaccine will need to undergo final lot release testing. As described in the regulations for General Biological Product Standards (21 CFR 610) the following tests must be performed for each lot of vaccine.

   a. Test for Potency. A test for potency (21 CFR 610.10) will evaluate in an in vitro or in vivo test the specific ability of the vaccine to effect a given response, such as an immune response in mice, which should be supportive of the efficacy of the vaccine in humans. In the case of DNA vaccines potency may be evidenced by the production of the pertinent antigen in a transfected cell line. This test will be performed by and at the Vaccine Research Center, NIAID, NIH.

   b. Test for General Safety. The general safety test (21 CFR 610.11) must be performed in mice and guinea pigs on each lot of vaccine to detect extraneous toxic contaminants potentially introduced during manufacture.

   c. Test for Sterility. A test for sterility (21 CFR 610.12) must be performed as described in the regulations.

   d. Test for Purity. A test for purity (21 CFR 610.13) must be performed on each lot to ensure that the product is free from extraneous material except for that which is unavoidable due to the manufacturing process. In addition, the test for purity includes an evaluation of residual ethanol and the presence of pyrogenic substances in the product as necessary.

   e. Test for Identity. The test for identity (21 CFR 601.14) is generally a physical or chemical test performed to establish the identity of the material in the final container.

   f. Test for Quantity. A measure of the amount of material present is imperative for calculating the dilution of the bulk material required for the final container fill.

   g. For materials produced at the 100 liter scale, perform stability testing at 3, 6, 9, 12, 18 and 24 months post-fill, or at the first time point following last clinical use. The Government shall inform Contractor of the specific stability tests (ex: gel electrophoresis, HPLC analysis for conformers, pH as appropriate) requested 60 days prior to initiation of such tests. Contractor will not be responsible for developing or administering expression / potency assays.

4. Contractor shall provide the following information to the VRC to aid in applicable regulatory submissions for products produced under this contract:

   a. IND/BMF cross-reference authorization

   b. CMC documentation for finished product

   c. Quality Assurance review / certificates of analysis

5. Participate in discussions with the FDA during pre-IND and IND meetings.

6. Meet with the COTR at periodic intervals, to be scheduled after contract award.

7. Retain all records, samples, histopathological slides, etc. as indicated and as applicable under GLP and cGMP guidelines and make them available.

ARTICLE C.2. DELIVERABLES

A. The Contractor shall provide the following deliverables at each of the designated milestones:

Milestone	Deliverable	Delivery Date
1/4 of total processing weeks completed	A quality assurance document specifying the following: 1) Results of wet cell weight assay from completed fermentations during period. 2) Results of crude yield estimate based on optical density from lysis completed during period. 3) Results of chromatography yield estimate based on optical density from chromatography completed during period. 4) Any final product completed during period.	One calendar month following achievement of milestone.
1/2 of total processing weeks completed	A quality assurance document specifying the following: 1) Results of wet cell weight assay from completed fermentations during period. 2) Results of crude yield estimate based on optical density from lysis completed during period. 3) Results of chromatography yield estimate based on optical density from chromatography completed during period. 4) Any final product completed during period.	One calendar month following achievement of milestone.
3/4 of total processing weeks completed	A quality assurance document specifying the following: 1) Results of wet cell weight assay from completed fermentations during period. 2) Results of crude yield estimate based on optical density from lysis completed during period. 3) Results of chromatography yield estimate based on optical density from chromatography completed during period. 4) Any final product completed during period.	One calendar month following achievement of milestone.
Completion of all processing weeks	A quality assurance document specifying the following: 1) Results of wet cell weight assay from completed fermentations during period. 2) Results of crude yield estimate based on optical density from lysis completed during period. 3) Results of chromatography yield estimate based on optical density from chromatography completed during period. 4) Any final product completed during period.	One calendar month following achievement of milestone.

B. The Contractor shall provide the following deliverables following completion of the final milestone:

- Clinical grade lots (cGMP) of DNA plasmids in suitable packaging and purity for clinical human vaccine trials in amount specified in Delivery Orders.
- IND/BMF cross-reference authorization
- CMC documentation for finished product
- Quality assurance review / certificates of analysis
- Certificate of conformance (see Attachment A for template)

ARTICLE C.3. GUARANTEED MINIMUM AMOUNTS

A. The Contractor shall deliver the following minimum quantity of bulk material for processing weeks purchased at either the 100-Liter or 500-Liter scale based on the table below:

Column A	Column B	Column C
Total Fermentation Yield (Sum of all grams of cell paste produced during fermentation runs)	Multiplication Factor	Minimum Quantity of Bulk Material (in milligrams) be Delivered by Contractor
[Determined upon completion of fermentations]	**[**…***…**]**	Column A * Column B

Example:
1) Contractor completes two fermentation runs and produces **[**…***…**]** grams of cell paste.
2) Using the above table, multiply **[**…***…**]** by **[**…***…**]** = **[**…***…**]**. Contractor will deliver a minimum of **[**…***…**]** mg of bulk plasmid DNA.

B. In addition, Contractor shall also perform a minimum of two fermentation runs per "block" of processing time purchased at the 100 liter scale, and a minimum of one fermentation run per "block" of processing time purchased at the 500 liter scale. Contractor shall also achieve a minimum cell paste of **[**…***…**]** grams per fermentor at the 100 liter scale, and **[**…***…**]** grams of cell paste per fermentor at the 500 liter scale.

SECTION D - PACKAGING AND SHIPMENT

ARTICLE D.1. PACKAGING AND SHIPMENT

Contractor shall prepare all materials for shipment in accordance with applicable International Air Transport Association (IATA) guidelines.

All deliverables shall be shipped F.O.B. – Origin

ARTICLE D.2. RELEASE OF MATERIALS

The Contractor shall submit the Certificate of Analysis and other appropriate documentation to SAIC-Frederick, Inc. following completion of the production of plasmids. The SAIC-Frederick, Inc. COTR will be responsible for review and acceptance of the documentation and materials. Prior to release of any materials produced by Contractor, the Government shall review applicable batch records at the Contractor's facility. Upon acceptance of materials, the Government shall send written verification of its acceptance of materials. Prior to final release of materials for shipment, the Government shall send written notification. The Contractor shall not release materials for shipment prior to receiving written authorization from the SAIC-Frederick, Inc. Contracting Officer. Following approval, SAIC-Frederick, Inc. will coordinate and pay for the shipment of materials.

The Contractor shall store complete bulk and finished materials for a maximum of three months.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

A. The acceptance criteria (i.e, expression test and pass/fail assays) for each plasmid shall be defined and documented in the Materials Ordering Form. The acceptance criteria for all materials shall be mutually agreed upon in writing prior to the issuance of the first Delivery Order.

B. The Contracting Officer or a duly authorized representative will perform the evaluation of the research services and acceptance of deliverables provided.

C. For the purpose of this Article, the SAIC Contracting Officer's Technical Representative (COTR) is the authorized technical representative of the Contracting Officer, unless specified otherwise in an individual Delivery Order.

D. This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Clause Title	Date
52.246-2	Inspection of Supplies – Fixed Price	Aug-1996

ARTICLE E.2. cGMP INSPECTION REQUIREMENTS

A. ***Review of Material Production Records.*** The Contractor shall have established procedures for regularly assessing a contract manufacturing facility's compliance with the applicable product and establishment standards. This may include, but is not limited to, review of all batch records and manufacturing deviations and defects, and periodic audits. Contract facilities engaged in the manufacture of a biological product are responsible for compliance with applicable provisions of the FD&C Act and will be subject to FDA inspection as provided for inspection 351(c) of the PHS Act and section 704(a) of the FD&C Act. The Contractor shall ensure that all owned and contract facilities are ready for inspection by SAIC-Frederick, Inc. and Government staff. Upon 15 business days advance written notice, the Contractor shall permit appropriately skilled representatives of SAIC-Frederick, Inc. or the Government, at SAIC-Frederick, Inc.'s expense, to have access, as necessary, during the Contractor's normal business hours to inspect Contractor's records as may be reasonably necessary to verify that the product manufactured by the Contractor are in accordance with Good Manufacturing Practices (GMP) and conform to the specifications outlined in this contract

B. ***Routine cGMP Audits.*** Upon 60 days advance written notice from SAIC-Frederick, Inc. or Government staff (other than FDA personnel), and not more than once per calendar year, (other than for cause) the Contractor shall permit appropriately skilled representatives of SAIC-Frederick, Inc. or the Government, at SAIC-Frederick, Inc.'s expense, to have access during the Contractor's normal business hours to inspect Contractor's records and facilities as may be reasonably necessary to verify that the production facilities and Standard Operating Processes (SOPs) used by the Contractor are in accordance

with Good Manufacturing Practices (GMP) and conform to the specifications outlined in this contract.

C. SAIC-Frederick, Inc. and the Government shall treat all information subject to review under this Article E.2. in strict confidence and shall cause its consultants who review such information to be bound by confidentiality agreements. The Contractor shall provide written documentation to the SAIC-Frederick, Inc. COTR and Sponsor of any FDA citation of a deviation from cGMP to allow evaluation of its impact on the purity, potency, and safety of the product.

D. Examples of documents available for audit include:

1. Documents listing raw materials, vendors, lot numbers, vendors' Certificate of Analysis, and internal release documentation (information required to trace starting materials to batch records)
2. A transaction history of all filled product inventories detailing the quantity of starting material used; quantity produced, sampled, and rejected; and final quantity placed in inventory and all subsequent distributions.
3. Environmental Monitoring (EM) data trends for production areas, including EM and personnel monitoring performed during aseptic operations. Data required to trace equipment and room identification to batch records.
4. Documentation demonstrating proper storage of process intermediaries and final product.
5. Chain of custody documentation for receipt and QA release of material including full reconciliation of material from release forward.
6. Batch Records

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

A. The initial period of performance of this contract shall be for twelve (12) months from the date of contract award. The Contracting Officer may extend the period of performance by exercising one or more of the four priced twelve (12) months option years in accordance with paragraph B below. The total duration of the contract shall not exceed five (5) years if all options are exercised.

B. Execution of option years will be based upon actual Contractor performance.

FAR 52.217-9 Option to Extend the Term of the Contract (Mar 1989)

The Government may extend the term of this contract by written notice to the Contractor within thirty (30) days provided, that the Government shall give the Contractor a preliminary written notice of its intent to extend at least sixty (60) days before the contract expires. The preliminary notice does not commit the Government to an extension.

If the Government exercises this option, the extended contract shall be considered to include this option provision.

The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 months.

C. If SAIC Frederick exercises its option(s) pursuant to Article F.1, paragraph B, the period of performance will be increased as listed below:

Option Year Number	Period of Performance
Option 1:	Twelve (12 months)
Option 2:	Twelve (12 months)
Option 3:	Twelve (12 months)
Option 4:	Twelve (12 months)

ARTICLE F.2. PLACE OF PERFORMANCE

The principle place of performance shall be at the Contractor's facility.

ARTICLE F.3. GOVERNMENT DELAY OF WORK

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Clause Title	Date
52.242-17	Government Delay of Work	Apr-1984

ARTICLE F.4. INDEFINITE DELIVERY/INDEFINITE QUANTITY CONTRACT (IDIQ)

A. This is an indefinite delivery/indefinite quantity contract for the supplies or services specified and effective for the period stated in the Schedule and any option periods. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract. Work shall proceed upon the issuance of a Delivery Order issued by the SAIC Contracting Officer. Payment shall be made at the unit contract price(s) established in Article B.2.

B. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the contract as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

C. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue Delivery Orders requiring delivery to multiple destinations.

D. Any Delivery Order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the Delivery Order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that Order to the same extent as if the Order were completed during the contract's effective period; *provided*, that the Contractor shall not be required to make any deliveries under this contract after 90 days beyond the ordering period.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACT REPRESENTATIVES

A. The following individual is designated as SAIC-Frederick's Contracting Officer and is authorized to conduct business, negotiate award and modifications.

Mr. Dennis Dougherty
SAIC-Frederick, Inc.

NCI-FCRDC, P.O. Box B, Building 244
Frederick, Maryland 21702—1201
Phone: 301-846-1087
Fax: 301-846-5414
E-mail: ddougherty@mail.ncifcrf.gov

B. The following individual is designated as SAIC-Frederick's Contracting Officer's Technical Representative (COTR) and is authorized to provide technical guidance and otherwise represent the Government as stated herein:

Dr. John W. Madsen
Vaccine Clinical Materials Program
SAIC-Frederick, Inc.
NCI Frederick
92 Thomas Johnson Drive, Suite 250
Frederick, MD 21702-1201
Phone: 301-644-2089
Fax: 301-694-9467
E-mail: madsenj@ncifcrf.gov

1. The Contracting Officer's Technical Representative is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

2. The Contracting Officer is the only person with the authority to act as an agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

C. The following individual is designated as the VRC Project Manager (PM) and is authorized to provide technical guidance:

Dr. Phillip Gomez
Vaccine Research Center
NIAID/NIH
Building 40, Room 5502
Bethesda, MD 20892
Phone: 301-594-8485
Fax: 301-480-2788
Email: pgomez@mail.nih.gov

D. The following individual has been designated as SAIC's-Frederick's Contract Specialist for purposes of administering, processing and handling contractual documentation:

Ms. Annette Bishop
SAIC Frederick
NCI-FCRDC, P.O. Box B
Frederick, Maryland 21702—1201
Phone: 301-644-2039
Fax: 301-644-2027
E-mail: abishop@mail.ncifcrf.gov

E. The following individuals are representatives designated by Vical, Incorporated:

(1) For contractual items:

Name:	Seth Goldblum
Title:	Exec. Director, Corporate Development
Phone:	(858) 646-1135
Fax:	(858) 646-1150
Address:	10390 Pacific Center Court San Diego, CA 92121
E-mail:	sgoldblum@vical.com

(2) For technical items:

Name:	Kevin Bracken
Title:	Vice President, Manufacturing
Phone:	(858) 646-1302
Fax:	(858) 646-1150
Address:	10390 Pacific Center Court San Diego, CA 92121
E-mail:	kbracken@vical.com

ARTICLE G.2. INVOICE SUBMISSION

A. Invoices shall be prepared and submitted as follows:

1. An original to the following designated payment office:

NCI-Frederick Cancer Research & Development Center
SAIC Frederick
Accounts Payable Department, Building 244
P. O. Box B - West 7th Street
Frederick, Maryland 21702-1201

2. A copy of the invoice should be sent via mail or facsimile to Annette Bishop (see Article G.1.D)

B. Inquiries regarding payment of invoices should be directed to the attention of Annette Bishop (see Article G.1.D).

C. An invoice is a written request for payment under the contract for items delivered, services rendered, or milestones achieved. In order to be proper, an invoice must include, as applicable, the following:

(1) Invoice date (note: date of Contractor's invoice shall not be earlier than delivery/service date
(2) Contractor's name
(3) Contract number (including ***Delivery Order number***, if applicable)
(4) Description of items or services, quantity, contract unit of measure, contract unit price, and extended total
(5) Payment terms and any trade discounts or allowances
(6) Wiring instructions for which the payment is to be made; and
(7) Name, title, phone number, and mailing address of person to be notified in event of a defective invoice.

E. The Contractor may invoice SAIC-Frederick, Inc. following the successful completion of milestones listed in Article C.2. The completion of the last milestone is defined as the earlier of shipment or 60 days following completion of vialing (100-Liter scale), or bulk material (500-Liter scale). The Contractor may invoice for master cell bank preparation, document preparation and shipping preparation, and stability testing after services are provided.

F. SAIC shall pay the Contractor, upon the submission of proper invoices or vouchers, the prices stipulated in this contract for products/services rendered and accepted, less any deductions provided in this contract.

G. A proper invoice will be deemed to have been received, when it is received by the office designated in the contract, or Delivery Order issued hereunder, for receipts of invoices and acceptance of the items delivered or services rendered has occurred.

H. Payment shall be considered made on the date on which a check for such payment is dated. If the Contractor opts to receive electronic funds transfer (EFT), payment shall be considered made on the date of the transfer.

ARTICLE G.3 GOVERNMENT PROPERTY

A. The parties agree that no non-expendable property or equipment will be acquired or furnished under this contract, unless prior written authorization is obtained from the Contracting Officer.

B. The following equipment/documentation will be provided by the Government:

[…***…**]**

ARTICLE G.4. ORDERING

A. Any services to be furnished under this contract shall be ordered by the issuance of a Delivery Order (See Attachment C for example) by the SAIC-Frederick, Inc. Contracting Officer. Such Delivery Orders may be issued commencing with the date of the contract award through the contract expiration date (ordering period). Prior to the placement of a Delivery Order, the Contractor shall provide detailed comparison data that will demonstrate to the Government the suitability of the 500-L process given

*** CONFIDENTIAL TREATMENT REQUESTED**

previous 100-L performance.

B. All Delivery Orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order and this contract, the contract shall control.

C. The Government shall place Delivery Orders a minimum of six (6) months in advance of the anticipated manufacturing start date. Delivery Orders may be issued via facsimile, email, or the mail by the SAIC-Frederick, Inc. Contracting Officer. If mailed, a Delivery Order is considered "issued" when SAIC deposits the order in the mail. The Contractor will notify the Contract Administrator (See ARTICLE G.1.D.) within 10 business days that the Order has been received and work shall begin in accordance with the order.

D. The Government shall submit rolling utilization forecasts (see Attachment E for example) to the Contractor a minimum of one year in advance of the anticipated manufacturing start date. The utilization forecast shall project all weeks of processing time requested for each manufacturing campaign that is anticipated to start during the one year utilization forecast period. The rolling forecast will be provided monthly throughout the term of this Agreement and will show production demand on a weekly basis for the next twelve months. The first rolling forecast is due upon award of this contract.

E. Nine months prior to the anticipated start date of work requiring the 500-Liter manufacturing train, the Government shall issue a Reservation Order (see Attachment B for example) reserving the necessary manufacturing weeks. The Reservation Order will have a fixed dollar amount equivalent to **[**…***…**]** of the price of the reserved manufacturing weeks (in accordance with Article B.2). In the event that the Government does not issue a Delivery Order for the time which the reservation fee has been committed, the Government will pay the Contractor the Reservation Fee. The reservation fee will be waived if a corresponding Delivery Order is issued.

F. If the Government Terminates for Convenience (FAR 52.249-2), the Contractor is released from its obligations under the Delivery Order to find other customers to fill the abandoned production spot. The Contractor shall make good-faith efforts to fill all abandoned weeks with another party. The Contractor may submit a termination settlement proposal to the government. If a third party is found to fill the production time, the amounts received by Contractor for these services shall off-set equal

amounts claimed by Contractor in the termination settlement proposal.

G. Modification to an Order may only be made/issued by the SAIC Contracting Officer.

ARTICLE G.5. GOVERNMENT ORDER PLACEMENT – EVENT TIMELINE

1. Twelve to nine months prior to anticipated work start date – Government notifies Contractor of its intention to utilize equipment based on rolling utilization forecasts that are submitted on a monthly basis.

2. Nine to six months prior to anticipated work start date – Government continues to notify Contractor of its intention to utilize equipment based on rolling utilization forecasts that are submitted on a monthly

*** CONFIDENTIAL TREATMENT REQUESTED**

basis for the upcoming twelve months. Nine months prior to the commencement of work at the 500-L scale, the Government shall issue a Reservation Order (see Article G.4.E.).

3. Six to zero months prior to anticipated work start date – Government continues to notify Contractor of its intention to utilize equipment based on rolling utilization forecasts that are submitted on a monthly basis. Delivery Orders for equipment usage at the 500 liter scale must be issued a minimum of six months prior to work start date.

4. No later than 90 days before work is scheduled to begin, the Government shall also complete and send via FAX and mail a Materials Ordering Form (see Attachment F for example) which shall include material acceptance criteria to the Contractor representative specified in Article G.E.2.

ARTICLE G.6. ORDER LIMITATIONS

A. *General Order Limitations*. The Contractor is not obligated to honor any Delivery Orders which:
   1. fall outside the scope of work as described in Article C.1.B; or
   2. require the manufacture of Select Agents for which the Contractor does not hold Select Agent Registration.
   3. require the use of the 500-L prior to July 1, 2004.

B. *Minimum order.* The Contractor is not obligated to honor any single Delivery Order:
   1. not requiring Government equipment as specified under Article G.3.B; or
   2. requiring less than **[**…***…**]** continuous weeks processing time.

C. *Maximum order.* The Contractor is not obligated to honor:
   1. any single Delivery Order requiring greater than **[**…***…**]** weeks processing time; or
   2. a series of Delivery Orders, when combined, exceed **[**…***…**]** weeks of processing time within any one period of 12 consecutive months.
   3. Delivery Orders causing overlapping processing time in the same equipment utilized by an existing Government Delivery Order.

ARTICLE G.7. MINIMUM AND MAXIMUM CONTRACT QUANTITIES

The Government shall purchase a minimum of **[**…***…**]** weeks of manufacturing processing at the 500 liter scale per year (including exercised option years) of this contract and a maximum of **[**…***…**]** weeks of manufacturing processing at the 500 liter scale per year for each year of this contract. The Government shall not be liable for purchasing the minimum quantity order in the event orders are refused because of facility/equipment delays experienced by the Contractor.

The Parties agree that the minimum and maximum contract quantities will not be in effect during the performance of the contract base year.

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SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REFERENCES TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES PROJECTS

All references to the Secretary, Department of Health, Education and Welfare, HEW, HEWPR, HEW forms, etc., shall be changed to Secretary, Department of Health and Human Services, HHS, HHSAR, etc., as appropriate.

ARTICLE H.2. SAFETY AND BIOSAFETY STANDARDS

All work performed under this contract shall be conducted in accordance with the Publication entitled, “Biosafety in Microbiological and Biomedical Laboratories” (HHS Publication No. (CDC) 93-8395).

ARTICLE H.3. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract.

ARTICLE H.4. HUMAN MATERIALS

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH*

Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 107-116, Section 510	2002	(10/1/01 - 9/30/02)

* In full force and affect in accordance with the Government Continuing Resolution.

ARTICLE H.6. NEEDLE EXCHANGE*

Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 107-116, Section 505	2002	(10/1/01 - 9/30/02)

ARTICLE H.7. ANIMAL WELFARE ASSURANCE

The Contractor shall obtain, prior to the start of any work utilizing laboratory animals under this contract, an approved Animal Welfare Assurance from the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

ARTICLE H.8. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

Under governing policy, Federal funds administered by the Public Health Service (PHS) shall not be expended for research involving live vertebrate animals without prior approval by the Office of Laboratory Animal Welfare (OLAW), of an assurance to comply with the PHS policy on humane care and use of laboratory animals. This restriction applies to all performance sites (e.g. collaborating institutions, subcontractors, subgrantees) without OLAW-approved assurances, whether domestic or foreign.

ARTICLE H.9. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. N01-CO-12400.

ARTICLE H.10. PRESS RELEASES

Pursuant to Public Law(s) cited in paragraph B., below, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or

* In full force and affect in accordance with the Government Continuing Resolution.

program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources in accordance to Public Law 107-116, Section 507.

ARTICLE H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The email address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, DC 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www1.od.nih.gov/oma/oma.htm)

ARTICLE H.12. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are deliverables under the procurement or are purchased by the contractor using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed

models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

ARTICLE H.13. cGMP COMPLIANCE REQUIREMENTS

The contractor shall be responsible for assuring compliance with both product and establishment standards consistent with the phase of clinical development. The product and establishment standards and cGMPs include, but are not limited to, the following:

1. Safety and effectiveness (identity, purity, strength, quality, potency, safety, efficacy, release and in-process specifications)
2. Adverse event, error and accident, and product complaint reporting systems
3. Development of the production process

4. Annual report submission as required by 21 CFR 312.33
5. Quality assurance oversight and change control for master and batch production records
6. Quality control methodology as it relates to the production process
7. Submission of protocols and samples for lot release where applicable
8. Content of the license application
9. Labeling
10. Contracts with the establishment(s) at which manufacturing and testing is being performed
11. Maintenance and proper functioning of all equipment and systems, as well as the facility itself
12. Environmental and other required monitoring
13. Report applicable CMC changes to the IND, as required in 21 CFR 312.31
14. Training of personnel

ARTICLE H.14. BUY AMERICAN ACT – BALANCE OF PAYMENTS PROGRAM CERTIFICATE

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product as defined in the clause of this solicitation entitled, "Buy American Act – Balance of Payments Program – Supplies" and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(b) Foreign End Products:
Line Item No.: N/A
Country of Origin: N/A

H.15. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

In the performance of any research and/or development under this contract involving recombinant DNA molecules, the Contractor agrees to abide by all NIH Guidelines relating to such activities, that are now current, or as may be updated from time-to-time. The Contracting Officer, upon request, will provide a copy of these Guidelines to the Contractor.

PART II

SECTION I – CONTRACT CLAUSES

ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at http://www.arnet.gov/far/.

A. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR Clause No.	Title	Date
52.202-1	Definitions	Dec 2001
52.203-3	Gratuities (Over $100,000)	Apr 1984
52.203-5	Covenant Against Contingent Fees (Over $100,000)	Apr 1984
52.203-6	Restrictions on Subcontractor Sales to the Government (Over $100,000)	Jul 1995
52.203-7	Anti-Kickback Procedures (Over $100,000)	Jul 1995
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)	Jan 1997
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)	Jan 1997
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)	Jun 1997
52.204-4	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)	Aug 2000
52.209-6	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)	Jul 1995
52.211-05	Material Requirements	Aug 2000
52.215-2	Audit and Records – Negotiation (Over $100,000)	Jun 1999
52.215-8	Order of Precedence – Uniform Contract Format	Oct 1997
52.215-14	Integrity of Unit Prices (Over $100,000)	Oct 1997
52.215-19	Notification of Ownership Changes	Oct 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications	Oct 1997
52.216-22	Indefinite Quantity	Oct 1995
52.219-8	Utilization of Small Business Concerns (Over $100,000)	Oct 2000
52.219-9	Small Business Subcontracting Plan (Over $500,000)	Jan 2002
52.219-16	Liquidated Damages – Subcontracting Plan (Over $500,000)	Jan 1999
52.222-19	Child Labor-Cooperation with Authorities and Remedies	Dec 2001
52.222-20	Walsh-Healey Public Contracts Act	Dec 1996

52.222-26	Equal Opportunity	Apr 2002
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	Dec 2001
52.222-36	Affirmative Action for Workers with Disabilities	Jun 1998
52.222-37	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	Dec 2001

FAR Clause No.	Title	Date
52.223-6	Drug-Free Workplace	May 2001
52.223-14	Toxic Chemical Release Reporting	Oct 2000
52.225-1	Buy American Act – Supplies	May 2002
52.225-13	Restrictions on Certain Foreign Purchases	Jul 2000
52.227-1	Authorization and Consent	Jul 1995
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)	Aug 1996
52.227-3	Patent Indemnity	Apr 1984
52.229-3	Federal, State and Local Taxes (Over $100,000)	Jan 1991
52.229-5	Taxes – Contracts Performed in U.S. Possessions or Puerto Rico	Apr 1984
52.232-1	Payments	Apr 1984
52.232-8	Discounts for Prompt Payment	Feb 2002
52.232-9	Limitation on Withholding of Payments	Apr 1984
52.232-11	Extras	Apr 1984
52.232-17	Interest (Over $100,000)	Jun 1996
52.232-23	Assignment of Claims	Jan 1986
52.232-25	Prompt Payment	Feb 2002
52.232-34	Payment by Electronic Funds Transfer-Other Than Central Contractor Registration	May 1999
52.233-1	Disputes	Dec 1998
52.233-3	Protest After Award	Aug 1996
52.242-13	Bankruptcy (Over $100,000)	Jul 1995
52.243-1	Changes – Fixed-Price	Aug 1987
52.244-2	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.	Aug 1998
52.245-2	Government Property (Fixed-Price Contracts)	Dec 1989
52.245-9	Use and Charges	Apr 1984
52.249-2	Termination for the Convenience of the Government (Fixed-Price)	Sep 1996
52.249-8	Default (Fixed-Price Supply and Service)(Over $100,000)	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

B. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR Clause No.	Clause Title	Date
352.202-1	Definitions	Jan-2001
352.223-70	Safety and Health	Jan-2001
352.232-9	Withholding of Contract Payments	Apr-1984
352.270-4	Pricing of Adjustments	Jan 2001
352.270-6	Publications and Publicity	Jul-1991
352.270-7	Paperwork Reduction	Jan-2001

C. SAIC-Frederick, Inc. Terms & Conditions

1. GOVERNMENT RELATIONSHIP

This Order is made by SAIC-Frederick, Inc., a Subsidiary of Science Applications International Corporation under its contract with the National Cancer Institute at Frederick (NCI-Frederick). The provisions and clauses contained herein are influenced by and reflect the relationship of the parties in that contract, which was awarded and is administered under the provision of the Federal Acquisition Regulation (FAR). There is no privity of contract between the Seller and the Government.

2. GENERAL RELATIONSHIP

The Seller is not an employee of SAIC-Frederick, Inc. for any purpose whatsoever. Seller agrees that in all matters relating to this Order it shall be acting as an independent contractor and shall assume and pay all liabilities and perform all obligations imposed with respect to the performance of this Order. Seller shall have no right, power or authority to create any obligation, expressed or implied, on behalf of Buyer and/or Buyer's customers and shall have no authority to represent Buyer as an agent.

3. DEFINITIONS

Buyer – SAIC-Frederick, Inc.

Seller – The party (contractor) receiving the award from SAIC-Frederick, Inc.

Contracting Officer – The SAIC-Frederick, Inc. person with the authority to enter into and administer Orders. The term includes authorized representatives of the Contracting Officer acting within their delegated authority.

Order – The contractual agreement between SAIC-Frederick, Inc. and the Seller.

Special Definitions – See paragraph 4 for the special definitions that apply in the use of the solicitation and award clauses of this Order.

4. SOLICITATION AND AWARD CLAUSES – SPECIAL DEFINITIONS

FAR clauses included in this Order, including any solicitation document, shall be interpreted as follows:

Unless a purposeful distinction is made clear and the context of the clause requires retention of the original definition, the term "Contractor" shall mean Seller, the term "Contract" shall mean this Order, the term "Subcontractor" shall mean subcontractors of Seller at any tier, and the terms "Government", "Contracting Officer" and equivalent phrases shall mean SAIC-Frederick, Inc. and SAIC-Frederick's Contracting Officer, respectively. It is intended that the referenced clauses shall apply to Seller in such manner as is necessary to reflect the position of Seller as a contractor to SAIC-Frederick, Inc. to insure Seller's obligations to SAIC-Frederick, Inc. and to the United States

Government, and to enable SAIC-Frederick, Inc. to meet its obligations under its Prime Contract.

Full text of the referenced clauses may be found in the FAR (Code of Federal Regulation [CFR] Title 48), obtainable from the Superintendent of Documents, Government Printing Office (GPO), Washington, DC 20402 or online at http://www.arnet.gov/far/. Copies of the clauses will be furnished by the Contracting Officer upon request.

5. ENTIRE AGREEMENT

This Order, including all attachments and/or documents incorporated by reference by Buyer, shall constitute the entire agreement between Buyer and Seller. No other document (including Seller's proposal, quotation or acknowledgement forms, etc.) shall be a part of this order, even if referred to, unless specifically agreed to in writing by Buyer. No right that Buyer has regarding this Order may be waived or modified except in writing by Buyer.

6. ACCEPTANCE AND MODIFICATION OF TERMS

Acceptance of this Order by Seller may be made by signing the acknowledgement copy hereof or by partial performance hereunder, and any such acceptance shall constitute an unqualified agreement to all terms and conditions set forth herein unless otherwise modified in writing by the parties. Any additions, deletions or differences in the terms proposed by Seller are objected to and hereby rejected, unless Buyer agrees otherwise in writing. No additional or different terms and conditions proposed by the Seller in accepting this Order shall be binding upon Buyer unless accepted in writing by Buyer and no other addition, alteration or modification to, and no waiver of any of the provisions herein contained shall be valid unless made in writing and executed by Buyer and Seller. Seller shall perform in accordance with the Description/Quantity schedule set forth in this Order and all attachments thereto.

7. LEGAL CONSTRUCTION AND INTERPRETATIONS

This Order shall be governed by and interpreted in accordance with the principles of Federal Contract Law, and to the extent that Federal Contract Law is not dispositive, and the state law becomes applicable, the law of the State of Maryland shall apply.

8. COMPLIANCE WITH LAWS AND REGULATIONS

Seller shall submit all certifications required by Buyer under this Order and shall at all times, at its own expense, comply with all applicable Federal, State and local laws, ordinances, administrative orders, rules or regulations.

9. GIFTS

Seller shall not make or offer a gratuity or gift of any kind to Buyer's employees or their families. Seller should note that the providing of gifts or attempting to provide gifts under government subcontracts might be a violation of the Anti-Kickback Act of 1986 (4 U.S.C. 51-58).

10. MARYLAND SALES AND USE TAX

The State of Maryland has issued Direct Payment Permit #3 to SAIC-Frederick, Inc. for all vendor purchases for the NCI-Frederick effective August 29, 1996. A copy of this certificate is available to vendors upon request. SAIC-Frederick, Inc. is authorized to make direct payment of sales and use tax to the State of Maryland and vendors are not to add sales tax to invoices, nor are they responsible for collection of such taxes for purchases by SAIC-Frederick.

11. BUYER FURNISHED DATA AND MATERIALS

All data and materials furnished by Buyer to Seller under this Order including drawings, specifications and written information and Buyer-owned parts and/or Buyer-owned tools and equipment shall be used solely for the work to be performed under this Order. Seller shall repair and maintain all tools at its own expense unless agreed to otherwise. Seller agrees to promptly return all such data and materials upon completion of the work or termination of this Order. Seller agrees to return all materials in the same condition as delivered to Seller, reasonable wear and tear excepted.

12. NOTICE OF DELAY

Seller agrees to immediately notify Buyer in writing of any actual or potential delay in Sellers performance under this Order. Such notice shall, at a minimum, describe the cause, effect, duration and corrective action proposed by Seller to address the problem. Seller shall give prompt written notice to the Buyer of all changes to such conditions.

13. CHANGES AND SUSPENSION

Buyer may, by written notice to Seller at any time, make changes within the general scope of this Order in any one or more of the following: (a) drawings, designs or specifications; (b) quantity; (c) time or place of delivery; (d) method of shipment or packing; and (e) the quantity of Buyer furnished property. Buyer may, for any reason, direct Seller to suspend, in whole or in part, delivery of goods or performance of services hereunder for such period of time as may be determined by Buyer in its sole discretion. If any such change or suspension causes a material increase or decrease in the cost of, or the time required for the performance of any part of the work under this Order, an equitable adjustment shall be made in the Order price or delivery schedule, or both, provided Seller shall have notified Buyer in writing of any claim for such adjustment within twenty (20) days from the date of notification of the change or suspension from Buyer. No such adjustment or any other modification of the terms of this Order will be allowed unless authorized by Buyer by means of a written modification to the Order. Seller shall proceed with the work as changed without interruption and without awaiting settlement of any such claim.

14. ADVERTISING

Seller agrees that prior to the issuance of any publicity or publication of any advertising that in either case makes reference to this Order, or to Buyer, Seller will obtain the written permission of Buyer with respect thereto.

Notwithstanding the foregoing, Seller may disclose the existence of this Order and material information related to the Order as required to fulfill its regulatory obligations (i.e., Securities and Exchange Commission (SEC) reportings and in its annual report.)

15. CONFIDENTIAL INFORMATION

Seller shall not at any time, even after the expiration or termination of this Order, use or disclose to any person for any purpose other than to perform this Order, any information it receives, directly or indirectly from Buyer in connection with this Order, except information that is or becomes publicly available, or is rightfully received by Seller from a third party without restriction. Upon request by Buyer, Seller shall return to Buyer all documentation and other material containing such information.

Seller shall not disclose to Buyer any information that it deems to be confidential or proprietary, and it is understood that no information received by Buyer, including manuals, drawings and documents, will be of a confidential nature or restrict in any manner the use or disclosure of such information by Buyer. Seller agrees that any legend or other notice on or pertaining to any information or materials supplied by it that is inconsistent with the preceding sentence shall create no obligation on the part of Buyer.

16. INDEMNIFICATION

Seller shall indemnify, defend and hold Buyer, including its officers, agents, and employees, harmless from and against any, liability, including attorney's fees, arising out of or in connection with Seller's failure to comply with the specifications provided by the Buyer under this agreement, provided however that Seller may assume the legal defense of any legal proceedings by a third person against SAIC-Frederick, Inc., paying all attorney's fees, costs, and expenses, and satisfying any judgment rendered.

17. NON-WAIVER OR RIGHTS

The failure of Buyer to insist upon strict performance of any of the terms and conditions in this Order or to exercise any rights or remedies, shall not be construed as a waiver of its rights to assert any of same or to rely on any such terms or conditions at any time thereafter. Any rights and remedies specified under this Order shall be cumulative, non-exclusive and in addition to any other rights and remedies available at law or equity. The invalidity in whole or in part of any term or condition of this Order shall not affect the validity of other parts thereof.

18. EXPORT OF CONTROLLED TECHNOLOGY

Seller shall not, nor shall Seller authorize or permit its employees, agents or lower tiers to disclose, export or re-export any Buyer information, or any process, product or service that is produced under this Order, without prior notification to Buyer and complying with all applicable Federal, State and local laws, regulations and ordinances, including the regulations of the U.S. Department of Commerce and/or the U.S. Department of State. In addition, Seller agrees to immediately notify Buyer if Seller is listed in the Table of Denial Orders published by the Department of Commerce, or it Seller's export privileges are otherwise denied, suspended or revoked in whole or in part.

Under its contract with NCI-Frederick, Buyer conducts research activities that include export-controlled technology that cannot be readily segregated. Buyer may require Seller (including any lower tiers) to place restrictions on their work force performing onsite at

SAIC-Frederick, Inc., to protected individuals as established under the guidelines of the Commerce Department Export Administration Regulations (EAR) and the State Department International Traffic in Air Regulation (ITAR).

Contractors (including any lower tiers) will be required to disclose the status of personnel proposed to perform work onsite prior to award.

19. ASSIGNMENT

Neither this Order nor any interest herein may be assigned, in whole or in part, without the prior written consent of Buyer except that the Seller shall have the right to assign this Order to any successor of such party by way of merger or consolidation or the acquisition of substantially all of the business and assets of the Seller relating to the subject matter of this Order. This right shall be retained provided that such successor shall expressly assume all of the obligations and liabilities of the Seller under this Order, and that the Seller shall remain liable and responsible to Buyer for the performance and observance of all such obligations.

Notwithstanding the foregoing, any amounts due the Seller may be assigned in accordance with the provisions of the clause 52.232-

20. Assignment of Claims.

In the event the prime contract of SAIC-Frederick, Inc. with the Government is succeeded by a successor contractor selected by the Government, this Order may be assigned to the successor contractor.

21. DISPUTES

Buyer and Seller agree to first enter into negotiations to resolve any controversy, claim or dispute ("dispute") arising under or relating to this Order. The parties agree to negotiate in good faith to reach a mutually agreeable resolution of such dispute within a reasonable period of time. If good faith negotiations are unsuccessful, Buyer and Seller agree to resolve the dispute by binding and final arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association then in effect. The arbitration shall take place in the County of Frederick, State of Maryland. The arbitrator(s) shall be bound to follow the provisions of this Order in resolving the dispute, and may not award punitive damages. The decision of the arbitrator(s) shall be final and binding on the parties, and any award of the arbitrator(s) may be entered or enforced in any court of competent jurisdiction.

Pending any decision, appeal or judgment referred to in this provision or the settlement of any dispute arising under this Subcontract, Seller shall proceed diligently with the performance of this Subcontract.

22. NOTIFICATION DEBARMENT/SUSUPENSION

By acceptance of this Order either in writing or by performance, Seller certifies that as of the date of award of this Order neither the Seller, lower tiers, nor any of its principals, is debarred, suspended, or proposed for debarment by the Federal Government. Further, Seller shall provide immediate written notice to the Buyer in the event that during performance of this Order the Seller or any of its principals is debarred, suspended, or proposed for debarment by the Federal Government.

23. QUALITY ASSURANCE

The Buyer, and/or personnel authorized by Buyer, shall have the right, at all reasonable times, to visit Seller's facilities or such parts thereof as may be engaged in work relating to this Order in order to verify that Seller's performance is in accordance with all requirements of this Order. In addition, the Buyer, and/or personnel authorized by Buyer, shall have the right, at all reasonable times, to visit the facilities of the Seller's lower tiers or such parts thereof as may be engaged in work relating to this Order. The Seller shall include a like provision in all related lower-tier subcontracts. Nothing herein shall give the Buyer the right to issue direct orders or instructions to Seller's lower tiers. Seller shall be furnished prior notice of any planned visit.

24. ORDER OF PRECEDENCE

In the event of an inconsistency or conflict between these SAIC Terms and Conditions and the Order issued, the inconsistency or conflict shall be resolved by giving precedence in the following order:

1) The Order and any provisions.

2) SAIC-Frederick, Inc. Standard Terms and Conditions and Exhibits thereto.

3) Specifications and/or drawings.

4) Other documents or exhibits when attached.

25. TERMINATION

Buyer may terminate this Order (in whole or in part) for convenience or for cause pursuant to the Federal Acquisition Regulation Part 49, "Terminations of Contracts" and/or the provisions of the individual Order.

ARTICLE I.2. DATA RIGHTS

For the purposes of this clause, the following data are considered "limited rights data."

1. Contractor's proprietary manufacturing process
2. Batch Records
3. Standard Operating Procedures (SOP) and protocols
4. Analytical methods
5. Equipment specifications and qualification
6. Material specifications
7. Documents prepared in support of the manufacture, test, and release of materials
8. Master Files (DMF, BMF) and communication file with the Federal Drug Administration related to the Master Files
9. Data generated via rental of Government equipment

In lieu of providing copies of the proprietary manufacturing process and batch records to the Government, the Contractor shall allow the Government to cross-reference the Biologics Master File (BMF) and review the batch records at the Contractor's facility.

FAR 52.227-14 Rights in Data-General.

As prescribed in 27.409(a), insert the following clause with any appropriate alternates:

Rights in Data-General (June 1987)

(a) *Definitions*. "Computer software," as used in this clause, means computer programs, computerdata bases, and documentation thereof.

"Data," as used in this clause, means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

"Form, fit, and function data," as used in this clause, means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, as well as data identifying source, size, configuration, mating, and attachment characteristics, functional characteristics,

and performance requirements; except that for computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithm, process, formulae, and flow charts of the software.

"Limited rights," as used in this clause, means the rights of the Government in limited rights data as set forth in the Limited Rights Notice of paragraph (g)(2) if included in this clause.

"Limited rights data," as used in this clause, means data (other than computer software) that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications thereof.

"Restricted computer software," as used in this clause, means computer software developed at private expense and that is a trade secret; is commercial or financial and is confidential or privileged; or is published copyrighted computer software, including minor modifications of such computer software.

"Restricted rights," as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of paragraph (g)(3) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

"Technical data," as used in this clause, means data (other than computer software) which are of a scientific or technical nature.

"Unlimited rights," as used in this clause, means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) *Allocation of rights.*
(1) Except as provided in paragraph (c) of this clause regarding copyright, the Government shall have unlimited rights in-
(i) Data first produced in the performance of this contract;
(ii) Form, fit, and function data delivered under this contract;
(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and
(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this

clause.
(2) The Contractor shall have the right to-
(i) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;
(ii) Protect from unauthorized disclosure and use those data which are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause;
(iii) Substantiate use of, add or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and
(iv) Establish claim to copyright subsisting in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause.
(c) *Copyright*-
(1) *Data first produced in the performance of this contract.* Unless provided otherwise in paragraph (d) of

this clause, the Contractor may establish, without prior approval of the Contracting Officer, claim to copyright subsisting in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings or similar works. The prior, express written permission of the Contracting Officer is required to establish claim to copyright subsisting in all other data first produced in the performance of this contract. When claim to copyright is made, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting in its behalf, a paid-up nonexclusive, irrevocable worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly by or on behalf of the Government.
(2) *Data not first produced in the performance of this contract.* The Contractor shall not, without prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract and which contains the copyright notice of 17 U.S.C. 401 or 402, unless the Contractor identifies such data and grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause; *provided*, however, that if such data are computer software the Government shall acquire a copyright license as set forth in paragraph (g)(3) of this clause if included in this contract or as otherwise may be provided in a collateral agreement incorporated in or made part of this contract.
(3) *Removal of copyright notices.* The Government agrees not to remove any copyright notices placed on data pursuant to this paragraph (c), and to include such notices on all reproductions of the data.
(d) *Release, publication and use of data.*
(1) The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except to the extent such data may be subject to the Federal export control or national security laws or regulations, or unless otherwise provided in this paragraph of this clause or expressly set forth in this contract.
(2) The Contractor agrees that to the extent it receives or is given access to data necessary for the performance of this contract which contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless otherwise specifically authorized in writing by the Contracting Officer.
(e) *Unauthorized marking of data.*
(1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(2) or (g)(3) of this clause and use of such is not authorized by this clause, or if such data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may at any time either return the data to the Contractor, or cancel or ignore the markings. However, the following procedures shall apply prior to canceling or ignoring the markings.
(i) The Contracting Officer shall make written inquiry to the Contractor affording the Contractor 30 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;
(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 30-day period (or a longer time not exceeding 90 days approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure

prohibitions.
(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in subdivision (e)(1)(i) of this clause, the Contracting Officer shall consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor shall be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer shall furnish the Contractor a written determination, which determination shall become the final agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government shall continue to abide by the markings under this subdivision (e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government shall thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.
(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request thereunder.
(3) This paragraph (e) does not apply if this contract is for a major system or for support of a major system by a civilian agency other than NASA and the U.S. Coast Guard agency subject to the provisions of Title III of the Federal Property and Administrative Services Act of 1949.
(4) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph (e) from bringing a claim under the Contract Disputes Act, including pursuant to the Disputes clause of this contract, as applicable, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.
(f) *Omitted or incorrect markings*.
(1) Data delivered to the Government without either the limited rights or restricted rights notice as authorized by paragraph (g) of this clause, or the copyright notice required by paragraph (c) of this clause, shall be deemed to have been furnished with unlimited rights, and the Government assumes no liability for the disclosure, use, or reproduction of such data. However, to the extent the data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer for good cause shown) after delivery of such data, permission to have notices placed on qualifying data at the Contractor's expense, and the Contracting Officer may agree to do so if the Contractor-
(i) Identifies the data to which the omitted notice is to be applied;
(ii) Demonstrates that the omission of the notice was inadvertent;
(iii) Establishes that the use of the proposed notice is authorized; and
(iv) Acknowledges that the Government has no liability with respect to the disclosure, use, or reproduction of any such data made prior to the addition of the notice or resulting from the omission of the notice.
(2) The Contracting Officer may also (i) permit correction at the Contractor's expense of incorrect notices if the Contractor identifies the data on which correction of the notice is to be made, and demonstrates that the correct notice is authorized, or (ii) correct any incorrect notices.
(g) *Protection of limited rights data and restricted computer software.*
(1) When data other than that listed in subdivisions (b)(1)(i), (ii), and (iii) of this clause are specified to be delivered under this contract and qualify as either limited rights data or restricted computer software, if the Contractor desires to continue protection of such data, the Contractor

shall withhold such data and not furnish them to the Government under this contract. As a condition to this withholding, the Contractor shall identify the data being withheld and furnish form, fit, and function data in lieu thereof. Limited rights data that are formatted as a computer data base for delivery to the Government are to be treated as limited rights data and not restricted computer software.
(2) [Reserved]
(3) [Reserved]
(h) *Subcontracting*. The Contractor has the responsibility to obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government such rights, the Contractor shall promptly bring such refusal to the attention of the Contracting Officer and not proceed with subcontract award without further authorization.
(i) *Relationship to patents*. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause)

PART III

SECTION J – LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

ARTICLE J.1. ATTACHMENTS

Attachment A - Certificate of Conformance Template

Attachment B – Sample Reservation Order

Attachment C – Sample Delivery Order

Attachment D – Utilization Forecast - 500-L scale

Attachment E – Utilization Forecast - 100-L scale

Attachment F – Materials Ordering Form

PART IV—REPRESENTATIONS AND INSTRUCTIONS

SECTION K—REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following document(s) are incorporated by reference in this contract:

Representations and Certifications, dated March 26, 2003.

Attachement A
Certificate of Conformance Template

Certificate of Conformance

Final Lot Number
Part Number
Description
Date of Manufacture
Unit Quantity (number of vials filled and fill volume)

- Batch Records have been reviewed per SOP and all issues/observations have been resolved
- All deviations have been identified and resolved per SOP and approved by QA
- OOS and Process related investigations are closed per SOP and approved by QA
- EM and WFI test data is within specified limits. All excursions have been identified and assessed for potential product impact
- All materials used in the manufacture of this lot have been QA released and used within established expiry period
- All equipment used in the manufacture of this lot were used within the specified calibration cycle
- Certificate of analysis is attached (CofA lists all tests, method, specification and result)

Material has been manufactured under cGMP and is acceptable

Auditor: compiled by / date

QA Manager: approval / date

Attachment B
Sample Reservation Order

RESERVATION ORDER – SUBCONTRACT No. 23XS003

CONTRACT NO.	RESERVATION ORDER NO.	DATE OF ORDER	REQUISITION PURCH. REQUEST NO.
23XS003	001	TBD	TBD

ISSUED BY:
SAIC Frederick
NCI-FREDERICK
P.O. BOX B
FREDERICK, MARYLAND 21702-1201

SUBCONTRACTOR NAME AND ADDRESS:
Vical, Inc.
10390 Pacific Center Court
San Diego, CA 92121

PAYMENT TERMS
Payment shall be made to the Contractor pursuant to Subcontract #23XS003, Articles C.2. Deliverables and G.2. Invoice Submission.

ACCOUNTING AND APPROPRIATION DATA
Cost Center No.20048075311

RESERVATION FEE

[...*...]**

DELIVERY ORDER TERMS AND CONDITIONS
In accordance with Articles G.4. and G.5. of Subcontract#23XS003, this Reservation Order shall reserve manufacturing time requiring the use of the 500-L manufacturing train. A Delivery Order will be issued, six months prior to the commencement of work, delineating a contract for cGMP production of DNA plasmids. The terms and conditions of Subcontract #23XS003 shall be made part of this Reservation Order in full force and effect.

This Reservation Order reserves the 500-Liter manufacturing training for**[**...***...**]** weeks, from date to date. During this time, the Contractor shall manufacture DNA plasmids (to be specified in the resulting Delivery Order) in accordance with Government specifications. Pursuant to the conditions of the contract, a Delivery Order for manufacture during this period will be issued six months prior to the commencement of work.

In the event that the Government does not issue a Delivery Order for the time reserved by this Reservation Order, the Contractor may invoice and the Government will pay the Reservation Fee of **[**...***...**]**. If a Delivery Order is issued for the time reserved by this order, the reservation fee shall be waived.

THE CONTRACTOR HEREBY ACCEPTS THE OFFER REPRESENTED BY THE NUMBERED DELIVERY ORDER AS IT IS NOW/MODIFIED, SUBJECT TO ALL OF THE TERMS AND CONDITIONS SET FORTH, AND AGREES TO PERFORM THE SAME.

Vical, Inc.	SAIC-Frederick, Inc.
Vijay Samant	Dennis J. Dougherty, Manager, Research Contracts
Signature *DATE:*	*Signature* *DATE:*

*** CONFIDENTIAL TREATMENT REQUESTED**

Attachment C
Sample Delivery Order

DELIVERY ORDER – SUBCONTRACT No. 23XS003

CONTRACT/DELIVERY ORDER NO.	DELIVERY ORDER NO.	DATE OF ORDER	REQUISITION PURCH. REQUEST NO.
23XS003	001	TBD	TBD

ISSUED BY:
SAIC Frederick
NCI-FREDERICK
P.O. BOX B
FREDERICK, MARYLAND 21702-1201

SUBCONTRACTOR NAME AND ADDRESS:
Vical, Inc.
10390 Pacific Center Court
San Diego, CA 92121

PAYMENT TERMS
Payment shall be made to the Contractor pursuant to Subcontract #23XS003, Articles C.2. Deliverables and G.2. Invoice Submission.

ACCOUNTING AND APPROPRIATION DATA
Cost Center No. 20048075311

AMOUNT
$TBD

DELIVERY ORDER TERMS AND CONDITIONS
Pursuant to Subcontract#23XS003A, Section C, “Specifications/Work Statement”, this delivery order shall delineate a contract for cGMP production of DNA plasmids. The

terms and conditions of Subcontract #23XS003A shall be made part of this delivery order in full force and effect.

1. DESCRIPTION OF WORK:

The Contractor shall provide **[**…***…**]** weeks of manufacturing, in accordance with Section C of the contract, using the 500-Liter manufacturing train.

2. DATES OF MANUFACTURE:

The dates of manufacture are date to date.

3. DELIVERABLES:

a) The Contractor shall deliver all DNA plasmid material manufactured under this Delivery Order. The minimum amount of material the Contractor is responsible for delivering is specified in Article C.3. of the contract.
b) Documents/information specified in Articles C.1.C.4. and C.2.

4. ACCEPTANCE CRITERIA:

a) The manufacture and documentation must be in accordance with cGMP requirements.
b) The DNA plasmids must meet Government specifications (attached).
c) The material must meet the acceptance criteria detailed on the Materials Ordering Form which shall be sent to Contractor as specified under Article G.5.4.

5. GOVERNMENT FURNISHED MATERIAL:

The Government shall provide:

a) Plasmid(s)

b) Sequencing information, if available.

In the event items are not furnished by the date specified, the Delivery Order will be modified, as necessary, to accommodate the delay.

6. PRICE: The total price for the materials/services is **[**…***…**]** in accordance with base year pricing outlined in Article B.2. of the contract, as follows::

Manufacturing: **[**…***…**]** per week **[**…***…**]** weeks = **[**…***…**]**
Document preparation and shipping: **[**…***…**]** per shipment **[**…***…**]** shipments = **[**…***…**]**
Stability testing: **[**…***…**]** per stability test **[**…***…**]** = **[**…***…**]**

THE CONTRACTOR HEREBY ACCEPTS THE OFFER REPRESENTED BY THE NUMBERED DELIVERY ORDER AS IT IS NOW/MODIFIED, SUBJECT TO ALL OF THE TERMS AND CONDITIONS SET FORTH, AND AGREES TO PERFORM THE SAME.

Vical, Inc.	SAIC-Frederick, Inc.
Vijay Samant	Dennis J. Dougherty, Manager, Research Contracts
Signature *DATE:*	*Signature* *DATE:*

Attachment D
Utilization Forecast- 500 L Scale- **Any order placed must be shown through completion.**

[...***...]

[...***...]

CONFIDENTIAL

*** CONFIDENTIAL TREATMENT REQUESTED**

CONFIDENTIAL

[...***...]

CONFIDENTIAL

*** CONFIDENTIAL TREATMENT REQUESTED**

CONFIDENTIAL

Attachment E

Utilization Forecast- 100 L Scale- **Any order placed must be shown through completion.**

[...***...]

CONFIDENTIAL

*** CONFIDENTIAL TREATMENT REQUESTED**

CONFIDENTIAL

[...***...]

CONFIDENTIAL

*** CONFIDENTIAL TREATMENT REQUESTED**

CONFIDENTIAL

[...***...]

CONFIDENTIAL

*** CONFIDENTIAL TREATMENT REQUESTED**

Attachment F

Materials Ordering Form

Client:

Contact:

Product name:

Contract: (VICAL USE)

Date:

Order #: (VICAL USE)

1. MATERIAL REQUIREMENTS:

DNA requested for:

☐ Clinical study

☐ Pre-clinical studies
(check all that apply):
- ☐ Safety study
- ☐ PK
- ☐ Biodistribution
- ☐ Material for use TBD

☐ Single plasmid ☐ Cocktail

Plasmid designation(s):
Configuration:

Vector Name	Concentration (mg/ml)	Vehicle

Product Configuration: ☐ Bulk ☐ Filled

Plasmid provided to Vical: ☐ DNA ☐ MCB ☐ None provided

---

2. EXPERIMENTAL PROTOCOL:

Experimental Protocol Attached: ☐ Yes ☐ No

3. SAFETY STUDY DESIGN/ FILL SCOPE:

Date material required:

Experimental design: Number of Groups:
Number of Animals:
Vial dose/volume (µg/mL pDNA):
Number injections/subject:

Container: ☐ Vials ☐ Tubes

Size- ml. Size- ml.

Shipping Information: Contact- Address-

Packaging configuration:
containers per box Ph #

☐ Single shipment Fax #

# of containers-

☐ Split shipment

(1st set) # of containers-

(2nd set) # of containers-

---

4. CLINICAL STUDY DESIGN/ FILL SCOPE:

Date material required:

Clinical design:
(Needed if no protocol attached or to clarify the protocol)

	Cohort 1	Cohort 2	Cohort 3
Number of subjects			
Product concentration (ug/mL pDNA)			
Vial fill volume (uL)			
Total no. of vials			
Number injections/subject			

Clinical Protocol Attached:	☐ Yes	☐ No If no, please supply title of protocol-
Container:	☐ Vials Size-	Please specify if needed-
Shipping Information: Packaging configuration: vials/ box	Contact-	Address-
☐ Single shipment # of vials- ☐ Split shipment (1st set) # of vials- (2nd set) # of vials-	Ph # Fax #	

---

5. PLASMID DNA TEST REQUIREMENTS AND RESULTS:

Check as Required	Test	Standard Specification	Other Specification
☐	Appearance	☐ Clear, colorless solution Other:	
☐	DNA concentration	± mg/mL	
☐	Circular plasmid DNA	☐ > **[**…***…**]** of visualized DNA Other:	
☐	Total Size (Please attach plasmid map)	Number of base pairs:	
☐	Restriction sites	Enzyme(s): Size(s) (bp's):	
☐		Enzyme(s): Size(s) (bp's):	
☐		Enzyme(s): Size(s) (bp's):	
☐		Enzyme(s): Size(s) (bp's):	
☐		Enzyme(s): Size(s) (bp's):	
☐		Enzyme(s): Size(s) (bp's):	
☐	% Supercoiled pDNA	%	
☐	Endotoxin	☐ < **[**…***…**]** EU/vial Value:	
☐	*E. coli* DNA	☐ £**[**…***…**]**ug/ug Value:	

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*** CONFIDENTIAL TREATMENT REQUESTED**

☐	RNA	☐ None by ethidium bromide Other:
☐	Expression testing	To be determined by customer unless otherwise states Result:
☐	Residual amino acid analysis	☐ £ **[**…***…**]** ug/mg of pDNA Other:
☐	Residual ethanol	☐ £ **[**…***…**]**ppm Other:
☐	Sterility; Bulk	☐ No Growth through 14 days Other:
☐	Sterility; Filled vials	☐ No Growth through 14 days Other:
☐	pH	Specific for vehicle. Value:
☐	Stability testing If checked, please specify: 1. Duration of testing	Performed at every 3 months for the first yeatr, then at 6 month intervals. Last test one timepoint after last clinical use.

☐ Certificate of Analysis **Send to:**

Assay Development Required? **☐ Yes** **☐ No**

Other information:

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*** CONFIDENTIAL TREATMENT REQUESTED**

VICAL USE ONLY BELOW:
Date Order Received by Vical:
Estimated Fill Date:

Kevin Bracken-Vice President, Manufacturing Date

Vical Incorporated

Name of authorized signature- Date

Vaccine Research Center

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Materials Ordering Form

[…*…]**

*** CONFIDENTIAL TREATMENT REQUESTED**

[…*…]**

*** CONFIDENTIAL TREATMENT REQUESTED**

[…*…]**

*** CONFIDENTIAL TREATMENT REQUESTED**

EQUIPMENT INVENTORY LIST			BUILDING		
			FIELD OFFICE	DATE	PREPARED BY
PM GUIDE NUMBER	EQUIPMENT NUMBER	LOCATION	DESCRIPTION AND REMARKS		

GENERAL SERVICES ADMINISTRATION **GSA FORM 1736 (REV. 6-80)**

Exhibit 23.1

Independent Auditors' Consent

The Board of Directors
Vical Incorporated:

We consent to the incorporation by reference in the 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, No. 333-97019, and No. 333-107581) on Form S-8 of Vical Incorporated of our report dated February 6, 2004, except as to the third paragraph of Note 13, which is as of March 4, 2004, with respect to the balance sheets of Vical Incorporated as of December 31, 2003 and December 31, 2002 and the related statements of operations, stockholders' equity, and cash flows for the two-year period ended December 31, 2003, which report appears in the December 31, 2003 annual report on Form 10-K of Vical Incorporated.

/s/ KPMG LLP
San Diego, California
March 5, 2004

Exhibit 23.2

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.

Exhibit 31.1

CERTIFICATION

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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; 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 over financial reporting.

Date: March 11, 2004

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

Exhibit 31.2

CERTIFICATION

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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; 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 over financial reporting.

Date: March 11, 2004

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

Exhibit 32.1

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, 2003, to which this Certification is attached as Exhibit 32.1 (the "Annual 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 Annual Report and results of operations of the Company for the period covered by the Annual Report.

Dated: March 11, 2004

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

THIS CERTIFICATION "ACCOMPANIES" THE ANNUAL REPORT, 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 ANNUAL REPORT), 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.

Exhibit 32.2

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, 2003, to which this Certification is attached as Exhibit 32.2 (the "Annual 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 Annual Report and results of operations of the Company for the period covered by the Annual Report.

Dated: March 11, 2004

/s/ MARTHA J. DEMSKI
Martha J. Demski
Vice President, Chief Financial Officer,
Treasurer and Secretary

THIS CERTIFICATION "ACCOMPANIES" THE ANNUAL REPORT, 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 ANNUAL REPORT), 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.