

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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, 2005.

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)

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

93-0948554
(I.R.S. Employer
Identification No.)

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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). 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 registrant's common stock reported on the National Association of Securities Dealers Automated Quotation National Market System on June 30, 2005, was approximately \$114,766,000.

The number of shares of common stock outstanding as of February 23, 2006, was 28,298,149.

Documents Incorporated by Reference:

Document

Part of Form 10-K

Proxy Statement for the Annual Meeting of
Stockholders to be held May 19, 2006

Part III

VICAL INCORPORATED
FORM 10-K
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FORWARD-LOOKING STATEMENTS

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery technologies, and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery technologies. Actual results could differ materially from those discussed in this Annual Report on Form 10-K. Factors that could cause or contribute to such differences include, but are not limited to, those identified in Item 1A entitled “Risk Factors” beginning on page 21 of this report, as well as those discussed in our other filings with the Securities and Exchange Commission, or SEC, including our Quarterly Reports on Form 10-Q. As a result, you are cautioned not to unduly rely on these forward-looking statements. 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.

ITEM 1. BUSINESS

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, 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; and
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise.

In 2005, the first product utilizing our patented DNA delivery technology received approval for use in animals. Our licensee, Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of Novartis Animal Health, received approval from the Canadian Food Inspection Agency to sell a DNA vaccine to protect farm-raised salmon against an infectious disease. We believe this approval is the first step in the validation of our DNA delivery technology. We plan to continue leveraging our patented technologies through licensing and collaborations. We also plan to use our expertise, infrastructure, and financial strength to explore both in-licensing and acquisition opportunities.

We have licensed our technologies to:

- Merck & Co., Inc., or Merck;
- Two divisions of the Sanofi-Aventis Group, or Sanofi-Aventis:
 - Sanofi Pasteur; and
 - Centelion SAS, or Centelion, a wholly-owned subsidiary of Aventis Pharmaceuticals S.A.;
- Merial Ltd., or Merial, a joint venture between Merck and Sanofi-Aventis;
- Corautus Genetics Inc., or Corautus;
- Aqua Health;
- Invitrogen Corporation, or Invitrogen;
- AnGes MG, Inc., or AnGes;
- Stanford University, or Stanford;
- Harvard University, or Harvard;
- Massachusetts Institute of Technology, or MIT; and
- Yale University, or Yale.

We have also licensed complementary technologies from:

- The Wisconsin Alumni Research Foundation, or WARF;
- The University of Michigan;
- Inovio Biomedical Corporation, or Inovio (formerly Genetronics Biomedical Corporation);
- CytRx Corporation, or CytRx;
- The National Institutes of Health, or NIH; and
- The U.S. Centers for Disease Control and Prevention, or CDC.

Available Information

We were incorporated in Delaware in 1987. 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 free of charge on our website at www.vical.com as soon as reasonably practicable after such reports and amendments are electronically filed with or furnished to the SEC.

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, or pDNAs. These pDNAs contain a DNA segment encoding the protein of interest, as well as short segments of DNA that control protein expression. Plasmids can be manufactured using uniform methods of fermentation and processing. 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 continue to develop other formulation and delivery technologies, including the use of lipid molecules, synthetic polymers called poloxamers, electroporation and other approaches, to enhance DNA expression or increase the immune response in DNA vaccine applications. We own broad patent rights in the United States and in key foreign markets to certain non-viral polynucleotide delivery technologies. Benefits of our DNA delivery technologies 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 technologies may be useful in developing 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 tumor suppressor; and 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 targeted cells’ 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 uniform fermentation and purification procedures; and
- *Cost-Effectiveness.* Our DNA delivery technologies 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 infectious disease vaccines and cancer therapeutics. We intend to retain significant participation in the commercialization of any of these proprietary DNA vaccines and therapeutics that receive regulatory approval, although we may choose to enlist the support of partners to accelerate product development and commercialization.

Infectious Disease Vaccines. Vaccines are perceived by government and medical communities as an efficient and cost-effective means of healthcare. According to the CDC, “Vaccines are among the very best protections we have against infectious diseases.” In the infectious disease area, we have focused our resources on the development of a DNA based immunotherapeutic vaccine against cytomegalovirus, or CMV. We believe our technologies 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 certain conventional vaccines; and
- DNA vaccines use uniform manufacturing processes that may be simpler, ultimately more cost-efficient, and more generally applicable across a range of products than conventional vaccine production methods.

Cancer Therapies. In the cancer area, we are developing gene-based, electroporation, or EP, enhanced delivery of interleukin-2, or IL-2, an immunotherapeutic agent, as a potential treatment for solid tumors, with an initial indication in metastatic melanoma, an aggressive form of skin cancer. In the past, we have also focused our resources on the development of Allovectin-7[®], for which we are currently seeking a development partner, as a potential treatment for metastatic melanoma. We have no other potential cancer products currently under independent development, but we may continue to explore 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 efficacy. 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, such as electroporation, to leverage the potential of our own DNA delivery technologies 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 to leverage our technologies for applications that may not be appropriate for our independent product development.

Pursue Contract Manufacturing Opportunities

We selectively pursue contract manufacturing opportunities to leverage our infrastructure and expertise in pDNA manufacturing, to support advancement and application of our technologies by others, and to provide revenues that contribute to our independent research and development efforts. We currently have an active contract manufacturing agreement with the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the NIH.

Product Development

We, together with our licensees and collaborators, are currently developing a number of DNA-based vaccines and therapeutics for the prevention or treatment of infectious diseases, cardiovascular diseases and

cancer. Our current independent development focus is on our novel pDNA vaccines for cytomegalovirus, or CMV, and avian influenza, as well as our cancer immunotherapeutic, IL-2 EP. 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
Infectious Disease			
Infectious disease vaccine	Cytomegalovirus	Phase 2	Vical
"	<i>Bacillus anthracis</i> (anthrax)	Phase 1	Vical
"	Influenza	Research	Vical
"	Ebola virus	Phase 1	Vical/NIH
"	West Nile virus	Phase 1	Vical/NIH
"	HIV EP	Research	Vical/NIH
"	SARS coronavirus	Phase 1	NIH
"	HIV	Phase 2	NIH
"	HIV	Phase 1	Merck
"	Hepatitis B virus	Research	Merck
"	Hepatitis C virus	Research	Merck
Cardiovascular			
Angiogenic growth factor	HGF, peripheral arterial disease	Phase 3	AnGes/Daiichi Pharma
"	HGF, ischemic heart disease	Phase 1	AnGes/Daiichi Pharma
"	VEGF-2, coronary artery disease	Phase 2	Corautus
"	FGF-1, peripheral arterial disease	Phase 2	Centelion
Cancer			
Immunotherapeutic	IL-2/EP for metastatic melanoma	Phase 1	Vical
"	High-dose Allovectin-7 [®] for metastatic melanoma	Phase 2	Vical
Tumor-associated antigen therapeutic vaccines	HER-2 and CEA, unspecified cancer ²	Phase 1	Merck
"	Unspecified cancer ²	Research	Merck
Veterinary			
Preventive infectious disease vaccine(s)	Infectious Haematopoietic Necrosis Virus	Marketed in Canada	Aqua Health
"	Various undisclosed ²	Research-Clinical	Merial
Protective cancer vaccine	Melanoma in dogs	Conditional U.S. license expected in 2006	Merial

¹ "Research" indicates exploration and/or evaluation of a potential product candidate in a nonclinical laboratory setting. "Phase 1" clinical trials include the first use of an investigational new drug in humans and are conducted in a small group of patients or normal volunteer subjects (20-80) to evaluate safety, determine a safe dosage range, and identify side effects, and, if possible, gain early evidence on effectiveness. "Phase 2" clinical trials are typically well controlled and conducted in a larger group of subjects (no more than several hundred) to evaluate effectiveness of an investigational drug for a defined patient population, and to determine common short-term side effects and risks associated with the drug. "Phase 3" clinical trials are conducted in an even larger group of subjects (several hundred to thousands) to evaluate the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling. For veterinary products, "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. Additionally, some project targets and indications cannot currently be disclosed because they have not yet been selected by our collaborators.

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 and ease 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 potential to induce potent T-cell responses against target pathogens as well as 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. In July 2005, our licensee Aqua Health received Canadian approval to sell its proprietary product, APEX-IHN, a DNA vaccine to protect farm-raised salmon against Infectious Haematopoietic Necrosis Virus, or IHNV.

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 certain conventional vaccine approaches may offset their potential benefits. We believe our potential vaccine products may 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 technologies may accelerate certain aspects of vaccine product development such as nonclinical evaluation and manufacturing.

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 technologies, because of their 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 Vaccine

In 2003, we announced our first independent product development program focused on infectious diseases, a DNA-based immunotherapeutic vaccine against cytomegalovirus, or CMV. Our CMV immunotherapeutic vaccine is intended to induce both cellular and antibody immune responses against the target pathogen without the safety concerns that live-attenuated virus vaccines pose for immunocompromised patients. Currently, there is no approved vaccine 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 is on the transplantation indication, which we believe, if successful, 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 at-risk women of reproductive age.

Our CMV immunotherapeutic vaccine product development program is based on:

- CMV genes that encode immunogenic proteins associated with protective antibody and cellular immune responses;

-
- Our DNA vaccine technologies that have the ability to induce 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.

Our CMV immunotherapeutic vaccine uses plasmid DNA encoding two highly immunogenic proteins of the CMV virus, phosphoprotein 65, or pp65, and glycoprotein B, or gB. In laboratory animal testing, our vaccine candidate demonstrated potent and specific immune responses against the encoded CMV immunogens. Preclinical testing of our CMV vaccine also established its safety.

We initiated a Phase 1 clinical trial with our CMV immunotherapeutic vaccine in March 2004. Subjects in the trial were healthy adults that were monitored primarily for safety, with secondary endpoints of immunogenicity. The trial tested two dosing levels and two dosing schedules, with approximately half of the subjects in the trial having prior exposure to CMV (seropositive) and half with no evidence of prior exposure (seronegative).

Results from the Phase 1 trial indicated that our CMV immunotherapeutic vaccine was safe and well-tolerated by a majority of subjects, with temporary injection site pain being the most common side effect. The vaccine induced antibody and T-cell immune responses, at both dose levels and both dosing schedules tested. Based on these results, we designed a Phase 2 study in hematopoietic cell transplant, or HCT, patients. The Phase 2 human trials began enrolling HCT donor-recipient pairs in February 2006.

In June 2005, the Office of Orphan Products Development of the U.S. Food and Drug Administration, or FDA, designated our vaccine against CMV as an orphan drug for the prevention of clinically significant CMV viremia, CMV disease and associated complications in at-risk HCT and solid organ transplant populations. In addition, we have been awarded approximately \$4.1 million for research and development related to our CMV vaccine program under three grants from the National Institute of Allergy and Infectious Diseases, or NIAID, of the NIH. In 2005 and 2004, we recognized approximately \$1.3 million and \$0.7 million, respectively, in revenues from these grants.

About CMV

CMV is a herpes virus that infects more than half of all adults in the United States by age 40, and is even more widespread in developing countries. While a healthy immune system typically protects an infected person against CMV disease, it rarely succeeds in completely eliminating the infection, and those whose immune systems are not fully functional are at high risk of CMV proliferation, potentially leading to severe illness or death. These include transplant patients who take immunosuppressive drugs, AIDS patients, and fetuses and newborns of mothers who first become infected during pregnancy.

CMV infection affects approximately 60 percent of the estimated 7,200 HCT patients and approximately 20 percent of the estimated 25,000 patients receiving solid organ transplants in the United States annually, 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. Anti-CMV immune globulin and relatively toxic antiviral drug therapy are used to control the disease, but do not fully 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.

Approximately one in a hundred CMV seronegative women in the United States develop primary CMV infection during pregnancy and give birth to a congenitally infected infant, leading to severe consequences in

about 3,000 infants and death in about 800 infants per year. Congenital CMV infection is the leading infectious cause of deafness, learning disabilities, and mental retardation in children. 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.

Influenza

In April 2005, we received a \$0.5 million grant from the NIAID to support the development of a DNA vaccine against influenza. In September 2005, we received a two-year, \$2.9 million challenge grant from the NIAID to support the development of a DNA vaccine against naturally emerging or weaponized strains of avian influenza. Funding under the challenge grant will be released in stages contingent upon the achievement of development milestones. In the initial activities covered by the grant, we are collaborating with St. Jude Children's Research Hospital, a world-renowned center of expertise in influenza research, including avian influenza research. During the fourth quarter of 2005, we achieved the first milestone in this challenge grant which was based on the successful design, manufacturing, and initial immunogenicity testing of an avian flu vaccine.

We have shown that our avian flu HA surface protein vaccine is immunogenic in animals. The second milestone under the challenge grant includes challenging DNA-vaccinated animals with a virulent Vietnam strain of H5N1 avian flu. For these studies we are using our proprietary Vaxfectin™ cationic lipid formulation as an adjuvant, as we believe this will significantly enhance the protective immune responses from DNA vaccinations. Our approach is to include vaccine components which we believe will provide potential cross strain protection, particularly against severe disease and mortality, unlike conventional flu vaccines which provide symptomatic relief through antibodies and are unlikely to protect against severe disease and mortality if the strain match is not correct. Our initial influenza vaccine candidate uses pDNA encoding five distinct influenza targets including two conserved proteins for human flu strains, two conserved proteins for avian flu strains, and one variable surface protein for an avian flu strain.

Anthrax Vaccine

In 2003, we announced our second independent infectious disease DNA vaccine development program, a third-generation anthrax vaccine designed to provide broader protection against weaponized forms of anthrax than any of the other anthrax vaccines either on the market or in development. Preclinical data from the anthrax vaccine program demonstrated complete protection of rabbits against a lethal aerosolized spore inhalation challenge administered up to 7.5 months after vaccination. In addition, post-challenge immune response data from the rabbit study suggest that the vaccine-generated antibodies may inhibit germination of anthrax spores, potentially providing sterile immunity. This preclinical research has been supported, in part, by \$6.8 million received under two grants from the NIAID. We recognized revenues under these grants of \$1.3 million, \$2.0 million and \$1.9 million in 2005, 2004 and 2003, respectively.

Based on the award of a procurement contract to a third party for a second-generation anthrax vaccine, the grant of Emergency Use Authorization for the first-generation anthrax vaccine, and our discussions with government agencies, it appears that funding needed to support further clinical development of our third-generation anthrax vaccine will not be available in the foreseeable future. Therefore, we do not intend to pursue further development of our anthrax vaccine candidate at this time.

NIH Vaccine Research Center

In 2002, we entered into a subcontract agreement, which was subsequently amended, to manufacture HIV, Ebola, West Nile Virus, or WNV, and severe acute respiratory syndrome, or SARS, DNA vaccines for the VRC. In 2003, we entered into a separate subcontract agreement to manufacture bulk DNA vaccines for the VRC. These subcontracts are issued and managed on behalf of the VRC by SAIC-Frederick, Inc. under the umbrella of

a federally funded contract with the NIH. We recognized revenues under these agreements of \$1.1 million, \$8.4 million and \$2.9 million in 2005, 2004 and 2003, respectively.

Using clinical supplies provided under these agreements, the VRC began a Phase 1 trial in healthy human subjects of an investigational DNA vaccine against HIV in 2002. The trial involved priming an immune response with multiple doses of a plasmid DNA vaccine, based on our proprietary DNA delivery technology, and boosting the response with an adenoviral vector vaccine given at a later date. The vaccine incorporates parts of four HIV genes. Three of these vaccine components are modified versions of HIV genes called gag, pol and nef, synthetically made based on a sequence from clade B, the subtype that predominates in Europe and North America. The fourth vaccine component is a modified version of the HIV gene named env. The env gene codes for a protein on the outer coat of the virus that allows it to recognize and attach to human cells. VRC scientists combined modified env from clades A and C, which are the most common in Africa and parts of Asia, with the modified env gene from clade B. HIV subtypes, clades A, B and C, which are involved in about 85% of all HIV infections around the world. The study was performed by the HIV Vaccine Trials Network (HVTN), an NIAID-supported clinical trials group that evaluated and compared different HIV/AIDS vaccine candidates.

In September 2005, data on eight healthy volunteers from the Phase 1 trial were presented at the AIDS Vaccine 2005 International Conference in Montreal, Canada. Cellular and antibody responses were several-fold higher in subjects vaccinated with a DNA prime followed by an adenoviral vector boost than in subjects who had received either DNA or adenoviral vector vaccine alone. In October 2005, the NIH initiated a Phase 2 clinical trial of the “prime-boost” vaccine approach against HIV. The NIH anticipates starting a larger Phase 2 trial of the “prime boost” vaccine approach in 2007. In June 2005, we received approximately \$12.1 million in production orders under the 2003 subcontract agreement for multiple clinical lots of DNA vaccines against HIV for the VRC in support of the NIH’s larger Phase 2 trial. Production began in late 2005 with shipments anticipated in 2006.

Also using clinical supplies provided under these agreements, the VRC began testing investigational DNA vaccines against Ebola in 2003, against SARS in December 2004, and against WNV in April 2005 in healthy human subjects. In 2003, we secured a license from the NIH for the commercialization rights and the technology used in its Ebola vaccine. In 2003, we obtained an option to secure exclusive commercialization rights for a WNV 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 WNV after a single injection. In June 2005, we entered into a CRADA with the NIH for development of a therapeutic and preventative DNA vaccine against HIV using electroporation.

In February 2006, the VRC presented data indicating that the Ebola vaccine was safe and well tolerated, and produced both antibody and T-cell Ebola-specific responses in all healthy volunteers who received the full three doses of vaccine. The DNA vaccine used in the Phase 1 trial incorporates genetic material encoding core and surface proteins from two strains of Ebola.

International AIDS Vaccine Initiative

In 2002, we entered into a one-year agreement with the IAVI, a not-for-profit entity, to provide clinical trial supplies. The agreement automatically renews annually for a one-year term unless terminated by one of the parties. In 2003, the IAVI began testing in healthy human subjects of an investigational DNA vaccine against HIV, using clinical supplies provided by us. We recognized revenues under this agreement of \$0.9 million in 2003. Revenue recognized in 2005 and 2004 was immaterial. Dr. Douglas, our Chairman, served on the Board of Directors of the IAVI through June 2003. Our President and Chief Executive Officer, Vijay B. Samant, serves on the Project Management Subcommittee of the IAVI.

U.S. Department of Defense

In September 2005, we were awarded funding for a one-year, \$0.5 million project for the Defense Advanced Research Projects Agency, or DARPA, of the U.S. Department of Defense. The award will fund feasibility

studies of a new approach for rapidly manufacturing large quantities of DNA vaccines. Conventional vaccine development and manufacturing methods require years of effort after the emergence of a new pathogen for production of even a single dose for testing. Current DNA vaccine development and manufacturing processes allow initial production of vaccines in as little as three months after selection of a gene sequence associated with a pathogen, but quantities are limited by the batch-processing capacity of available manufacturing equipment. We intend to use the funding to evaluate new methods that may dramatically reduce the manufacturing time and increase yields, potentially allowing for production of millions of doses within weeks.

Other Infectious Diseases

In April 2005, we were awarded a grant from the NIAID for the partial funding of the development of a DNA vaccine against herpes simplex virus.

To supplement our independent vaccine development programs, we have licensed our technologies to Merck for the development of vaccines against certain infectious disease targets. We also have provided 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.”

Cardiovascular Programs

Our core 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 new 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 expression of these growth factors from plasmids will be both safe and effective. Although several attempts by others to intermittently deliver recombinant specific angiogenic growth factors directly have been unsuccessful, we believe our proprietary approach to deliver locally DNA segments that encode the desired growth factors is promising. Local delivery of angiogenic growth factor genes using our core technology is currently being evaluated in Phase 1, 2 and 3 clinical trials. See “—Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing.”

Cancer Therapies

Cancer is a disease of uncontrolled cell growth. When detected early and still confined to a single location, cancer may be cured by surgery or irradiation. However, neither surgery nor irradiation can cure cancer that has spread throughout the body. Although chemotherapy can sometimes effectively treat cancer that has spread throughout the body, 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, it is common to see cancer return after apparently successful treatment by each of these means.

Immunotherapy, a process which uses the patient’s own immune system to treat cancer, may have advantages over surgery, irradiation, and chemotherapy. 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 IL-2 and interferon-alpha, or IFN-a, 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 and may help us develop cancer therapies. Our current clinical-stage approach consists of injecting directly into lesions certain plasmids, which, upon uptake into cells, direct the production of the encoded immunostimulatory proteins. The plasmids may be complexed with a cationic lipid-based delivery system or injection may be

followed by electroporation. The ease of manufacture, convenience, and ability to repeat administration may offer advantages over current modalities of therapy. In addition, cancer therapies using non-viral DNA delivery may offer an added margin of safety compared with viral-based delivery, as no viral DNA/RNA or viral particles are contained in the formulation.

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. In addition, a pDNA melanoma vaccine for dogs developed by Merial that utilizes our proprietary DNA technology is expected by Merial to receive approval for conditional use in 2006. Our Allovectin-7[®] and IL-2/EP non-viral cancer immunotherapeutics under development are reviewed below.

Allovectin-7[®]

Allovectin-7[®] is a plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and β 2 microglobulin, which together form a Class I Major Histocompatibility Complex, or MHC-I antigen. Injection of Allovectin-7[®] directly into tumor lesions, or intralesional injection, may augment the immune response to both local and metastatic tumors by one or more mechanisms. In HLA-B7 negative patients, a T-cell response may be initiated by the expression of a foreign HLA, similar to that observed in tissue transplant rejections. In HLA-B7 positive patients, enhanced HLA-B7 and β 2 microglobulin surface expression by transfected tumor cells could increase antigen presentation to tumor specific T-cells. In any patient, a pro-inflammatory anti-tumor response may occur following intralesional injection of the pDNA/lipid complex, as demonstrated in preclinical animal tumor models.

In 2001, we began a high-dose, 2 mg, Phase 2 trial evaluating the Allovectin-7[®] immunotherapeutic alone for patients with Stage III or IV metastatic melanoma, who have few other treatment options. Our high-dose Phase 2 trial completed enrollment in 2003. During the third quarter of 2004, we completed our data collection and locked the database for the high-dose Phase 2 Allovectin-7[®] trial. We presented data from the high-dose study in November 2004 at the annual meeting of the International Society for Biological Therapy of Cancer.

Based on detailed guidance received from the FDA in End-of-Phase 2 meetings, we successfully completed a Special Protocol Assessment, or SPA, with the FDA for a Phase 3 trial of high-dose, 2 mg, Allovectin-7[®] for certain patients with metastatic melanoma. The SPA specifies the trial objectives and design, clinical endpoints, and planned analyses expected to be needed for product approval.

We are currently in discussions with potential partners for the further development and commercialization of Allovectin-7[®], and do not expect to conduct the Phase 3 trial independently.

IL-2/EP

In July 2005, we initiated a Phase 1 study which incorporated the enhanced delivery of plasmids encoding human IL-2 for patients with recurrent metastatic melanoma. Intravenous delivery of IL-2 protein is approved as a treatment for metastatic melanoma and renal cell carcinoma, but frequently causes severe systemic toxicities. The novel treatment approach being studied in this trial involves direct injection into a tumor lesion of pDNA encoding IL-2 followed by electroporation, a process involving the application of electrical pulses to targeted tissues to potentially open pores in cell membranes and allow greater transfer of material into the targeted cells. The pDNA is designed to cause cells within the tumor to produce high levels of IL-2 protein locally and stimulate the immune system to attack the tumor without the associated systemic toxicities.

Our Phase 1 study consists of treatments which will be administered once a week in two four-week cycles, with each cycle followed by a four-week observation period. The initial dose-escalation phase of the trial is enrolling up to three patients each at doses of 0.5 mg, 1.5 mg and 5 mg delivered to a single tumor lesion per patient, with a final group receiving 5 mg in each of three tumor lesions per patient. Up to 17 additional patients will be treated at the highest tolerated dose. The primary endpoint in the trial is safety. Secondary efficacy endpoints will also be monitored.

We have entered into an exclusive worldwide licensing and supply agreement with Inovio for the use of its electroporation technology for specified applications. This Phase 1 study is the first application of the electroporation technology we have licensed from Inovio to advance to human safety testing.

About Metastatic Melanoma

The American Cancer Society estimated that approximately 62,000 new diagnoses of, and approximately 7,900 deaths from, melanoma will occur in 2006 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 advanced metastatic melanoma, median survival typically ranges from six to ten months.

FDA-approved drugs for treatment of metastatic melanoma include: hydroxyurea, which is no longer commonly used as a single agent; dacarbazine, and IL-2. The toxicity associated with FDA-approved treatments such as dacarbazine or IL-2 is often significant, resulting in serious or life-threatening side effects in many of the patients treated. Patients with metastatic melanoma often are treated with non-approved drugs such as IFN- α , which is approved for adjuvant therapy to surgery, or temozolomide, which is approved for certain types of brain cancer.

Out-licensing of Cancer Targets

Details of our collaborations regarding cancer targets can be found in “Collaboration and Licensing Agreements—Corporate Collaborators—Out-licensing.”

Veterinary Applications

Prior to its development for human therapy, our DNA delivery technologies were 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 specialized manufacturing facilities and distribution channels beyond our current capacity, and therefore we have licensed certain rights to utilize our DNA delivery technologies for development and commercialization of specific vaccine candidates to Merial and Aqua Health. Aqua Health has received approval to market a product in Canada using our proprietary DNA technology. 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

Merck. In 1991, we entered into an agreement with Merck, which was subsequently amended, providing Merck with certain exclusive rights to develop and commercialize vaccines using our core DNA delivery technology for specified human diseases. Under the agreement, as amended, Merck licensed preventive and therapeutic human infectious disease vaccines using our core DNA delivery technology.

In 2003, we amended the agreement, providing Merck options for rights to use our core DNA delivery technology for three cancer targets. In addition, Merck returned rights to us for certain preventive vaccines.

Merck has retained rights to use the licensed technology for HIV, hepatitis C virus, and hepatitis B virus. In June 2005, Merck exercised the options related to three cancer targets that were granted under the 2003 amendment. As a result of the option exercise, we received a payment of \$3.0 million.

In September 2005, we further amended the agreement with Merck to grant renewable options for rights to use our patented non-viral gene delivery technology for additional cancer targets. In exchange, we obtained non-exclusive, sublicenseable rights to use the licensed technology for vaccines against HIV. Merck also obtained a fixed-term option to exclusively sublicense from us electroporation-enhanced delivery technology for use with HIV vaccines, on terms to be negotiated.

In November 2005, Merck initiated a Phase 1 clinical trial of a DNA cancer vaccine based on our DNA gene delivery technology that uses pDNA encoding human epidermal growth factor receptor 2, or HER-2, and carcinoembryonic antigen, or CEA. As a result of Merck reaching this milestone, we received a payment of \$1.0 million. The Phase 1 trial will evaluate the safety, tolerability and immunogenicity of the vaccine. Further development may lead to additional milestone and royalty payments.

Merck is currently testing single-gene DNA vaccines for HIV, including a vaccine based on our technology and a vaccine using an adenoviral vector, in uninfected human subjects and in human subjects 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. In 2005, Merck announced the initiation of a Phase 2 study of its adenoviral vector HIV vaccine. Merck continues to evaluate the potential for use of all of its HIV vaccine candidates, including those based on our core DNA delivery technology, and expects to make further decisions regarding these programs after all of the data from ongoing clinical trials are evaluated.

Merck is obligated to pay fees if certain research milestones are achieved, and royalties on net sales if any products covered by our agreement with Merck 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 upon 90 days prior written notice. Revenue recognized under this agreement was \$4.0 million in 2005. No revenues were recognized under this agreement in 2004 or 2003.

AnGes. In 2005, we granted an exclusive worldwide license to AnGes for use of our core DNA delivery technology in the development and commercialization of DNA-based products encoding Hepatocyte Growth Factor (HGF) for cardiovascular applications. Under the license agreement, we received an initial upfront payment of \$1.0 million, and further development may lead to milestone and royalty payments. AnGes has the right to terminate this agreement without cause upon tendering written notice to us.

AnGes is developing DNA-based delivery of HGF for indications related to peripheral arterial disease, or PAD, a severe condition caused by blockage of arteries feeding the foot and lower leg, and ischemic heart disease, or IHD, which affects blood supply to the heart muscle. AnGes initiated Phase 2 trials in the United States and Phase 3 trials in Japan in 2003 and 2004, respectively, with DNA-based HGF for PAD. AnGes also initiated Phase 1 trials in the United States for IHD in 2004. AnGes has partnered with Daiichi Pharmaceutical Co., Ltd. for worldwide development and commercialization of DNA-based HGF for PAD and IHD. In February 2006, AnGes announced that it had completed the dosing phase of its Phase 2 trials in the United States and that early indications suggest that the treatment was well tolerated and showed signs of efficacy with no safety problems.

Sanofi-Aventis. In 1999, Centelion, a division of Sanofi-Aventis, began testing the DNA delivery of a gene encoding FGF-1, an angiogenic growth factor, in patients with PAD. In 2000, Centelion licensed the rights to our

core DNA delivery technology for cardiovascular applications using FGF-1. Published interim results from an open-label Phase 1 clinical trial indicated that the FGF-1 plasmid-based therapeutic was well-tolerated, with no serious adverse events considered related to the treatment. Interim results reported in this same publication demonstrated reduction in pain and evidence of newly visible blood vessels three months after treatment. Centelion has completed its double-blind, placebo-controlled Phase 2 trials of its FGF-1 plasmid-based therapeutic in the United States and Europe and plans to release the data from this trial in the first quarter of 2006. In February of 2006, Centelion announced its intent to initiate a Phase 3 trial of its FGF-1 plasmid therapeutic in the fourth quarter of 2006.

Our agreement with Centelion specifies that we will receive milestone payments plus royalties as products advance through commercialization. Centelion has the right to terminate our agreement without cause upon 60 days prior written notice. We recognized revenues of \$1.2 million in 2004 under the Centelion agreement. Revenue recognized in 2005 and 2003 was immaterial.

In 1994, we entered into an agreement with Sanofi Pasteur granting rights to certain infectious disease targets. In 2001, all such rights were exchanged for an option to acquire an oncology target. In 2005 the option expired.

Corautus. In 2000, Vascular Genetics Inc., or VGI, a predecessor company to Corautus, licensed the rights to our core DNA delivery technology for cardiovascular applications using vascular endothelial growth factor 2, or VEGF-2. In 2004, Corautus initiated a Phase 2b clinical trial to evaluate the safety and efficacy of pDNA-based delivery of VEGF-2 to promote the localized growth of blood vessels as a treatment for severe cardiovascular disease. Corautus expects enrollment in the Phase 2b trial to be complete in the first quarter of 2006. In March 2005, Corautus announced the publication of two-year follow-up results of an earlier Phase 1 study demonstrating prolonged clinical benefit with no directly related complications in patients with severe angina treated with pDNA encoding VEGF-2.

In exchange for the rights to our technology, we received shares of VGI stock with an estimated fair value of \$5.0 million on the date of investment in 2000, and rights to future royalty payments on resulting product sales. We classified the shares as an investment and recorded the \$5.0 million value as deferred license revenues, of which we recognized \$0.8 million, \$1.1 million and \$1.1 million in 2004, 2003 and 2002, respectively. In 2002, upon announcement of a planned merger of VGI with GenStar Therapeutics Corporation, we recognized a loss of \$4.2 million on our investment in VGI. In 2003, following the merger which resulted in the formation of Corautus, we received shares of Corautus in exchange for our shares of VGI and recognized an additional loss of \$0.5 million on our investment in Corautus. We subsequently reclassified our investment as marketable securities available for sale. During 2004, we sold our Corautus shares and recognized a \$0.9 million gain.

Aqua Health. In 2003, we granted a non-exclusive license to Aqua Health for use in Canada of our core DNA delivery technology in a vaccine against a disease that affects both wild and farm-raised fish. In 2005, Aqua Health received notification of approval from the Canadian Food Inspection Agency to sell its proprietary product, APEX-IHN, a DNA vaccine to protect farm-raised salmon against Infectious Haematopoietic Necrosis Virus. We have recognized *de minimus* license fees and royalty revenues on sales of this vaccine.

Merial. In 2004, we granted an exclusive license to Merial for use of our core DNA delivery technology in a vaccine to protect dogs against melanoma. Under the agreement, Merial is responsible for research and development activities. If Merial is successful in developing and marketing this product, milestone payments and royalties on sales of the resulting product would be due to us.

In 2005, Merial advised us that initial trials of a pDNA melanoma vaccine for dogs had been completed and that Merial expected the vaccine to receive approval from the United States Department of Agriculture, or USDA, for conditional license use by early 2006.

We recognized revenues of \$0.3 million in 2004 under the Merial agreement. No revenue was recognized in 2005 or 2003. Merial has the right to terminate this agreement without cause upon 60 days prior written notice.

Invitrogen. In 1991, we licensed the use of certain proprietary lipids for research products applications to Invitrogen. Invitrogen manufactures and markets these lipid compounds, and pays royalties to us on the sales of the lipids. We recognized \$1.0 million, \$1.1 million and \$0.9 million in 2005, 2004 and 2003, respectively, in royalty revenues under this agreement.

Corporate Collaborators—In-licensing

Inovio. In 2003, we entered into an agreement with Inovio, giving us options to worldwide exclusive licenses to use Inovio's proprietary electroporation technology in combination with our DNA delivery technologies for undisclosed targets. In October 2004, we exercised options and we amended the agreement to include HIV. Our first application of the licensed technology is for enhanced delivery in solid tumors of the pDNA encoding IL-2. In 2005, we began Phase 1 safety testing of intralesional administration of IL-2 pDNA followed by local electroporation in certain patients with metastatic melanoma. As part of the agreement, we paid *de minimus* option and license fees to Inovio in 2005, 2004 and 2003. We invested \$0.8 million in Inovio in December 2005, for which we received 0.3 million shares of common stock and five year warrants to purchase 0.1 million shares of common stock at an exercise price of \$2.93 per share.

CytRx. In 2001, we entered into an exclusive agreement with CytRx which grants us 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, including CMV. 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

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 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.

University of Michigan. In 1992, we licensed from the University of Michigan rights to various U.S. and international patents related to the injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7[®]. In July 2005, we amended the agreement to exclude certain patents. In February 2006, we entered into an additional agreement with the University of Michigan which provides for rights to a lipid patent related to the injection of DNA-based therapeutics which we believe provides additional protection for Allovectin-7[®].

Office of Naval Research. In 2003, we entered into an agreement with the Office of Naval Research, or ONR, under which the ONR agreed to provide funding to us for research and development work on a malaria vaccine. Revenue recognized under this agreement was \$0.9 million and \$0.2 million in 2005 and 2003, respectively. No revenue was recognized under this agreement in 2004. We do not plan to participate in development of a malaria vaccine.

Academic Licenses

In January 2006, we granted non-exclusive, academic licenses to our DNA delivery technology patent estate to four of the nation's top research institutions—Stanford, Harvard, Yale and MIT. The academic licenses are intended to encourage widespread commercial use of our innovative DNA delivery technologies in the

development of new antibodies, vaccines, therapeutic proteins, and diagnostics. The non-exclusive academic licenses allow university researchers to use our technology free of charge for educational and internal, non-commercial research purposes. In exchange, we have the option to exclusively license from the universities potential commercial applications stemming from their use of the technology on terms to be negotiated.

Payments to Others

Under the Merck, Centelion, Merial, Corautus, Aqua Health, and AnGes agreements, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the WARF and certain amounts to the University of Michigan. The CytRx and Inovio agreements require us to make payments 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, the Naval Medical Research Center, and the U.S. Army Medical Research Institute of Infectious Diseases to promote the development and use of our technologies in DNA vaccine candidates. 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 result from the CRADA.

Intellectual Property

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technologies, inventions, and improvements to our inventions that we consider important to the development of our business. We believe we have a comprehensive patent portfolio in the United States and in key foreign markets. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

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 AnGes, Centelion and Corautus in the field of angiogenesis;
- *Lipid Technologies.* 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, Canada and Japan;
- *Specific DNA Therapeutics.* We have supplemented the broad patent coverage described above with patents covering specific product applications of our technologies. To date, we have received patents issued in the United States and granted in Japan covering Allovectin-7® and other patents related to DNA delivery to the heart, including gene-based delivery of vascular endothelial growth factors, and gene-based delivery of IL-2 for the treatment of cancer;

- *DNA Process Technologies.* 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. and granted European patents covering various steps involved in the process of economically producing pure plasmids for pharmaceutical use; and
- *Licensed DNA Delivery Technologies.* We have licensed from the University of Michigan rights to various U.S. and international patents related to the injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7®.

During 2005, we were issued two U.S. patents, two Canadian patents and one Japanese patent related to our core DNA delivery technology, enhancements of that technology, and applications of that technology:

- U.S. patent No. 6,867,195, covering the use of cationic lipid-mediated delivery of DNA for both immunization and delivery of biologically active proteins;
- U.S. patent No. 6,875,748, covering certain improved formulations and their use *for in vivo* delivery of polynucleotide genetic material;
- Canadian patent No. 2,425,745, covering the direct administration with cationic lipids of polynucleotide genetic material such as DNA or RNA;
- Canadian patent No. 2,049,287, covering the direct administration without cationic lipids of polynucleotide genetic material such as DNA or RNA; and
- Japanese patent No. JP3683798, directed to the use of cationic lipids *for in vivo* polynucleotide delivery.

We are the assignee of 43 issued U.S. and granted foreign patents having remaining lives ranging from approximately 4 to 15 years, which are listed below:

Patent No.	Description
U.S. Patents	
6,875,748	Improved formulations and their use for <i>in vivo</i> delivery of polynucleotide genetic material
6,867,195	Cationic lipid-mediated delivery of DNA for immunization and delivery of biologically active proteins
6,710,035	Generation of an immune response to a pathogen
6,706,694	Expression of exogenous polynucleotide sequences in a vertebrate
6,696,424	Cytoskeleton dimers and methods of use thereof
6,673,776	Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human
6,670,332	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 cytoskeletons
5,994,317	Quaternary cytoskeletons
5,910,488	Plasmids suitable for gene therapy
5,891,718	Tetracycline inducible/repressible systems
5,861,397	Piperazine based cytoskeletons
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

Patent No.	Description
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

CA2,425,745	Direct administration with cationic lipids of polynucleotide genetic material such as DNA or RNA
CA2,049,287	Direct administration without cationic lipids of polynucleotide genetic material such as DNA or RNA
EP1183231	Cytoskeleton dimers and methods of use thereof
EP1165140	Adjuvant compositions for enhancing immune responses to polynucleotide-based vaccines
EP1026253	Expression of exogenous polynucleotide sequences in a vertebrate
EP0929536	Piperazine based cytofectins
EP0920497	Purification of plasmid DNA by PEG-precipitation and column chromatography
EP0902780	Quaternary cytofectins
EP0802975	Process for reducing RNA concentration in a mixture of biological material using diatomaceous earth
EP0795015	Plasmids suitable for IL-2 expression
EP0742820	Production of pharmaceutical-grade plasmid DNA
EP0523189	Cationic lipids for intracellular delivery of biologically active molecules
JP3683798	Use of cationic lipids for <i>in vivo</i> polynucleotide delivery
JP3626127	Plasmids suitable for gene therapy
JP2538474	Cationic lipids for intracellular delivery of biologically active molecules

We are also co-assignee, together with Sanofi 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 DNA delivery technology that is subject to Trials for Invalidation, or TFIs; a recently granted patent in Europe related to our core DNA delivery technology has been opposed by eight parties; a patent granted in Europe covering a range of applications of our core DNA delivery technology using cationic lipid formulations has been opposed; and a patent granted in Europe covering gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer has also been opposed.

We are also prosecuting 62 pending patent applications in the U.S. and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners. Three 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 U.S. and foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

See “Item 3—Legal Proceedings,” for a discussion of patent-related disputes, oppositions, and prosecution status. See also “—Risk Factors—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 technologies, we intend to develop and commercialize products both on our own and through our collaborators and licensees. 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 2002, we signed a 15-year lease on a facility that we believe will be sufficient for our foreseeable commercial manufacturing requirements. The facility received a California Food and Drug Branch manufacturing facility license and began production in 2004. We also engage in contract manufacturing of plasmid investigational products for selected clients.

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, Sanofi-Aventis, Novartis, Crucell N.V., GlaxoSmithKline plc, MedImmune, Inc., Merck, VaxGen, and Wyeth among others. We may also experience competition from companies that have acquired or may acquire technologies 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, MedImmune, Roche, GlaxoSmithKline, ViroPharma Inc. and others have products or development programs for CMV treatment and prevention. Medarex Inc., Bristol-Myers Squibb Company, Pfizer Inc., Onyx Pharmaceuticals, Inc., Bayer AG, and others are developing treatments for 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 technologies or products obsolete or noncompetitive, or result in treatments or cures superior to ours.

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, ease of use, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

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 and U.S. companies developing DNA-based products for similar indications.

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. In the United States, drugs are subject to regulation under the Federal Food, Drug and Cosmetic Act, or the FDC Act. Biological products, in addition to being subject to provisions of the FDC Act, are regulated in the United States 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.

In 2003, the FDA proposed a new rule on "Safety Reporting Requirements for Human Drug and Biological Products" that changed the reporting requirements for drugs and biological products, such that any unexpected 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 events including those for which the relationship to the product has been deemed "unlikely" or "improbable." The effect of this proposed rule will likely be to increase the number of expedited reports to the FDA of serious adverse events whose relationships are "unlikely" or "improbable", 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.

Obtaining FDA approval of a drug or biologic is a costly and time-consuming process. Generally, FDA approval requires that preclinical studies 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 IND application which the FDA must review and allow before human clinical trials can start. The IND application includes a detailed description of the proposed clinical investigations.

A company must sponsor and file an IND application for each proposed product and must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients.

To obtain FDA approval prior to marketing a pharmaceutical product in the United States typically requires several phases of clinical trials to demonstrate the safety and efficacy of the product candidate. Clinical trials are the means by which experimental drugs or treatments are tested in humans, and for new therapeutics, are typically conducted following preclinical 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 subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. Phase 2 clinical trials are conducted with a larger group of patients afflicted with a target disease to evaluate effectiveness of an investigational drug for a defined patient population, and to determine common short-term side effects and risks associated with the drug. Phase 3 clinical trials involve large scale, multi-center, comparative trials that are conducted with patients

afflicted with a target disease to evaluate the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling. For life-threatening diseases, initial human testing generally is done in patients afflicted with the target disease rather than healthy subjects. 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.

After completion of clinical trials of a new product, FDA marketing approval must be obtained. If the product is regulated as a biologic, a Biologics License Application, or 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 chemistry, manufacturing and control information.

A rule published in 2002 by the FDA, known commonly as the “Animal Rule,” established 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 win market approval under the Animal Rule for certain DNA-based products for which clinical efficacy trials are not feasible or ethical.

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 for a product can be secured, the facility in which the product is manufactured must be inspected by the FDA and must comply with current Good Manufacturing Practices, or cGMP, regulations. In addition, after marketing clearance is secured, the manufacturing facility must 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, Office of Biotechnology Activities, 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 for all clinical trials regardless of therapeutic area. 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.

Employees

As of December 31, 2005, we had 155 full-time employees, including 22 with doctorate degrees. Of these full-time employees, 128 are engaged in, or directly support, research and development and manufacturing activities, and 27 are in general and administrative positions. A significant number of our management and other employees have prior experience with pharmaceutical and/or biotechnology companies. None of our employees is covered by collective bargaining agreements, and our management considers relations with our employees to be good.

Executive Officers and Other Executives

Our executive officers and other executives are as follows:

Name	Age ¹	Position
Vijay B. Samant ²	53	President, Chief Executive Officer and Director
David C. Kaslow, M.D. ²	47	Chief Scientific Officer
Jill M. Church ²	44	Vice President, Chief Financial Officer and Secretary
Alain P. Rolland, Pharm.D., Ph.D.	46	Senior Vice President, Product Development
Kevin R. Bracken	57	Vice President, Manufacturing
Robin M. Jackman, Ph.D.	36	Vice President, Business Development

¹ As of December 31, 2005.

² Executive officer.

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 20 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.

Jill M. Church joined us as Vice President, Chief Financial Officer and Secretary in October 2004. From February 1999 until joining us, Ms. Church held various positions at dj Orthopedics, Inc., a publicly-traded medical device company, most recently as Vice President of Finance and Controller with broad responsibilities in finance, accounting, treasury, risk management, and corporate governance. From September 1994 until joining dj Orthopedics, Ms. Church served as an audit manager at Ernst & Young LLP, where her clients included life sciences, computer software and telecommunications companies as well as government contractors. From June 1990 until joining Ernst & Young, she was Division Controller at Medical Imaging Centers of America, Inc., a chain of freestanding imaging centers and mobile imaging centers, where she held divisional accounting and financial reporting responsibilities. Ms. Church received her bachelor's degree in business administration and accounting from San Diego State University, and is a Certified Public Accountant.

Alain P. Rolland, Pharm.D., Ph.D., joined us as Vice President, Product Development in August 2002 and was named Senior Vice President, Product Development in April 2004. Dr. Rolland was Senior Vice President of Pre-Clinical Research and Development, and Head of The Woodlands Center of Valentis, Inc. from 2000 to 2002. From 1993 to 1999, he served in several positions at a predecessor company to Valentis, Inc., GeneMedicine, Inc., where he progressed from Director of Gene Delivery to Vice President of Research. From 1989 to 1993, he was the Head of Formulation Research at the Research & Development Center of Galderma International, or CIRI, in France. Prior to that, he was a scientist at the Advanced Drug Delivery Research Center of Ciba Geigy Pharmaceuticals in the United Kingdom. He received his Pharm.D., D.E.A., and Ph.D. degrees from Rennes University, France. Dr. Rolland holds several U.S. and European patents on advanced drug and gene delivery for medical applications. He has authored numerous publications and books in the area of nonviral gene delivery resulting from his active career in research and development. He also serves on the editorial board of several journals and he is the Editor-in-Chief of "Current Pharmaceutical Biotechnology."

Kevin R. Bracken joined us as Vice President, Manufacturing in October 2001. From July 1998 to October 2001, Mr. Bracken was Vice President, Process Engineering and Manufacturing for Universal Preservation Technologies, Inc., and from November 1995 to July 1998, he was Director of Engineering for Molecular Biosystems, Inc. Prior to November 1995, he held a variety of process and engineering positions with Gilead Sciences, Inc., and a predecessor company, Vestar, Inc., with Baxter International, and with E.I. duPont de Nemours and Company. He brings experience in commercial scale-up of biopharmaceutical manufacturing facilities, process development and optimization, and direction of research, pre-clinical, clinical, production and contract manufacturing. Mr. Bracken earned his master's degree in chemical engineering from the University of Rochester in 1973, and his bachelor's degree in chemical engineering from the University of Delaware in 1970.

Robin M. Jackman, Ph.D., joined us as Vice President, Business Development in June 2004. Since 2002, Dr. Jackman had been Vice President of Corporate Development at Sequenom, Inc., where he focused primarily on business development and investor relations. From 1998 to 2002, he served in positions of increasing responsibility within the Life Sciences Investment Banking group at Robertson Stephens, culminating as Vice President. He managed a broad range of transactions for biotechnology, medical device, and emerging pharmaceutical companies with an aggregate transaction value over \$11 billion. Dr. Jackman received a Ph.D. in immunology from Harvard University, and a master's degree in medicine from Harvard Medical School, during which time he was a biomedical consultant to the investment community. He began his career as a research associate at Protein Design Labs. Dr. Jackman received a bachelor's degree with honors in biological science from Stanford University.

ITEM 1A. RISK FACTORS

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 independently developed products has been approved for sale, and we have a limited number of independent product candidates in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our independent product candidates 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. Limited data exist regarding the safety and efficacy of DNA-based vaccines or therapeutics compared with conventional vaccines or therapeutics. 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, our independent product candidates currently in clinical evaluation include our CMV vaccine, for which we initiated Phase 2 clinical testing in early 2006, and our IL-2 EP program, which is currently in Phase 1 clinical testing. We may not conduct additional CMV vaccine trials, leading transplant centers may not participate in our trials, and our CMV vaccine may not elicit sufficient immune responses in humans. We may not conduct additional IL-2 EP trials, and our IL-2 EP program may not demonstrate sufficient safety and efficacy to support product approval.

Additionally, we are in various stages of development with several other product candidates. These product candidates will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not support approval by the FDA or comparable foreign agencies. 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.

We may not be able to identify and reach agreement with a potential partner for the further development and commercialization of Allovectin-7.

We are currently seeking a partner for Allovectin-7[®] and do not expect to pursue further development of Allovectin-7[®] until such time, if any, as we identify and reach agreement with a partner. We may not be able to reach agreement with a potential partner on acceptable terms, if at all. Failure to reach agreement with a partner in a timely manner will prevent or delay continued development and potential commercialization of Allovectin-7[®]. Even if approved, Allovectin-7[®] may not be commercially successful.

Our revenues partially depend on the development and commercialization of products by others to whom we have licensed our technologies. 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, and may continue to license, our technologies 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, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our products, and we may be forced to curtail or cease operations.

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 future. For example, we have entered into an agreement to manufacture bulk DNA vaccines for the VRC. In connection with this agreement, the VRC has provided a 500-liter fermenter and related purification equipment as Government Furnished Equipment, or GFE, in our 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 GFE or other 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. Many of our government agreements are subject to audits which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful or ineligible to enter into future government agreements.

There are only a limited number of other contractors that could manufacture bulk DNA in the unlikely event that we were unable to perform our responsibilities under these agreements. The price these other contractors 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 apply for and have received funding from government agencies under Small Business Technology Transfer, or STTR, and Small Business Innovation Research, or SBIR, grants. Eligibility of public companies to receive such grants is based on size and ownership criteria which are under review by the Small Business Administration, or SBA. As a result, our eligibility may change in the future, and additional funding from this source may not be available.

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 pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$24.4 million, \$23.7 million and \$24.5 million for 2005, 2004 and 2003, respectively. As of December 31, 2005, we had incurred cumulative net losses totaling approximately \$162.9 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive 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. In January 2006, we filed a shelf registration statement with the SEC which, if and when it is declared effective, would allow us to issue from time to time an aggregate of up to \$70 million of common or preferred stock. We also have on file an effective shelf registration statement that allows us to raise up to an additional \$8.8 million from the sale of common or preferred stock. However, we may not be able to raise additional funds on favorable terms, or at all.

If we are unable to obtain additional funds, we may have 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 would depend on many factors, including:

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

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

Our product candidates under development and those of our collaborators and licensees are subject to extensive and rigorous regulations by numerous governmental authorities in the U.S. 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 have limited experience in filing BLAs or NDAs with the FDA. Because a BLA or NDA must be filed with and approved by the FDA before a biologic product or new drug product, respectively, may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our products, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the U.S. may impede our ability to commercialize our products in those countries

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we must sponsor and file a regulatory application for each proposed use. We 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.

In March 2004, the NIH Office of Biotechnology Activities and the FDA Center for Biologics Evaluation and Research launched the jointly developed Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. In its current form, GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials, and includes special security features designed to protect patient privacy and confidential commercial information. These security features may be inadequate in design or enforcement, potentially resulting in disclosure of confidential commercial information. We understand that both the FDA and the NIH are considering rules and regulations that would require public disclosure of additional commercial development data that is presently confidential. In addition, the NIH, in collaboration with the FDA, has developed an Internet site, ClinicalTrials.gov, which provides public access to information on clinical trials for a wide range of diseases and conditions. Such disclosures of confidential commercial information, whether by implementation of new rules or regulations, by inadequacy of GeMCRIS security features, or by intentional posting on the Internet, may result in loss of advantage of competitive secrets.

A rule published in 2002 by the FDA, known commonly as the “Animal Rule,” established 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 win market approval under the Animal Rule for certain DNA-based products for which human clinical efficacy trials are not feasible or ethical. At the moment, however, we cannot determine whether the Animal Rule would 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, January 2003, and January 2005, three children in France who received viral-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. Certain gene therapy clinical trials were placed on clinical hold following the second child’s death, and the trial in which the children had been enrolled was again placed on hold following the third child’s death. In October 2004, the FDA requested that clinical trials of another company’s viral-delivered gene therapy product candidate be placed on clinical hold pending review of information pertaining to potential adverse events. A portion of one of the trials was subsequently allowed to resume.

In 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 events 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 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, in our Phase 2 trial, we plan to administer our investigational CMV vaccine to patients who are at risk of CMV reactivation. 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. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events.

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 43 issued U.S. and foreign patents. We are also co-assignee, together with Sanofi 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 DNA delivery technology that is subject to Trials for Invalidation, or TFIs; a recently granted patent in Europe related to our core DNA delivery technology has been opposed by eight parties; a patent granted in Europe covering a range of applications of our core DNA delivery technology using cationic lipid formulations has been opposed; and a patent granted in Europe covering gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer has also been opposed.

We are also prosecuting 62 pending patent applications in the U.S. and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners. Three 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 U.S. and 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. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies 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 technologies 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: in Europe, four patents granted to us have been opposed and one was revoked as a consequence of opposition; in Japan, one patent granted to us was opposed and subsequently subjected to TFIs;

and in Canada, a protest was lodged against a patent application filed by us. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic 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 U.S. 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 technologies. 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 may 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 U.S. 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 technologies. 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 technologies.

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 have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

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 technologies 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 than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us. Further 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.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to achieve our business objectives.

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. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel and therefore we may not be able to achieve our business objectives.

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 current Good Manufacturing Practices, or 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 may need to complete the installation and validation of additional large-scale fermentation and related purification equipment to produce the quantities of product expected to be required for commercial purposes. We have limited experience in manufacturing at this scale. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional 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 service 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. There are a limited number of third parties that could manufacture our product candidates. 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 U.S., but we currently do not possess pharmaceutical marketing or sales capabilities. 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, we may not be able to generate sufficient product revenue to become profitable.

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, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which provides a new Medicare prescription drug benefit that was recently implemented and mandates other reforms. We expect that there will continue to be a number of legislative proposals to implement government controls. The adoption of such proposals or reforms could impair our business.

Certain portions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, have become effective and may complicate the process by which clinical trials may be initiated. We believe we have taken the necessary action to ensure compliance with HIPAA; however, the specific nature and degree of impact are not yet fully 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 million 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 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. 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. However, if we are sued for any injury caused by our technologies 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. From January 1, 2002 to December 31, 2005, our stock price has ranged from \$2.12 to \$12.48. 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 announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;
- 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, including our entry into new collaborative or licensing arrangements;
- 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;
- 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.

Anti-takeover provisions in 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.

Our certificate of incorporation and bylaws include 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 January 2006, we filed a shelf registration statement with the SEC which, if and when it is declared effective, would allow us to issue from time to time an aggregate of up to \$70 million of common or preferred stock. We also have on file an effective shelf registration statement that allows us to raise up to an additional \$8.8 million from the sale of common 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 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 79,000 square feet of manufacturing, research laboratory and office space in San Diego, California, at two sites.

Location	Use	Owned/Leased	Lease Termination Date	Size (Square Feet)
San Diego	Manufacturing, research, office	Leased	August 2017	68,400
San Diego	Research	Leased	November 2009	10,494

ITEM 3. LEGAL PROCEEDINGS

In 2003, the WARF filed a complaint against us in the U.S. 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. We counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement. In May 2004, we settled this matter for \$1.5 million, of which \$1.0 million had been paid as of December 31, 2005, with the remaining payment due in 2006. Pursuant to the settlement and an amendment to the license agreement with the WARF, the lawsuit was dismissed.

European Patent 1026253, covering a significant portion of our core DNA delivery technology, was granted in September 2004. European Patent 0465529 was granted to us in 1998, and was subsequently opposed by seven companies under European patent procedures. This '529 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, we filed an appeal seeking to overturn this initial ruling. The claims that were allowed in the newly granted '253 patent cover substantially the same scope as those claims in the '529 patent which were under appeal. For this reason, we withdrew from the '529 appeal upon grant of the '253 patent in September 2004. In June 2005, the '253 patent was opposed by eight parties. However, we may also use additional issued patents and patent applications that are pending in Europe to protect our core DNA delivery technology.

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 Japanese Patent Office, or 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. Four Trial for Invalidation, or TFI, requests were filed in the JPO by two companies in 2003. We filed responses to the TFI requests in a timely manner. The JPO combined two of the four TFI requests into a single action, and in December 2004, ruled in our favor on the combined TFI requests by accepting the corrected claims and finding the demand for the trials groundless. We are still awaiting further action by the JPO on the other two TFI requests.

A European patent issued in 2003 covering a range of applications of the 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. This patent has been opposed by two companies. We responded to the oppositions in a timely manner, and are preparing to defend the patent at an upcoming oral hearing in early 2006 at the EPO.

A European patent issued to us in 2003 with broad claims related to 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. Three companies opposed this patent. We responded to the oppositions in a timely manner, and will continue to defend our position vigorously in upcoming oral hearings.

We prosecute our intellectual property estate vigorously to obtain the broadest valid scope for our patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future results is not subject to reasonable estimates.

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 which, individually or in the aggregate, are deemed to be material to our financial condition or results of operations.

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 listed on the Nasdaq National Market under the symbol VICL. The following table presents quarterly information on the range of high and low sales prices for our common stock as reported on the Nasdaq National Market.

<u>2005</u>	<u>High</u>	<u>Low</u>
First Quarter	\$5.85	\$3.55
Second Quarter	4.88	3.47
Third Quarter	5.65	4.06
Fourth Quarter	6.98	4.05
<u>2004</u>		
First Quarter	\$8.14	\$4.69
Second Quarter	6.39	4.55
Third Quarter	5.99	4.01
Fourth Quarter	5.28	4.11

As of February 7, 2006, there were approximately 391 stockholders of record of our common stock with 28,280,505 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 of our common stock in the fourth quarter of 2005.

The equity compensation plan information required by this item is incorporated by reference from Item 12 herein.

ITEM 6. SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data derived from our audited financial statements. The information presented should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and notes thereto appearing elsewhere in this report.

	Years ended December 31,				
	2005	2004	2003	2002	2001
(in thousands, except per share amounts)					
Statement of Operations Data:					
Revenues:					
Contract and grant revenue	\$ 5,953	\$ 11,168	\$ 6,012	\$ 3,008	\$ 3,794
License and royalty revenue	6,050	3,377	2,066	3,999	7,572
Total revenues	<u>12,003</u>	<u>14,545</u>	<u>8,078</u>	<u>7,007</u>	<u>11,366</u>
Operating expenses:					
Research and development	17,772	19,597	18,296	20,104	17,521
Manufacturing and production	12,203	11,581	8,482	6,270	4,573
General and administrative	7,679	8,510	6,922	8,061	6,501
Write-down of investment ¹	—	—	482	4,200	—
Total operating expenses	<u>37,654</u>	<u>39,688</u>	<u>34,182</u>	<u>38,635</u>	<u>28,595</u>
Loss from operations	(25,651)	(25,143)	(26,104)	(31,628)	(17,229)
Investment income, net ¹	1,827	2,205	2,067	3,984	8,286
Interest expense	(533)	(795)	(413)	(288)	(297)
Net loss	<u>\$ (24,357)</u>	<u>\$ (23,733)</u>	<u>\$ (24,450)</u>	<u>\$ (27,932)</u>	<u>\$ (9,240)</u>
Net loss per share (basic and diluted)	<u>\$ (0.99)</u>	<u>\$ (1.05)</u>	<u>\$ (1.22)</u>	<u>\$ (1.39)</u>	<u>\$ (0.46)</u>
Weighted average shares used in per share calculation	<u>24,581</u>	<u>22,695</u>	<u>20,091</u>	<u>20,079</u>	<u>20,032</u>
Balance Sheet Data (at end of period):					
Cash, cash equivalents and marketable securities, including restricted	\$ 66,486	\$ 73,996	\$ 84,518	\$ 111,513	\$ 134,087
Working capital	63,484	67,300	76,983	105,672	130,638
Total assets	94,530	101,226	110,707	129,426	154,495
Long-term obligations, less current portion	5,444	8,209	8,662	4,319	4,545
Total stockholders' equity	80,306	82,909	89,822	114,307	142,159

¹ In 2003 and 2002, we recorded write-downs of \$0.5 million and \$4.2 million, respectively, to shares of stock received under a license agreement with Corautus. We subsequently reclassified this investment as marketable securities. In 2004, we sold our Corautus shares and recognized a \$0.9 million gain, which has been included in investment income. See Note 2 in Notes to Financial Statements for further discussion.

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

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, 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, and
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise.

In 2005, the first product utilizing our patented DNA delivery technology received approval for use in animals. Our licensee, Aqua Health, received approval from the Canadian Food Inspection Agency to sell a DNA vaccine to protect farm-raised salmon against an infectious disease. We believe this approval is the first step in the validation of our DNA delivery technology. We plan to continue leveraging our patented technologies through licensing and collaborations. We also plan to use our expertise, infrastructure, and financial strength to explore both in-licensing and acquisition opportunities.

Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal amounts of revenue from the sale of commercially marketed products by our licensees. We earn revenue by performing services under research and development contracts, grants, manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$118.6 million in revenue under these types of agreements. Revenues by source for each of the three years ended December 31, 2005, were as follows (in millions):

Source	2005	2004	2003
NIH contracts	\$ 1.1	\$ 8.4	\$ 2.9
CMV grants	1.3	0.7	—
Anthrax grant	1.3	2.0	1.9
U.S. Navy contract	0.9	—	0.2
Other contracts and grants	1.4	—	1.0
Total contract and grant revenues	6.0	11.1	6.0
Sanofi-Aventis licenses	—	1.2	—
Merck license	4.0	—	—
AnGes license	1.0	—	—
Invitrogen royalties	1.0	1.1	0.9
Other royalties and licenses	—	1.1	1.2
Total royalty and license revenues	6.0	3.4	2.1
Total revenues	\$ 12.0	\$ 14.5	\$ 8.1

Research, development, manufacturing and production costs by major program, as well as other expenses for each of the three years ended December 31, 2005, were as follows (in millions):

Program	2005	2004	2003
CMV	\$ 8.1	\$ 8.9	\$ 7.2
Allovectin-7®	5.2	4.9	5.2
Anthrax	1.5	2.7	6.6
IL-2/EP	2.6	2.4	—
Other research, development, manufacturing and production	12.6	12.3	7.8
Total research, development, manufacturing and production	\$ 30.0	\$ 31.2	\$ 26.8

Since our inception, we estimate that we have spent approximately \$244 million on research, development, manufacturing and production. Our current independent development focus is on novel DNA vaccines for CMV and our cancer immunotherapeutic IL-2/EP, as well as other preclinical targets such as influenza. We are in the early stages of clinical development of vaccine candidates for CMV and our IL-2/EP program for solid tumors and these programs will require significant additional costs to advance through development to commercialization. From inception, we have spent approximately \$26 million on our CMV program, and approximately \$5 million on our IL-2 EP program.

We are currently performing research testing of vaccine candidates for human and avian influenza under separate grants. 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 approval of a product by the FDA or comparable foreign agencies. 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 or comparable foreign agencies.

For instance, we have spent approximately \$61 million from inception on our Allovectin-7® program. We have successfully completed an SPA with the FDA for a Phase 3 trial of high-dose Allovectin-7® that would be needed to support submission of a BLA. We are currently in discussions with potential partners for the further development and commercialization of Allovectin-7®, and do not expect to conduct the Phase 3 trial independently.

In addition, we are in the early stages of clinical development of an anthrax vaccine candidate, however, due to the lack of additional government funding, we do not intend to pursue further development of our anthrax vaccine candidate at this time except for the ongoing non-clinical development supported by an SBIR grant.

As a result, 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 facilities, and possible advancement toward commercialization activities.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, actual results may differ from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and royalty agreements, manufacturing contracts, and grant revenues. Our critical accounting policies also include recognition of expenses in research and development expenses and the valuation of long-lived and intangible assets.

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin Topic 13 (“SAB Topic 13”), “Revenue Recognition” and Emerging Issues Task Force No. 00-21 (“EITF 00-21”), “Accounting for Revenue Arrangements with Multiple Deliverables.” Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Contract Manufacturing Revenue. Our contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. In accordance with EITF 00-21, we analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (a) the delivered item(s) has value to the customer on a standalone basis; (b) there is objective and reliable evidence of the fair value of the undelivered item(s); and (c) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If the delivered item does not have standalone value or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred.

License and Royalty Revenue. Our license and royalty revenues are generated through agreements with strategic partners. Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by us under the arrangements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if we have continuing performance obligations. If we have continuing involvement through contractual obligations under such agreement, such up-front fees are deferred and recognized over the period for which we continue to have a performance obligation, unless all of the following criteria exist: (1) the delivered item(s) have standalone value to the customer, (2) there is objective and reliable evidence of the fair value of the undelivered item(s), and (3) there is no general right to return the delivered item(s).

We recognize royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of returns, cash discounts, and freight and warehousing, which may vary over the course of the license agreement. Payments received related to milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process.

Government Research Grant Revenue. We recognize revenues from federal government research grants during the period in which the related expenditures are incurred.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred.

We assess our obligations to make milestone payments that may become due under licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;

- There is substantial uncertainty of the technology or product being successful;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

Capitalization and Valuation of Long-Lived and Intangible Assets

Intangible assets with finite useful lives consist of capitalized legal costs incurred in connection with patents, patent applications pending and technology license agreements. Payments to acquire a license to use a proprietary technology are capitalized if the technology is expected to have alternative future use in multiple research and development projects. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter.

For patents pending, we amortize the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents and patent applications pending that we abandon, we charge the remaining unamortized accumulated costs to expense.

Intangible assets and long-lived assets are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or long-lived assets are not recoverable, their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

- A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or
- A significant negative industry or economic trend.

When we determine that the carrying value of intangible assets or long-lived assets are not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets. As of December 31, 2005, our largest group of intangible assets with finite lives was patents and patents pending for or DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$3.2 million.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements impacting our business, see Note 1 of the Notes to Financial Statements included in this report.

Results of Operations

Year Ended December 31, 2005, Compared to Year Ended December 31, 2004

Total Revenues. Total revenues decreased \$2.5 million, or 17.5%, to \$12.0 million in 2005 from \$14.5 million in 2004. Revenues from our contracts and grants were \$6.0 million in 2005 as compared to \$11.2 million in 2004. The decrease in contract and grant revenue was due primarily to decreased manufacturing contract shipments to the VRC under our NIH agreement, which was partially offset by increases in contract shipments to the U.S. Navy and in other grants. License and royalty revenues were \$6.0 million in 2005 as compared to \$3.4 million in 2004. The increase in 2005 was primarily due to the recognition of \$4.0 million in license and milestone revenues related to Merck's use of our technology for the development of specific cancer targets.

Research and Development Expenses. Research and development expenses decreased \$1.8 million, or 9.3%, to \$17.8 million for 2005 from \$19.6 million for 2004. The decrease was primarily a result of the \$1.1 million decrease in royalty expenses, including those related to the WARF litigation settlement, and \$0.9 million in lower facility expenses.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$0.6 million, or 5.4%, to \$12.2 million for 2005 from \$11.6 million for 2004. The increase was primarily due to increased costs associated with our expanded manufacturing capabilities, which were not fully functional until 2004. The primary focus of manufacturing and production during the year ended December 31, 2005, was the production of plasmids for programs under clinical development and the fulfillment of commitments under manufacturing contracts.

General and Administrative Expenses. General and administrative expenses decreased \$0.8 million, or 9.8%, to \$7.7 million for 2005 from \$8.5 million for 2004. The decrease was primarily due to a \$0.4 million decrease in professional fees related to compliance with the Sarbanes-Oxley Act of 2002, legal fees associated with the WARF litigation and lower severance costs of \$0.5 million which were recorded in the prior year.

Investment Income. Investment income was \$1.8 million in 2005 as compared to \$2.2 million in 2004. Investment income in 2004 included a \$0.9 million gain on the sale of Corautus shares, which is partially offset by higher rates of return in 2005.

Interest Expense. Interest expense was \$0.5 million in 2005 as compared to \$0.8 million in 2004. The decrease was the result of lower interest rates and lower principal amounts outstanding on our equipment financing obligations.

Year Ended December 31, 2004, Compared to Year Ended December 31, 2003

Total Revenues. Total revenues increased \$6.4 million, or 80.1%, to \$14.5 million in 2004 from \$8.1 million in 2003. Revenues from our contracts and grants were \$11.2 million in 2004 as compared to \$6.0 million in 2003. The increase in contract and grant revenue was due primarily to increased manufacturing contract shipments to the VRC under our NIH agreement and increased funding under two NIAID grants for our Phase 1 CMV vaccine programs, partially offset by a reduction in shipments to the IAVI. License and royalty revenues were \$3.4 million in 2004 as compared to \$2.1 million in 2003. The increase in 2004 was primarily due to a \$1.2 million milestone we earned from Centelion under our license agreement for certain cardiovascular applications of our core DNA delivery technology as well as revenue we recognized from a new license with Merial for cancer in companion animals. License and royalty revenue for both periods included recognition of deferred license fees from Corautus and royalty revenue from Invitrogen.

Research and Development Expenses. Research and development expenses increased \$1.3 million, or 7.1%, to \$19.6 million for 2004 from \$18.3 million for 2003. The increase was primarily a result of the \$1.5 million accrual for settlement of the WARF litigation in addition to personnel related expenses related to our expanded preclinical and clinical programs.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$3.1 million, or 36.5%, to \$11.6 million for 2004 from \$8.5 million for 2003. The increase was primarily due to costs associated with our increased manufacturing capabilities within our new facility. We moved to our new facility in 2003, however, our manufacturing facilities were not fully functional until 2004. In addition, the increase was partially due to our expanded preclinical and clinical programs and an increase in manufacturing contract shipments in 2004.

General and Administrative Expenses. General and administrative expenses increased \$1.6 million, or 22.9%, to \$8.5 million for 2004 from \$6.9 million for 2003. The increase was primarily due to \$0.4 million of increased legal fees associated with the WARF litigation, \$0.7 million of higher professional fees related to compliance with the Sarbanes-Oxley Act of 2002, and severance expense of \$0.5 million related to the resignations of two officers during 2004.

Write-down of Investment. In 2003, we recorded a \$0.5 million write-down of our investment in Corautus shares received under a licensing agreement. We subsequently reclassified these shares as marketable securities. See Note 2 in Notes to Financial Statements for further discussion.

Investment Income. Investment income was \$2.2 million in 2004 as compared to \$2.1 million in 2003. Investment income in 2004 included a \$0.9 million gain on the sale of Corautus shares.

Interest Expense. Interest expense was \$0.8 million in 2004 as compared to \$0.4 million in 2003. The increase was primarily due to increased capital lease obligations related to property and equipment expenditures.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, public offerings of common stock, and revenues from collaborative agreements. From our inception through December 31, 2005, we have received approximately \$118.6 million in revenues from performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$241.2 million from the sale of equity securities. As of December 31, 2005, we had working capital of approximately \$63.4 million, compared with \$67.3 million at December 31, 2004. Cash, cash equivalents and marketable securities, including restricted securities, totaled approximately \$66.5 million at December 31, 2005, compared with \$74.0 million at December 31, 2004. The declines in our cash, cash equivalents and marketable securities in the year ended December 31, 2005, were due primarily to cash used to fund our operations and to pay our long-term debt obligations, offset by approximately \$21.0 million in net proceeds from our registered direct offering which closed in October 2005.

Net cash used in operating activities was \$22.8 million and \$21.1 million for the years ended December 31, 2005 and 2004, respectively. The increase in net cash used in operating activities for the year ended December 31, 2005, compared with the same period in the prior year, was primarily the result of an increase in deferred manufacturing contract costs and an increase in the net loss during the current period, which was partially offset by a decrease in deferred revenue.

Net cash (used in) provided by investing activities was (\$6.7) million and \$8.0 million for the years ended December 31, 2005 and 2004, respectively. The increase in cash used in investing activities for the year ended December 31, 2005, compared with the same period in the prior year, was primarily the result of an increase in net purchases of investments.

Net cash provided by financing activities was \$17.6 million and \$14.2 million for the years ended December 31, 2005 and 2004, respectively. The increase in cash provided by financing activities for the year ended December 31, 2005, compared with the same period in the prior year, was primarily the result of an increase in the net proceeds received from our registered direct offerings of common stock, which was partially offset by a net decrease in borrowings under our equipment financing arrangements.

We expect to incur substantial additional research and development expenses, manufacturing and production 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 January 2006, we filed a shelf registration statement with the SEC which, if and when it is declared effective, would allow us to issue from time to time an aggregate of up to \$70.0 million of common or preferred stock. We also have on file an effective shelf registration statement that allows us to raise up to an additional \$8.8 million from the sale of common or preferred stock. However, additional financing may not 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 December 31, 2007.

Contractual Obligations and Off-Balance Sheet Arrangements

The following table sets forth our contractual obligations, including all off-balance sheet arrangements, as of December 31, 2005 (in thousands):

Contractual Obligations¹	Payment Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Equipment financing obligations	\$ 7,519	\$ 4,093	\$ 3,271	\$ 155	\$ —
Operating lease obligations	39,808	3,263	6,792	6,669	23,084
WARF settlement	500	500	—	—	—
Unconditional purchase obligations	998	998	—	—	—
Total contractual obligations	\$ 48,825	\$ 8,854	\$ 10,063	\$ 6,824	\$ 23,084

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.

“Unconditional Purchase obligations” presented above represent contractual commitments entered into for goods and services in the normal of course of our business. The purchase obligations do not include potential severance payment obligations to our executive officers in the event of termination without cause or a resignation for good reason under their existing employment contracts. For information regarding these severance, refer to the final paragraph in this Item 7.

In December 2004, we modified an equipment financing agreement which provided for \$5.3 million of financing, with interest rates ranging from 3.0% to 3.2%. A portion of the financing was used to repay outstanding debt of approximately \$2.2 million under another credit facility. Additional amounts were used to finance equipment purchases. The draw down period for this equipment financing arrangement ended in October 2005. The agreement requires a non-interest-bearing cash security deposit in the amount of 60.0% of the amount of each drawdown which amounts are included in current and long-term other assets. This financing involves restrictive financial covenants, including a requirement that we maintain unrestricted cash and marketable securities of at least \$25.0 million or obtain a letter of credit from another lender in the amount of outstanding borrowings.

Under the Merck, Centelion, Merial, Corautus, Aqua Health and AnGes agreements, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the WARF. The CytRx and Inovio agreements require us to make payments 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.

In addition, we have undertaken certain commitments under license agreements with collaborators, and under indemnification agreements with 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. Under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

As of December 31, 2005, we have employment agreements that contain severance arrangements with each of our three executive officers and three other executives. Under these agreements, we are obligated to pay severance if we terminate an executive officer's or other executive's employment without “cause,” or if an

executive officer or other executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance would consist of continued payments 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. The maximum payments due under these employment agreements would have been \$1.4 million if each executive officer and other executive was terminated at December 31, 2005.

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, both restricted and non-restricted, and marketable securities. The average maturity of our non-equity investments is approximately nine months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and marketable securities using the following assumptions: a 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 \$0.4 million lower than the reported fair value of our non-equity investments at December 31, 2005. At December 31, 2005, our unrealized loss on marketable securities was \$0.1 million. We expect lower investment income in 2006 compared with 2005 due to lower investment balances.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Vical Incorporated:

We have audited the accompanying balance sheets of Vical Incorporated (the "Company") as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such financial statements present fairly, in all material respects, the financial position of Vical Incorporated as of December 31, 2005 and 2004, 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2006 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

San Diego, California

March 8, 2006

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Vical Incorporated:

We have audited the accompanying statements of operations, stockholders' equity, and cash flows of Vical Incorporated (the Company) for the year 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 audit.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Vical Incorporated for the year ended December 31, 2003, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Diego, California
February 6, 2004

VICAL INCORPORATED
BALANCE SHEETS
(in thousands, except per share data)

	December 31,	
	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,710	\$ 17,666
Restricted cash equivalents	—	2,703
Marketable securities, available-for-sale	58,337	53,627
Restricted marketable securities	2,439	—
Receivables and other	5,778	3,412
Total current assets	72,264	77,408
Property and equipment, net	15,170	16,277
Intangible assets, net	5,481	5,775
Other assets	1,615	1,766
Total assets	\$ 94,530	\$ 101,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,687	\$ 4,970
Current portion of equipment financing obligations	4,093	4,607
Deferred revenue	—	531
Total current liabilities	8,780	10,108
Long-term liabilities:		
Equipment financing obligations, net of current portion	3,426	5,822
Deferred rent	2,018	1,814
Other liabilities	—	573
Total long-term liabilities	5,444	8,209
Commitments and contingencies (Notes 5, 6 and 8)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.01 par value, 40,000 shares authorized, 28,261 and 23,502 shares issued and outstanding at December 31, 2005 and 2004, respectively	283	235
Additional paid-in capital	242,991	221,341
Accumulated deficit	(162,874)	(138,517)
Accumulated other comprehensive loss	(94)	(150)
Total stockholders' equity	80,306	82,909
Total liabilities and stockholders' equity	\$ 94,530	\$ 101,226

See accompanying notes to financial statements

VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2005	2004	2003
Revenues:			
Contract and grant revenue	\$ 5,953	\$ 11,168	\$ 6,012
License and royalty revenue	6,050	3,377	2,066
Total revenues	<u>12,003</u>	<u>14,545</u>	<u>8,078</u>
Operating expenses:			
Research and development	17,772	19,597	18,296
Manufacturing and production	12,203	11,581	8,482
General and administrative	7,679	8,510	6,922
Write-down of investment	—	—	482
Total operating expenses	<u>37,654</u>	<u>39,688</u>	<u>34,182</u>
Loss from operations	(25,651)	(25,143)	(26,104)
Other income (expense):			
Investment income, net	1,827	2,205	2,067
Interest expense	(533)	(795)	(413)
Net loss	<u>\$ (24,357)</u>	<u>\$ (23,733)</u>	<u>\$ (24,450)</u>
Basic and diluted net loss per share	<u>\$ (0.99)</u>	<u>\$ (1.05)</u>	<u>\$ (1.22)</u>
Weighted average shares used in computing basic and diluted net loss per share	<u>24,581</u>	<u>22,695</u>	<u>20,091</u>

See accompanying notes to financial statements

VICAL INCORPORATED

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS FOR EACH OF THE THREE YEARS IN THE PERIOD ENDED DECEMBER 31, 2005
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Amount				
Balance at January 1, 2003	20,091	\$ 201	\$203,554	\$ (90,334)	\$ 887	\$ 114,308
Net loss	—	—	—	(24,450)	—	(24,450)
Unrealized gain on marketable securities arising during holding period	—	—	—	—	101	101
Reclassification of realized gain included in net loss	—	—	—	—	(190)	(190)
Comprehensive loss	—	—	—	—	—	(24,539)
Exercise of options to purchase common stock	1	—	3	—	—	3
Non-cash compensation expense related to grant of stock options	—	—	50	—	—	50
Balance at December 31, 2003	<u>20,092</u>	<u>201</u>	<u>203,607</u>	<u>(114,784)</u>	<u>798</u>	<u>89,822</u>
Net loss	—	—	—	(23,733)	—	(23,733)
Unrealized loss on marketable securities arising during holding period	—	—	—	—	(19)	(19)
Reclassification of realized gain included in net loss	—	—	—	—	(929)	(929)
Comprehensive loss	—	—	—	—	—	(24,681)
Issuance of common stock	3,379	34	17,217	—	—	17,251
Exercise of options to purchase common stock	31	—	97	—	—	97
Non-cash compensation expense related to grant of stock options	—	—	420	—	—	420
Balance at December 31, 2004	<u>23,502</u>	<u>235</u>	<u>221,341</u>	<u>(138,517)</u>	<u>(150)</u>	<u>82,909</u>
Net loss	—	—	—	(24,357)	—	(24,357)
Unrealized gain on marketable securities arising during holding period	—	—	—	—	53	53
Reclassification of realized loss included in net loss	—	—	—	—	3	3
Comprehensive loss	—	—	—	—	—	(24,301)
Issuance of common stock, net of offering costs	4,704	47	21,046	—	—	21,093
Exercise of options to purchase common stock	55	1	174	—	—	175
Non-cash compensation expense related to grant of stock options	—	—	430	—	—	430
Balance at December 31, 2005	<u>28,261</u>	<u>\$ 283</u>	<u>\$242,991</u>	<u>\$ (162,874)</u>	<u>\$ (94)</u>	<u>\$ 80,306</u>

See accompanying notes to financial statements

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2005	2004	2003
Cash flows from operating activities:			
Net loss	\$ (24,357)	\$(23,733)	\$ (24,450)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,594	3,637	3,543
Write-down of investment	—	—	482
Loss on sublease	—	45	249
Write-off of abandoned patents	158	143	—
Compensation expense related to stock options and awards	430	420	50
Changes in operating assets and liabilities:			
Receivables and other	(2,264)	1,174	270
Other assets	841	(1,168)	36
Accounts payable, accrued expenses and other liabilities	(807)	(178)	(1,991)
Deferred revenue	(531)	(1,937)	(9)
Deferred rent	155	528	282
Net cash used in operating activities	(22,781)	(21,069)	(21,538)
Cash flows from investing activities:			
Maturities of marketable securities—including restricted	107,580	65,790	123,371
Purchases of marketable securities—including restricted	(114,672)	(54,777)	(109,826)
Maturities of restricted cash equivalents	2,703	4,857	—
Purchases of restricted cash equivalents	—	(5,204)	(2,356)
Purchases of property and equipment	(1,774)	(4,219)	(12,102)
Sale of property and equipment	—	2,240	—
Patent and licensed technology expenditures	(576)	(709)	(824)
Net cash (used in) provided by investing activities	(6,739)	7,978	(1,737)
Cash flows from financing activities:			
Proceeds from issuance of common stock	21,268	17,348	3
Payments on notes payable	—	(341)	(633)
Principal payments under equipment financing obligations	(4,867)	(6,147)	(2,612)
Proceeds from equipment financing arrangements	1,163	3,323	10,482
Net cash provided by financing activities	17,564	14,183	7,240
Net (decrease) increase in cash and cash equivalents	(11,956)	1,092	(16,035)
Cash and cash equivalents at beginning of year	17,666	16,574	32,609
Cash and cash equivalents at end of year	\$ 5,710	\$ 17,666	\$ 16,574
Non-cash investing and financing activities:			
Property and equipment acquired under capital lease financing	\$ —	\$ 2,240	\$ —
Investment accounted for on the cost method, subsequently reclassified to marketable securities available for sale, at quoted market value	\$ —	\$ —	\$ 318
Supplemental information:			
Interest paid	\$ 533	\$ 715	\$ 459

See accompanying notes to financial statements

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization and Business Activity

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 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 research and development agreements with pharmaceutical collaborators and grant and contract arrangements with government entities. 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. 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. We anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least December 31, 2007.

Issuance of Common Stock

In October 2005, the Company raised approximately \$21.0 million in net proceeds from the sale of approximately 4.7 million shares of its common stock at \$4.80 per share in a registered direct offering to a select group of institutional investors. In March 2004, the Company raised approximately \$17.3 million in net proceeds from the sale of approximately 3.4 million shares of its common stock at \$5.50 per share in a registered direct offering to a select group of institutional investors. All of the common stock was offered by the Company pursuant to the shelf registration statement declared effective in December 2003. The shelf registration allows the Company to issue from time to time up to approximately \$8.8 million of additional common or preferred stock.

Basis of Presentation

These financial statements are prepared in conformity with accounting principles generally accepted in the United States of America.

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 amounts reported in the financial statements and disclosures made in the accompanying notes. Actual results could differ from those estimates.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Restricted Marketable Securities and Restricted Cash Equivalents

The Company is required to maintain a letter of credit securing an amount equal to twelve months of the current monthly installment of base rent for the term of its primary facilities lease, which ends in August 2017. Under certain circumstances the Company may be able to eliminate the need for the letter of credit. At December 31, 2005 and 2004 restricted marketable securities of \$2.4 million and restricted cash equivalents of \$2.7 million, respectively, were pledged as collateral for the letter of credit.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of 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 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.

Property and Equipment

Property and equipment is recorded at cost and depreciation is computed using the straight-line method over the estimated useful lives of the assets. Assets acquired pursuant to capital lease arrangements and leasehold improvements are amortized using the straight-line method over the shorter of the life of the remaining lease term or the remaining useful life of the asset. Manufacturing equipment has estimated useful lives of ten years. All other property and equipment have estimated useful lives of 3 to 5 years.

Intangible Assets

Intangible assets include licensed technology rights and certain costs related to patent applications. 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 using the straight-line method over the estimated ten-year useful life of the technology. Certain costs related to patent applications 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. Amortization expense for licensed technology and capitalized patent cost is included in research and development expenses.

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment at least annually, quarterly for intangible assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Should a impairment exist, the impairment loss would be measured based on the excess of the carrying amount of the asset over the asset's fair value. The Company expensed approximately \$0.1 million in each of the years ended December 31, 2005 and 2004, related to patents which value was deemed to be impaired. The Company believes the future cash flows to be received from its remaining long-lived assets will exceed the assets' carrying value, and accordingly has not recognized any additional impairment losses.

Revenue Recognition

The Company earns revenue by performing services under research and development agreements, grants, manufacturing contracts and from licensing its proprietary technology. 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.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

The Company enters into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used primarily for preclinical and clinical research. Under these contracts, revenue and related expenses are recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met. Any advance payments received in excess of amounts earned are classified as deferred revenue.

Revenue under research and development agreements, grants, and manufacturing contracts, except for fixed-price contracts, is recognized as the research and development or manufacturing expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met.

Other revenues include amounts received from licensing the Company's proprietary technology, which occurs under a variety of circumstances including licenses, options and royalties. Any initial license or option payment received under a research and development agreement is recognized as revenue over the term of the research and development period. Upfront license payments are recognized as revenue upon contract signing only if the fee is nonrefundable and noncreditable, and if there are no performance obligations remaining. Payments for options to license the Company's technology are recognized as revenue over the option period. Royalty revenue is recognized when earned and when collectibility is reasonably assured.

Revenue from milestones is recognized as agreed-upon events representing the achievement of substantive steps in the development process are achieved, or as agreed-upon passages of time occur, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured.

Accruals for Potential Disallowed Costs on Government Contracts

The Company has contracts with U.S. government agencies under which it bills for direct and indirect costs incurred. These billed costs are subject to audit by government agencies. The Company has established accruals of approximately \$0.2 million and \$0.5 million at December 31, 2005 and 2004, respectively, 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.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, supplies and materials, outside services, costs of conducting preclinical and clinical trials, facilities costs and amortization of intangible assets. 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.

Manufacturing and Production Costs

Manufacturing and production costs include expenses related to manufacturing contracts and expenses related to the production of plasmid DNA for use in the Company's research and development efforts.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Manufacturing expenses related to manufacturing contracts are deferred and expensed when the related revenue is recognized. Production expenses related to the Company's research and development efforts are expensed as incurred.

Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under restricted stock units, or RSUs, as the effect would be antidilutive. Common stock equivalents of 0.4 million, 0.4 million and 0.2 million for the years ended December 31, 2005, 2004 and 2003, respectively, were excluded from the calculation because of their antidilutive effect.

Stock-based Compensation

The Company has a stock incentive plan under which 5,700,000 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 Company accounts for stock options issued under this plan using the recognition and measurement principles of Accounting Principles Board, or APB, Opinion No. 25, "Accounting for Stock Issued to Employees" and its related interpretations, and has adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, "Accounting for Stock-Based Compensation," and its related interpretations.

Pro forma information regarding net loss and loss per share is required by SFAS No. 123 and has been determined as if the Company had accounted for its stock options under the fair value method of that Statement. The fair value for these options was estimated at the dates of grant using the Black-Scholes option valuation model. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period.

The Company's pro forma information is as follows (in thousands, except for net loss per share information):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss, as reported	\$(24,357)	\$(23,733)	\$(24,450)
Add stock-based compensation expense included in reported net loss	430	420	50
Less stock-based compensation expense determined under fair value based method for all awards	<u>(2,509)</u>	<u>(3,225)</u>	<u>(3,569)</u>
Pro forma net loss	<u>\$ (26,436)</u>	<u>\$ (26,538)</u>	<u>\$ (27,969)</u>
Basic and diluted net loss per share, as reported	<u>\$ (0.99)</u>	<u>\$ (1.05)</u>	<u>\$ (1.22)</u>
Basic and diluted pro forma net loss per share	<u>\$ (1.08)</u>	<u>\$ (1.17)</u>	<u>\$ (1.39)</u>
Weighted average fair value of stock options	<u>\$ 3.29</u>	<u>\$ 4.18</u>	<u>\$ 2.45</u>
Assumptions:			
Assumed risk-free interest rate	3.98%	3.10%	2.55%
Assumed volatility	78%	80%	80%
Expected option life	4 years	4 years	4 years
Dividend yields	—	—	—

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Fair Value of Financial Instruments

The carrying amounts of cash, cash equivalents, restricted cash equivalents, marketable securities, receivables, other current assets, accounts payable and accrued expenses at December 31, 2005 and 2004, are considered to reasonably approximate fair value because of the short term nature of those items. The Company believes the carrying amounts of the Company's equipment financing obligations at December 31, 2005 and 2004, approximate fair value because the interest rates on these instruments change with, or approximate, market interest rates.

Income Taxes

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement bases and the tax bases of assets and liabilities using enacted tax rates. A valuation allowance is established to reduce a deferred tax asset to the amount that is expected more likely than not to be realized.

Comprehensive Loss

Comprehensive loss consists of net loss and certain changes in equity that are excluded from net loss. Comprehensive loss for the years ended December 31, 2005, 2004 and 2003, has been reflected in the Statements of Stockholders' Equity. Accumulated other comprehensive income (loss), which is included in stockholders' equity, represents unrealized gains and losses on marketable securities.

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, which is within the U.S., dedicated to research and development of DNA delivery technology.

Recent Accounting Standards

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123(R), "Share-Based Payment," which is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS 123(R) requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. The compensation cost will be measured based on the fair value of the equity or liability instruments issued. The Company will adopt SFAS No. 123(R) on a modified prospective basis beginning on January 1, 2006. The Company is evaluating the requirements of SFAS 123(R) and expects the adoption of SFAS 123(R) to have a material impact on its results of operations. The Company has \$2.0 million of unamortized expense related to options that were outstanding as of December 31, 2005. Approximately \$1.2 million of that expense will be recognized during the year ending December 31, 2006. The ultimate amount of expense recognized in future periods will vary based on the frequency of cancellations of existing and future awards and the grants of future awards.

In May 2005, the FASB issued FAS 154, "Accounting Changes and Error Corrections." FAS 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. FAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. FAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company does not expect the adoption of FAS 154 to significantly affect its financial condition or results of operations.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Reclassifications

The accompanying Statement of Cash Flows for the year ended December 31, 2005, presents the cash flows related to purchases and maturities of restricted cash equivalents as investing activities. Such changes were previously presented as financing activities. Accordingly, the accompanying Statements of Cash Flows for the years ended December 31, 2004 and 2003, have been reclassified to present these changes in restricted cash equivalents consistent with the 2005 presentation, resulting in a \$0.3 million and \$2.4 million decrease in investing cash flows and a corresponding increase to financing cash flows from the amounts previously reported.

In addition, the Company has separately classified its research and development costs as research and development costs and as manufacturing and production costs in its 2003 Statement of Operations to conform to the 2005 and 2004 presentations.

Correction of the Method of Accounting for Equipment Financing Arrangements

The Company has financed certain of its equipment purchases under various financing arrangements. Historically, these arrangements were accounted for on a net basis as capital lease obligations. During the third quarter of 2005, Vical determined that these arrangements should be accounted for on a gross basis, either as a sale lease back pursuant to a capital lease obligation or as a loan collateralized by the related equipment, depending on the nature of the arrangement. Vical corrected its accounting treatment for these arrangements and analyzed the financial impact that such accounting correction would have on its current and prior year financial statements. As a result of this analysis, Vical determined that the impact was limited to reclassifications within its Cash Flow Statement which did not affect the total net cash flows of the Company. It was determined that the amount of the reclassifications were not material to the year ended December 31, 2005 or to the years prior to 2005. These reclassifications resulted in a \$1.5 million and a \$10.5 million decrease in investing cash flows and a corresponding increase to financing cash flows from the amounts previously reported for the years ended December 31, 2004 and 2003, respectively.

2. Marketable Securities

The Company invests its excess cash in U.S. government obligations and debt instruments of financial institutions and of corporations with strong credit ratings. 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. Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company employs a methodology that primarily considers rating agencies' actions. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established. Included in marketable securities is a \$0.8 million investment in the common stock and warrants of Inovio which was completed by the Company in December 2005.

At December 31, marketable securities consisted of the following (in thousands):

<u>2005:</u>	<u>Amortized Cost</u>	<u>Unrealized Gain</u>	<u>Unrealized (Loss)</u>	<u>Market Value</u>
Equity securities	\$ 750	\$ 25	\$ —	\$ 775
U.S. government obligations	26,668	—	(43)	26,625
Corporate bonds	21,531	1	(43)	21,489
Corporate asset backed securities	9,445	—	(34)	9,411
Certificate of deposit	2,476	—	—	2,476
	<u>\$ 60,870</u>	<u>\$ 26</u>	<u>\$ (120)</u>	<u>\$60,776</u>

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

2004:	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. government obligations	\$ 35,504	\$ 3	\$ (131)	\$35,376
Corporate bonds	12,762	7	(13)	12,756
Corporate asset backed securities	5,511	3	(19)	5,495
	<u>\$ 53,777</u>	<u>\$ 13</u>	<u>\$ (163)</u>	<u>\$53,627</u>

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. In February 2003, VGI and GenStar Therapeutics Corporation merged, resulting in the creation of a new public company, Corautus Genetics Inc., or Corautus. In connection with the merger, the shares of VGI were exchanged for common stock of Corautus. Subsequent to the merger, the Company reclassified this investment from other assets to marketable securities. Based on the value of the Company's Corautus shares in 2003, the Company wrote down its investment to \$0.3 million. During 2004, the Company sold its Corautus shares and recognized a gain of \$0.9 million, which is included in other income consistent with all other available-for-sale gains and losses. As of December 31, 2005, no individual security has been in an unrealized loss position for more than twelve months.

At December 31, 2005, approximately 98 percent of these securities mature within one year, with the remaining two percent maturing within two years. Net realized gains on sales of available-for-sale securities for the years ended December 31, 2004 and 2003, were \$0.9 million and \$0.2 million, respectively. The net realized loss was immaterial in 2005.

3. Other Balance Sheet Accounts

Property and equipment consists of the following at December 31 (in thousands):

	2005	2004
Equipment	\$ 20,197	\$ 19,009
Leasehold improvements	9,973	12,194
	30,170	31,203
Less accumulated depreciation and amortization	(15,000)	(14,926)
	<u>\$ 15,170</u>	<u>\$ 16,277</u>

Depreciation and amortization of equipment and leasehold improvements for the years ended December 31, 2005, 2004 and 2003, was \$2.9 million, \$3.0 million and \$2.9 million, respectively. These amounts include depreciation related to equipment under equipment financing arrangements. See Note 5 for equipment financing arrangements.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Intangible assets consist of the following at December 31 (in thousands):

	2005	2004
Licensed technology rights	\$ 3,830	\$ 3,830
Patent application costs	4,584	4,201
	8,414	8,031
Less accumulated amortization	(2,933)	(2,256)
	\$ 5,481	\$ 5,775

Amortization of licensed technology rights and patent application costs for the years ended December 31, 2005, 2004 and 2003, was \$0.7 million, \$0.7 million and \$0.6 million, respectively. Estimated annual amortization for these assets for each of the years in the period from 2006 to 2010 is \$0.7 million.

Accounts payable and accrued expenses consist of the following at December 31 (in thousands):

	2005	2004
Employee compensation	\$ 2,115	\$ 1,985
Accrued contract liabilities	190	492
Accounts payable	298	560
Accrued royalty	500	500
Other accrued liabilities	1,584	1,433
	\$ 4,687	\$ 4,970

4. Significant Contracts, Grants, License and Royalty Agreements

Contract and Grant Agreements

NIH Vaccine Research Center

In 2002, the Company entered into a subcontract agreement, which was subsequently amended, to manufacture HIV, Ebola, West Nile Virus and severe acute respiratory syndrome, or SARS, DNA vaccines for the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institute of Health, or NIH. In 2003, the Company entered into a separate subcontract agreement to manufacture bulk DNA vaccines for the VRC, which are produced in a 500-liter fermenter and related purification equipment that were installed as Government Furnished Equipment, or GFE. Under Federal Acquisition Regulations, or FARs, the government has the right to terminate these agreements for convenience. These subcontracts are issued and managed on behalf of the VRC by SAIC-Frederick, Inc. under the umbrella of a federally funded contract with the NIH. The Company recognized revenues under these agreements of \$1.1 million, \$8.4 million and \$2.9 million in 2005, 2004 and 2003, respectively. See also Note 8 for related party agreements.

NIH Grants

The Company's preclinical research for its anthrax vaccine candidate has been supported, in part, by grants from the National Institute of Allergy and Infectious Diseases, or NIAID. The most recent award was a \$5.8 million three-year Phase II Small Business Innovation Research, or SBIR, grant initially awarded in 2003 for additional non-clinical development of its anthrax vaccine candidate. The Company recognized revenues under these grants of \$1.3 million, \$2.0 million and \$1.9 million in 2005, 2004 and 2003, respectively.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

In addition, the Company has been awarded approximately \$1.0 million for research and development related to its cytomegalovirus, or CMV, vaccine program under two grants from the NIAID. In March 2005, the Company was awarded an additional three-year, \$3.1 million grant by the NIAID. The grant will partially fund the ongoing development of the Company's CMV immunotherapeutic vaccine. In 2005 and 2004, the Company recognized approximately \$1.3 million and \$0.7 million, respectively, in revenues from these grants. No revenue was recognized in 2003.

Office of Naval Research

In 2003, the Company entered into an agreement with the Office of Naval Research, or ONR, under which the ONR agreed to provide funding to the Company for research and development work on a malaria vaccine. Revenue recognized under this agreement was \$0.9 million and \$0.2 million in 2005 and 2003, respectively. No revenue was recognized in 2004. The Company does not plan to pursue this program independently.

License and Royalty Agreements

Merck

In 1991, the Company entered into an agreement with Merck, which was subsequently amended, providing Merck with certain exclusive rights to develop and commercialize vaccines using the Company's core DNA delivery technology for specified human diseases. Under the agreement, as amended, Merck licensed preventive and therapeutic human infectious disease vaccines using the Company's core DNA delivery technology.

In 2003, the Company amended the agreement, providing Merck options for rights to use the Company's core DNA delivery technology for three cancer targets. In addition, Merck returned rights to the Company for certain preventive vaccines. Merck has retained rights to use the licensed technology for HIV, hepatitis C virus, and hepatitis B virus. In June 2005, Merck exercised options related to three cancer targets that were granted under the 2003 amendment. As a result of the option exercise, the Company received a payment of \$3.0 million.

In September 2005, the Company further amended the agreement with Merck to grant renewable options for rights to use the Company's patented non-viral gene delivery technology for additional cancer targets. In exchange, the Company obtained non-exclusive, sublicenseable rights to use the licensed technology for vaccines against HIV. Merck also obtained a fixed-term option to exclusively sublicense from the company electroporation-enhanced delivery technology for use with HIV vaccines, on terms to be negotiated.

In November 2005, Merck initiated a Phase 1 clinical trial of a DNA cancer vaccine based on the Company's DNA gene delivery technology that uses pDNA encoding human epidermal growth factor receptor 2, or HER-2, and carcinoembryonic antigen, or CEA. As a result of Merck reaching this milestone, the Company received a payment of \$1.0 million. The Phase 1 trial will evaluate the safety, tolerability and immunogenicity of the vaccine. Further development may lead to additional milestone and royalty payments.

Merck is obligated to pay fees if certain research milestones are achieved, and royalties on net sales if any products covered by the Company's agreement with Merck are developed and commercialized. Merck has the right to terminate this agreement without cause upon 90 days prior written notice. Total revenue recognized under this agreement was \$4.0 million in 2005. No revenues were recognized under this agreement in 2004 or 2003.

Sanofi-Aventis

In 2000, Centelion, a division of Sanofi-Aventis, licensed the rights to the Company's core DNA delivery technology for cardiovascular applications using FGF-1. The agreement with Centelion specifies that the

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Company will receive milestone payments plus royalties if products advance through commercialization. The Company recognized revenues of \$1.2 million in 2004 under the Centelion agreement. Revenue recognized under the Centelion agreement in 2005 and 2003 was immaterial. Centelion has the right to terminate the agreement without cause upon 60 days prior written notice.

Merial

In 2004, the Company granted an exclusive license to Merial for use of its core DNA delivery technology in a vaccine to protect dogs against melanoma. Under the agreement, Merial is responsible for research and development activities. If Merial is successful in developing and marketing this product, milestone payments and royalties on sales of the resulting product would be due to the Company. The Company recognized revenues of \$0.3 million in 2004 under the Merial agreement. No revenue was recognized under the Merial agreement in 2005 or 2003. Merial has the right to terminate this agreement without cause upon 60 days prior written notice.

Corautus

In February 2000, VGI, a predecessor company to Corautus, licensed the rights to the Company's core DNA delivery technology for cardiovascular applications using VEGF-2. In exchange, the Company received shares of VGI stock with an estimated fair value of \$5.0 million on the date of investment and rights to future royalty payments on resulting product sales. See Note 2 describing subsequent write-downs. License revenue recognized under the Corautus agreement was \$0.8 million and \$1.1 million for the years ended December 31, 2004 and 2003, respectively. No revenue was recognized under the Corautus agreement in 2005.

Aqua Health

In 2003, the Company granted a non-exclusive license to Aqua Health, an affiliate of Novartis Animal Health Inc., for use in Canada of its core DNA delivery technology in a vaccine against a disease that affects both wild and farm-raised fish. In 2005, Aqua Health received notification of approval from the Canadian Food Inspection Agency to sell its proprietary product, APEX-IHN, a DNA vaccine to protect farm-raised salmon against Infectious Haematopoietic Necrosis Virus. The Company has recognized *de minimus* license fees and royalty revenues on sales of this vaccine.

AnGes

In 2005, the Company granted an exclusive worldwide license to AnGes for use of its core DNA delivery technology in the development and commercialization of DNA-based products encoding Hepatocyte Growth Factor (HGF) for cardiovascular applications. Under the license agreement, the Company received an initial nonrefundable upfront payment of \$1.0 million which was recognized as revenue in 2005. Further development may lead to milestone and royalty payments.

Invitrogen Corporation

In 1991, the Company licensed the use of certain proprietary lipids for research product applications to Life Technologies, Inc., which was subsequently acquired by Invitrogen Corporation, or Invitrogen, in 2000. Invitrogen manufactures and markets these lipid compounds and pays royalties to the Company on the sales of the lipids. The Company recognized \$1.0 million, \$1.1 million and \$0.9 million in 2005, 2004 and 2003, respectively, in royalty revenues under this agreement.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

In-licensing Agreements

Inovio

In 2003, the Company entered into an agreement with Genetronics, which subsequently acquired and changed its name to Inovio, giving the Company options to worldwide exclusive licenses to use Inovio's proprietary electroporation technology in combination with the Company's DNA delivery technologies for undisclosed targets. In October 2004, the Company exercised options and amended the agreement to include HIV. The Company's first application of the licensed technology is for enhanced delivery in solid tumors of the pDNA encoding IL-2. In 2005, the Company began a Phase 1 safety testing of intralesional administration of IL-2 pDNA followed by local electroporation in certain patients with metastatic melanoma. Licenses granted under the agreement have a term of the later of the expiration of Inovio's patent rights or ten years from the effective date of the grant of the license. As part of the agreement, the Company paid *de minimus* option and license fees to Inovio in 2005, 2004 and 2003.

CytRx

In 2001, the Company entered into an exclusive agreement with CytRx which grants to the Company 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, including CMV. 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 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 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.

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, Merial, Centelion, Corautus, Aqua Health and AnGes agreements. The CytRx and Inovio agreements require the Company to make payments to the WARF if the Company or its sublicensees advance products through clinical development. Royalty expense for these agreements was \$0.4 million and \$1.4 million in 2005 and 2004, respectively. Royalty expense was immaterial in 2003. See also Note 6.

5. Equipment Financing Obligations

In December 2004, the Company modified an equipment financing agreement which provided for \$5.3 million of financing, with interest rates ranging from 3.0% to 3.2%. A portion of the financing was used to repay outstanding debt of approximately \$2.2 million under another credit facility. Additional amounts were used to finance equipment purchases. The draw down period for this equipment financing arrangement ended in October 2005. The agreement requires a non-interest-bearing cash security deposit in the amount of 60.0% of the amount of each drawdown. This financing includes a requirement that the Company maintain unrestricted cash and marketable securities of at least \$25.0 million or obtain a letter of credit from another lender in the amount of outstanding borrowings. The Company was in compliance with all of the agreements financial covenants at December 31, 2005.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

Minimum principal payments required under equipment financing arrangements are as follows at December 31, 2005 (in thousands):

Years ending December 31,	
2006	\$ 4,093
2007	2,716
2008	555
2009	155
2010	—
Thereafter	—
Total	<u>7,519</u>
Less current portion	<u>(4,093)</u>
Long-term equipment financing obligation	<u>\$ 3,426</u>

6. Commitments and Contingencies

Facility Leases

The Company is currently leasing two buildings in San Diego, California. The Company's primary facility has approximately 68,400 square feet of manufacturing, research laboratory and office space which the Company occupies under a lease which expires in 2017. The Company has the option to renew the 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 occupies approximately 10,500 square feet of research facility space under a lease which expires in 2009.

The Company leases its office, research and development, and manufacturing facilities under operating leases. The minimum annual rents on the facilities are subject to increases specified in each lease or based on changes in the Consumer Price Index subject to certain minimum and maximum annual increases also specified in each 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. The monthly rent 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. The \$2.0 million difference between the base rent paid and the level rent expensed through December 31, 2005, is recorded as deferred rent in the balance sheet.

Rent expense for the years ended December 31, 2005, 2004 and 2003, was \$3.5 million, \$3.7 million and \$4.0 million, respectively. Rent expense for 2003 included \$0.2 million for the expected loss on space in one of the Company's previously occupied facilities that was vacant or sublet at rental rates less than those incurred by the Company. Total sublease rental income in 2004 and 2003, was approximately \$0.7 million and \$0.2 million, respectively. The Company recognized no sublease rental income in 2005.

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NOTES TO FINANCIAL STATEMENTS—(Continued)

At December 31, 2005, annual payments due under the Company's facilities leases are as follows (in thousands):

Years ending December 31,	
2006	\$ 3,249
2007	3,346
2008	3,446
2009	3,509
2010	3,160
Thereafter	<u>23,084</u>
Total lease payments	<u>\$ 39,794</u>

Other Contingencies

If the Company fails to satisfy its contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the Company's manufacturing agreements with the VRC, the applicable FARs allow the VRC to cancel the agreements 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, and/or GFE, and/or other government property in its possession, and/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. Government agencies may fail to perform their responsibilities under these agreements and they may terminate the agreements.

In 2003, the WARF, filed a complaint against the Company in the U.S. 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. The Company counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement. In May 2004, the Company settled this matter for \$1.5 million, of which \$1.0 million had been paid as of December 31, 2005, with the remaining payment due in 2006. Pursuant to the settlement and an amendment to the license agreement with the WARF, the lawsuit was dismissed.

European Patent 1026253, covering a significant portion of the Company's core DNA delivery technology, was granted in September 2004. European Patent 0465529 was granted to Vical in 1998, and was subsequently opposed by seven companies under European patent procedures. This '529 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 seeking to overturn this initial ruling. The claims that were allowed in the newly granted '253 patent cover substantially the same scope as those claims in the '529 patent which were under appeal. For this reason, the Company withdrew from the '529 appeal upon grant of the '253 patent in September 2004. In June 2005, the '253 patent was opposed by eight parties. However, the Company may also use additional issued patents and patent applications that are pending in Europe to protect its core DNA delivery technology.

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. Four Trial for Invalidation, or TFI, requests were filed in the JPO by two companies in 2003. The Company filed responses to the TFI requests in a timely manner. The JPO combined two of the four TFI requests

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

into a single action, and in December 2004, ruled in the Company's favor on the combined TFI requests by accepting the corrected claims and finding the demand for the trials groundless. The Company is still awaiting further action by the JPO on the other two TFI requests.

A European patent issued in 2003 covering a range of applications of the Company's core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as the Company's clinical-stage Allovectin-7[®] treatment for melanoma, cationic lipid-formulated DNA vaccines such as the Company's investigational anthrax vaccine, and similar pharmaceutical products under development by others. This patent has been opposed by two companies. The Company responded to the oppositions in a timely manner, and is preparing to defend the patent at an upcoming oral hearing in early 2006 at the EPO.

A European patent issued to the Company in 2003 with broad claims related to 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. Three companies opposed this patent. The Company responded to the oppositions in a timely manner, and will continue to vigorously defend its position in upcoming oral hearings.

The Company prosecutes its intellectual property estate vigorously to obtain the broadest valid scope for its patents. Due to the uncertainty of the ultimate outcome of these matters, the impact on future results is not subject to reasonable estimates.

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 which, individually or in the aggregate, is deemed to be material to the financial condition or results of operations of the Company.

7. Stockholders' Equity

In December 2003, a shelf registration statement filed by the Company with the Securities and Exchange Commission, or SEC, was declared effective, which allows the Company to issue from time to time an aggregate of up to \$50.0 million of common or preferred stock, of which approximately \$8.8 million was remaining as of December 31, 2005. Specific terms of any offering under the shelf registration statements and the securities involved would be established at the time of sale. In addition, in January 2006, the Company filed a shelf registration statement with the SEC which, if and when it is declared effective, would allow the Company to issue from time to time an aggregate of up to \$70.0 million of common or preferred stock.

In October 2005, the Company raised approximately \$21.0 million in net proceeds from the sale of approximately 4.7 million shares of its common stock at \$4.80 per share in a registered direct offering to a select group of institutional investors. In March 2004, the Company raised approximately \$17.3 million in net proceeds from the sale of approximately 3.4 million shares of its common stock at \$5.50 per share in a registered direct offering to a select group of institutional investors. All of the common stock was offered by the Company pursuant to the shelf registration statement that was declared effective in December 2003.

Stock Plan and Directors' Stock Option Plan

The Company has a stock incentive plan, under which 5,700,000 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

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

the fair market value of the underlying common stock 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 also limits the number of options that may be granted to any plan participant in a single calendar year to 300,000 shares.

In 2004, the Company granted 90,500 RSUs to executive officers and other executives. These RSUs vest in equal quarterly installments over a two-year period and, once vested, allow the participants to acquire up to 90,500 shares of common stock at par value. In 2005, the Company granted 148,500 RSUs to executive officers and other executives. These RSUs vest 25% on the first anniversary date of the grant, with the remaining rights vesting quarterly over the remaining three years and, once vested, allow the participants to acquire up to 148,500 shares of common stock at par value. The participants are not entitled to vote, sell or transfer any unvested RSUs. Granted but unvested RSUs are forfeited at termination of employment.

In 2001, the Company granted options to purchase 60,000 shares of its common stock to members of its Scientific Advisory Board, or SAB, that was subsequently dissolved in 2003. In connection with the dissolution of the SAB, the Company amended the SAB members' option agreements to provide for continued four-year vesting commencing on the date of grant, notwithstanding the termination of the SAB members' service to the Company. The estimated fair value of the options continues to be remeasured at the end of each quarterly period during the vesting period and compensation expense is recognized based on the remeasured fair value.

Compensation expense related to the RSU and SAB grants for the years ended December 31, 2005, 2004, and 2003 was approximately \$430,000, \$312,000 and \$16,000, respectively. All of the options granted to the SAB members expired unexercised in December 2005.

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, 2005. It is not anticipated that there will be any future grants under the directors' stock option plan.

The following table summarizes stock option transactions for the Company's stock option plans for the years ended December 31, 2005, 2004 and 2003:

	Shares	Weighted Average Exercise Price
Outstanding December 31, 2002	2,910,347	\$ 13.55
Granted	929,508	\$ 3.44
Exercised	(1,250)	\$ 2.31
Forfeited	(504,912)	\$ 13.47
Outstanding December 31, 2003	3,333,693	\$ 10.74
Granted	887,020	\$ 5.84
Exercised	(30,780)	\$ 3.14
Forfeited	(339,197)	\$ 9.09
Outstanding December 31, 2004	3,850,736	\$ 9.82
Granted	520,340	\$ 4.70
Exercised	(51,269)	\$ 3.41
Forfeited	(529,333)	\$ 10.63
Outstanding December 31, 2005	<u>3,790,474</u>	\$ 9.09

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

The following table summarizes information about stock options outstanding under the Company's stock option plans at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 2.31 - \$ 4.55	762,071	7.5	\$ 3.29	453,373	\$ 3.19
\$ 4.58 - \$ 5.78	799,479	8.7	\$ 5.02	212,350	\$ 5.03
\$ 5.82 - \$ 9.40	896,420	7.1	\$ 7.51	622,625	\$ 7.93
\$ 9.60 - \$16.63	981,579	4.0	\$ 14.13	981,111	\$ 14.13
\$16.88 - \$39.25	350,925	3.9	\$ 20.88	350,925	\$ 20.88
\$ 2.31 - \$39.25	<u>3,790,474</u>	6.4	\$ 9.09	<u>2,620,384</u>	\$ 10.93

The number of shares and weighted average price of options exercisable at December 31, 2005, 2004 and 2003, were 2,620,384 shares at \$10.93, 2,330,648 shares at \$12.57 and 1,794,717 shares at \$14.53, respectively. At December 31, 2005, shares available for grant under the Company's stock option plans were 864,747.

8. Related Parties

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, was previously, but is no longer, a Director of Strategic Planning at the VRC, for which the Company has manufacturing sub-contracts. Revenue recognized under these contracts was \$1.1 million, \$8.4 million and \$2.9 million, for the years ended December 31, 2005, 2004 and 2003, respectively.

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 year ended December 31, 2003 was \$0.9 million. Revenue recognized in 2005 and 2004 was immaterial. The above related-party agreements were approved by a majority or more of the disinterested members of the Company's Board of Directors.

As of December 31, 2005, the Company had employment agreements with six of its executive officers and other executives that contained severance arrangements. Under these agreements, the Company is obligated to pay severance if the Company terminates an executive officer's or other executive's employment without "cause," or if an executive officer or other executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance would consist of continued payments 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. The maximum payments due under these employment agreements would have been \$1.4 million if each executive officer and other executive was terminated at December 31, 2005. The Company recorded severance expense of \$0.5 million in 2004 for two officers who left the Company during the year.

Three of the 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 each of 2005, 2004 and 2003, including payroll taxes paid by the Company on the officers' behalf. 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

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS—(Continued)

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. This loan was repaid in full in January 2006. The loans to officers were entered into before July 2002, the implementation date of the Sarbanes-Oxley Act of 2002.

The Company has entered into loan agreements with executives and other employees, including those discussed above. Certain of the agreements allow for the notes to be forgiven. The current portion, included in receivables and other, was \$0.1 and \$0.2 million at December 31, 2005 and 2004, respectively. The long-term portion included in other assets was \$0.2 million at December 31, 2004. There was no long-term portion outstanding as of December 31, 2005.

9. 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 (in thousands):

	2005	2004	2003
Computed "expected" tax benefit	\$(8,281)	\$(8,069)	\$ (8,313)
State income taxes, net of federal benefit	(1,421)	(1,385)	(2,161)
Tax effect of:			
Change in valuation allowance	8,179	7,109	12,865
Adjustment to prior year credits and deferred taxes	2,275	590	(1,405)
Effect of change to apportioned state rate	—	3,355	—
Research and development and other tax credits carryovers	(1,023)	(1,792)	(1,048)
Other	271	192	62
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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

Deferred Tax Assets	2005	2004
Net operating loss carryovers	\$ 56,411	\$ 45,418
Capital loss carryover	1,495	1,492
Research and development and other tax credits carryovers	15,770	17,023
Depreciation and amortization	4,685	6,648
Other	1,160	306
Accruals and reserves	374	777
Deferred revenue	—	52
Total gross deferred tax assets	79,895	71,716
Less valuation allowance	(79,895)	(71,716)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2005 and 2004, the Company had available federal net operating loss carryforwards of approximately \$152.3 million and \$130.1 million, respectively. In addition, the Company had research and development credit and orphan drug credit carryforwards of \$12.7 million and \$12.3 million as of December 31, 2005 and 2004, respectively, to reduce future federal income taxes, if any. These carryforwards expire from 2006 through 2025 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 \$79.3 million which expire

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NOTES TO FINANCIAL STATEMENTS—(Continued)

from 2006 to 2015. In addition, the Company has research and development credits and manufactures' investment credits of approximately \$4.7 million as of December 31, 2005 and 2004, to reduce future California income tax, if any.

The Company had deferred tax assets of approximately \$79.9 million and \$71.7 million as of December 31, 2005 and 2004, 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 the deferred tax asset will not be realized.

The tax benefit associated with the Company's stock incentive plan was \$5.1 million as of December 31, 2005 and 2004, 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-7[®], was granted orphan drug designation for the treatment of invasive and metastatic melanoma by the FDA's Office of Orphan Products Development. Orphan drug designation provides certain tax benefits for qualifying expenses. In 2005, another of the Company's product candidates, its bivalent vaccine for CMV, was granted orphan drug designation for the prevention of clinically significant CMV viremia, CMV disease and associated complications in at-risk hematopoietic cell transplant and solid organ transplant populations.

10. Employee Benefit Plans

The Company has a 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 each of 2005, 2004 and 2003.

11. 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 (in thousands, except per share amounts):

<u>2005:</u>	<u>March 31,</u>	<u>June 30,</u>	<u>Sept. 30,</u>	<u>Dec. 31,</u>
Total revenues	\$ 2,684	\$ 4,807	\$ 2,707	\$ 1,805
Research and development costs	4,473	4,756	4,252	4,291
Total operating expenses	10,500	10,032	9,115	8,007
Net loss	\$ (7,578)	\$ (4,982)	\$ (6,131)	\$ (5,666)
Basic and diluted net loss per share	\$ (0.32)	\$ (0.21)	\$ (0.26)	\$ (0.20)
Weighted average shares used in per share calculation	23,509	23,517	23,524	27,738
<u>2004:</u>	<u>March 31,</u>	<u>June 30,</u>	<u>Sept. 30,</u>	<u>Dec. 31,</u>
Total revenues	\$ 909	\$ 5,742	\$ 2,891	\$ 5,003
Research and development costs	6,172	4,681	4,200	4,544
Total operating expenses	10,122	11,189	8,626	9,751
Net loss	\$ (9,075)	\$ (5,317)	\$ (4,875)	\$ (4,466)
Basic and diluted net loss per share	\$ (0.45)	\$ (0.23)	\$ (0.21)	\$ (0.20)
Weighted average shares used in per share calculation	20,317	23,476	23,479	23,493

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report. Based on this 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 Annual Report.

Changes in Internal Controls

There has been no change in our internal control over financial reporting during the three months ended December 31, 2005, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* by the Committee of Sponsoring Organizations of the Treadway Commission, as of December 31, 2005, the end of the period covered by this Annual Report. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report shown below.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Vical Incorporated:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Vical Incorporated (the "Company") maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our

audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the years ended December 31, 2005 and 2004, of the Company and our report dated March 8, 2006 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 8, 2006

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

The information required by this item concerning our directors is incorporated by reference from the section under the caption, "Election of Directors," in our Proxy Statement for our 2006 Annual Meeting of Stockholders, or the Proxy Statement. The information required by this item concerning compliance with Section 16(a) of the Securities Act is incorporated by reference from the section under the caption, "Section 16(a) Beneficial Ownership Reporting Compliance," in our Proxy Statement. Additional required information concerning our executive officers is incorporated by reference from Part I, Item 1 of this report.

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the caption, "Director and Executive Officer Compensation," 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 section under the caption, "Security Ownership of Certain Beneficial Owners and Management," in our Proxy Statement.

The equity compensation plan information required by this item is incorporated by reference from the section under the caption, "Equity Compensation Plan Information," in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the section under the caption, "Certain Relationships and Related Transactions," contained in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the section under the caption, "Ratification of Selection of Independent Auditors," in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

The following independent auditors' reports and financial statements are filed as part of this report:

- Report of Independent Registered Public Accounting Firm—Deloitte & Touche LLP
- Report of Independent Registered Public Accounting Firm—KPMG LLP
- Balance Sheets as of December 31, 2005 and 2004
- Statements of Operations for each of the three years in the period ended December 31, 2005
- Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2005
- Statements of Cash Flows for each of the three years in the period ended December 31, 2005
- Notes to Financial Statements

(2) Financial Statement Schedules

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

(3) Exhibits

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

(b) Exhibits

Exhibit Number	Description of Document
3.1(i)(8)	Restated Certificate of Incorporation.
3.1(ii)(8)	Amended and Restated Bylaws of the Company.
4.1(8)	Specimen Common Stock Certificate.
10.1(3) ^a	Amended and Restated Stock Incentive Plan of Vical Incorporated.
10.2(4) ^a	1992 Directors' Stock Option Plan of Vical Incorporated.
10.3(14) ^a	Form of Indemnity Agreement between the Company and its directors and officers.
10.8(2)	Lease dated December 4, 1987, between the Company and Nexus/GADCo.-UTC, a California Joint Venture, as amended.
10.9(5) ^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(6)	Research, Option and License Agreement dated September 29, 1994, between the Company and Pasteur Mérieux Sérums & Vaccins (subsequently Sanofi Pasteur).

Exhibit Number	Description of Document
10.17(7)	Amendment dated April 27, 1994, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.19(18) ^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(9)	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).
10.22(10) ^b	License Agreement dated February 24, 2000, between the Company and Vascular Genetics Inc., subsequently Corautus Genetics Inc.
10.23(11) ^a	Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.25(12) ^a	Employment Agreement dated September 13, 2001, between the Company and David C. Kaslow.
10.26(13) ^b	Amendment No. 4 dated December 7, 2001, to Research, Option and License Agreement between the Company and Sanofi Pasteur (formerly Pasteur Mérieux Sérums & Vaccins).
10.27(13)	Lease dated January 30, 2002, between the Company and Kilroy Realty, L.P. a Delaware Limited Partnership.
10.28(13) ^a	Amendment dated February 5, 2002, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.30(14) ^b	Amendment No. 5 dated September 23, 2002, to Research, Option and License Agreement between the Company and Sanofi Pasteur (formerly Pasteur Mérieux Sérums & Vaccins).
10.31(14) ^a	Amendment dated March 10, 2003, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.32(15) ^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(16) ^b	Agreement dated May 6, 2003, between the Company and SAIC-Frederick, Inc.
10.34(17)	Amendment dated March 17, 2004, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.36(18) ^b	Amendment dated May 20, 2004, to License Agreement dated January 1, 1991, between the Company and the Wisconsin Alumni Research Foundation.
10.37(19)	Letter Agreement dated October 6, 2004 and related documents between the Company and General Electric Capital Corporation.
10.38 ^a (19)	Form of Delayed Issuance Stock Purchase Grant Notice, Delayed Issuance Stock Purchase Agreement and Delayed Issuance Stock Purchase Election Agreement under the Amended and Restated Stock Incentive Plan.
10.39 ^a (20)	Amendment dated October 4, 2001, to Employment Agreement dated September 13, 2001, between the Company and David C. Kaslow.
10.40 ^a (20)	Amendment dated April 15, 2005, to Employment Agreement dated September 13, 2001, between the Company and David C. Kaslow.
10.41 ^c (21)	License Agreement dated May 24, 2005, between the Company and AnGes MG, Inc.
10.42 ^a (22)	Vical Incorporated Non-Employee Director Compensation Policy.
10.43 ^a (23)	Separation Agreement dated April 13, 2004, by and between Vical Incorporated and Martha J. Demski.

Exhibit Number	Description of Document
10.44 ^a (23)	Separation Agreement dated June 29, 2004, by and between Vical Incorporated and Alan E. Dow.
10.45 ^a (23)	Employment offer letter effective October 11, 2004, by and between Vical Incorporated and Jill M. Church.
10.46 ^c (23)	Fifth Amendment dated September 8, 2005, to Research Collaboration and License Agreement dated May 31, 1991, by and between Vical Incorporated and Merck & Co., Inc.
23.1	Consent of Independent Registered Public Accounting Firm—Deloitte & Touche LLP.
23.2	Consent of Independent Registered Public Accounting Firm—KPMG LLP.
31.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Jill M. Church, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Church, Chief Financial Officer, 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 filed with the Company's Registration Statement on Form S-1 (No. 33-56830) filed on January 7, 1993.
- (3) 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.
- (4) 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.
- (5) 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).
- (6) Incorporated by reference to Exhibit A of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994.
- (7) 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).
- (8) 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.
- (9) 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.
- (10) 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.
- (11) 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.
- (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, 2001.
- (13) 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.
- (14) 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.
- (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 September 30, 2003.

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- (16) 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, 2003.
 - (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 March 31, 2004.
 - (18) 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, 2004.
 - (19) 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, 2004.
 - (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 March 31, 2005.
 - (21) 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, 2005.
 - (22) Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on September 23, 2005.
 - (23) Incorporated by reference to Exhibits 10.1 – 10.4 to the Company's Current Report on Form 8-K filed on October 12, 2005.
- ^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 SEC 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 SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in 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, No. 333-107581, and No. 333-116951 on Form S-8, and in Registration Statements No. 333-107986 and No. 333-131307 on Form S-3 of our reports dated March 8, 2006, relating to the financial statements of Vical Incorporated and management's report on the effectiveness of internal control over financial reporting, appearing in this Annual Report on Form 10-K of Vical Incorporated for the year ended December 31, 2005.

/s/ DELOITTE & TOUCHE LLP

San Diego, California
March 8, 2006

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, No. 333-107581, and No. 333-116951) on Forms S-8 and (No. 333-107986 and No. 333-131307) on Forms S-3 of Vical Incorporated of our report dated February 6, 2004, with respect to the statements of operations, stockholders' equity, and cash flows of Vical Incorporated for the year ended December 31, 2003, which report appears in the December 31, 2005 annual report on Form 10-K of Vical Incorporated.

/s/ KPMG LLP

San Diego, California
March 7, 2006

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) 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
 - d) 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 control over financial reporting.

Date: March 8, 2006

By:

/s/ VIJAY B. SAMANT

Vijay B. Samant
Chief Executive Officer

CERTIFICATION

I, Jill M. Church, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) 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
 - d) 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 control over financial reporting.

Date: March 8, 2006

By: _____ /s/ JILL M. CHURCH
Jill M. Church
Chief Financial Officer

**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 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, 2005, 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 8, 2006

/s/ VIJAY B. SAMANT

Vijay B. Samant
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.

**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), Jill M. Church, the Chief Financial Officer 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, 2005, 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 8, 2006

/s/ JILL M. CHURCH

Jill M. Church
Chief Financial 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.