### 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, 2004.

to

or

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

For the transition period from\_\_\_\_

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 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  $\square$  No  $\square$ 

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the last sale price of the registrant's common stock reported on the National Association of Securities Dealers Automated Quotation National Market System on June 30, 2004, was approximately \$135,404,894.

The number of shares of common stock outstanding as of March 1, 2005, was 23,511,399.

**Documents Incorporated by Reference:** 

Document

Part of Form 10-K

Proxy Statement for the Annual Meeting of Stockholders to be held May 19, 2005

Part III

# VICAL INCORPORATED FORM 10-K INDEX

<u>PART I.</u>		
ITEM 1.	Business	3
ITEM 2.	Properties	34
ITEM 3.	Legal Proceedings	34
ITEM 4.	Submission of Matters to a Vote of Security Holders	35
<u>PART II.</u>		
ITEM 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	36
ITEM 6.	Selected Financial Data	37
ITEM 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	38
ITEM 7A.	Quantitative and Qualitative Disclosures About Market Risk	44
ITEM 8.	Financial Statements and Supplementary Data	45
ITEM 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	69
ITEM 9A.	Controls and Procedures	69
ITEM 9B.	Other Information	69
PART III.		
ITEM 10.	Directors and Executive Officers of the Registrant	70
ITEM 11.	Executive Compensation	70
ITEM 12.	Security Ownership of Certain Beneficial Owners and Management	70
ITEM 13.	Certain Relationships and Related Transactions	70
ITEM 14.	Principal Accounting Fees and Services	70
<u>PART IV.</u>		
ITEM 15.	Exhibits and Financial Statement Schedules	71
Signatures		74

### 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, and Section 21E of the Securities Exchange Act of 1934, as amended, 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 the section of Item 1 entitled "Risk Factors" beginning on page 24 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.

# PART I

# ITEM 1. BUSINESS

#### Overview

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

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

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 established relationships through licensing our technologies to a number of commercial entities, including:

- Merck & Co., Inc., or Merck,
- Two divisions of the Sanofi-Aventis Group, or Sanofi-Aventis:
  - Sanofi Pasteur, and
  - · Centelion SAS, or Centelion, formerly Gencell SAS, 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 Ltd., or Aqua Health, an affiliate of Novartis Animal Health Inc., and
- Invitrogen Corporation, or Invitrogen.

We have also licensed complementary technologies from:

- The Wisconsin Alumni Research Foundation, or WARF,
- The University of Michigan,
- Genetronics Biomedical Corporation, or Genetronics,
- 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**

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 <u>www.vical.com</u> 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 are developing other formulation and delivery technologies, including the use of lipid molecules, synthetic polymers called poloxamers, and other approaches, to enhance DNA expression or increase the immune response in DNA vaccine applications. We own broad rights in the United States and in other key markets to certain non-viral polynucleotide delivery technologies through our series of patents. 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 our proprietary DNA vaccine and cancer products, 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." 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 conventional vaccines, and
- DNA vaccines use uniform manufacturing processes that may be simpler, more cost-efficient, and more generally applicable across a range of products than
  conventional vaccine production methods.

*Cancer Therapies.* In the cancer area, we have focused our resources on the development of Allovectin- $\mathcal{P}$  as a potential treatment for metastatic melanoma, an aggressive form of skin cancer, to best apply the expertise and relationships we have established through prior development and testing in this area. We also are developing gene-based, electroporation, or EP, enhanced delivery of interleukin-2, or IL-2, a potent immunotherapeutic agent, as a potential treatment for solid tumors, with an initial indication in 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 effectiveness. We also seek to develop additional applications for our technologies by testing new approaches to disease control or prevention. These efforts could lead to further independent product development or additional licensing opportunities. In addition, we continually evaluate compatible technologies or products that may be of potential interest for in-licensing or acquisition. We license intellectual property from companies holding complementary technologies 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**

In addition, we 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 contract manufacturing agreements with the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the NIH and the International AIDS Vaccine Initiative, or IAVI.

#### **Product Development**

We are focused on the development of biopharmaceutical product candidates based on our patented DNA delivery technologies. 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, cancer, and cardiovascular diseases. Our current independent development focus is on our cancer immunotherapeutics, Allovectin-7<sup>®</sup> and IL-2/EP, as well as a novel pDNA vaccine for cytomegalovirus, or CMV. The table below summarizes our independent, collaborative and out-licensed product development programs.

Product Area	Project Target and Indication(s)	Development Status <sup>1</sup>	Development Rights <sup>3</sup>	
Cancer				
Immunotherapeutic	High-dose Allovectin-7 <sup>®</sup> for metastatic melanoma	Phase 2	Vical	
>>	IL-2/EP for solid tumors	Preclinical	Vical	
Tumor-associated antigen therapeutic vaccines	Unspecified cancer <sup>2</sup>	Research	Sanofi Pasteur	
"	Unspecified cancer <sup>2</sup>	Research	Merck	
Infectious Disease				
Infectious disease vaccine	Plasmodium falciparum (malaria)	Phase 1/2	Vical	
"	Cytomegalovirus	Phase 1	Vical	
"	Bacillus anthracis (anthrax)	Phase 1	Vical	
"	Ebola virus	Phase 1	Vical/NIH	
>>	West Nile Virus	Preclinical	Vical/NIH	
"	SARS coronavirus	Phase 1	NIH	
"	HIV – preventive	Phase 1	Merck	
"	HIV – therapeutic	Phase 1	Merck	
"	Hepatitis B virus – preventive	Research	Merck	
"	Hepatitis B virus – therapeutic	Research	Merck	
"	Hepatitis C virus – preventive	Research	Merck.	
Cardiovascular				
Angiogenic growth factor	VEGF-2	Phase 2	Corautus	
"	FGF-1	Phase 2	Centelion	
Veterinary				
Preventive infectious disease vaccine(s)	Various undisclosed <sup>2</sup>	Research-Clinical	Merial	
"	Undisclosed fish disease <sup>2</sup>	Clinical	Aqua Health	
Protective cancer vaccine	Companion animal cancer <sup>2</sup>	Clinical	Merial	

<sup>1</sup> "Research" indicates exploration and/or evaluation of a potential product candidate in a nonclinical setting. "Preclinical" indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is undergoing toxicology testing in preparation for filing an Investigational New Drug, or IND, application. "Phase 1" clinical trials mark the first time a new drug or treatment is administered to humans and are normally conducted to determine the safety profile of a new drug. "Phase 2" clinical trials are conducted to determine preliminary effectiveness, or efficacy, optimal dosage, and to confirm the safety profile of a new drug. At times, a single trial may incorporate elements from different phases of development. An example might be a trial designed to determine both safety and initial efficacy. Such a trial may be referred to as a "Phase 1/2" clinical trial. For veterinary products, "Clinical" indicates testing in the target species.

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

<sup>3</sup> See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Research, Development and Manufacturing Programs" for costs associated with our independent product development programs.



### **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. Chemotherapy can sometimes effectively treat cancer that has spread throughout the body, however, a number of non-cancerous cells, such as bone marrow cells, are also highly susceptible to chemotherapy. As a result, chemotherapy often has fairly significant side effects. Finally, it is common to see cancer return after apparently successful treatment by each of these means.

Immunotherapy, using the patient's own immune system, may have advantages over surgery, irradiation, and chemotherapy in the treatment of cancer. Many cancers appear to have developed the ability to "hide" from the immune system. A treatment that can augment the immune response against tumor cells by making the cancer more "visible" to the immune system would likely represent a significant improvement in cancer therapy. Immune-enhancing proteins such as 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. 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.

The ease of manufacture, outpatient treatment with minimal discomfort, and the excellent tolerability profile suggest that cancer therapies using non-viral DNA delivery 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. Our Allovectin-7<sup>®</sup> and IL-2/EP non-viral cancer immunotherapeutics under development are reviewed below.

#### Allovectin-7®

Allovectin-7<sup>®</sup> is a plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and ß2 microglobulin, which together form a Class I Major Histocompatibility Complex, or MHC-I antigen. Injection of Allovectin-7<sup>®</sup> 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 ß2 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 a prior Phase 3 trial, we compared treatment of patients with metastatic melanoma using the low-dose, 10 mcg, Allovectin-7 immunotherapeutic in combination with the chemotherapy agent dacarbazine against treatment with dacarbazine alone. In connection with this trial, we developed an Endpoint Assessment and Adjudication Charter, or EAAC, which allowed us to determine shortly after completion of the trial that the results would fail to meet the endpoints required to pursue marketing approval. The process used to develop the EAAC is the subject of an article published in February 2005 in the *Drug Information Journal*, Vol. 39, pp 51-59.

In 2001, we began a high-dose, 2 mg, Phase 2 trial evaluating the Allovectin-7<sup>®</sup> 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-?? 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.

The 127 patients receiving the full 2 mg dose of Allovectin-7<sup>®</sup> were evaluated for efficacy, and safety data were evaluated for these 127 patients plus 6 additional patients receiving lower doses in a dose-escalation stage.

Highlights of the data, based on company-audited investigator reports, included:

- A total of 15 responders, or 11.8%, including 4 patients with complete responses and 11 with partial responses,
- A Kaplan-Meier estimated median duration of response of 12.7 months,
- A Kaplan-Meier estimated median survival of 21.3 months, and
- An excellent safety profile with no reported Grade 3 or Grade 4 adverse events associated with Allovectin-7<sup>®</sup>.

Based on detailed guidance received from the U.S. Food and Drug Administration, or FDA, in End-of-Phase 2 meetings, we have successfully completed a Special Protocol Assessment, or SPA, with the FDA for a Phase 3 trial of high-dose, 2 mg, Allovectin- $7^{\oplus}$  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.

The Phase 3, open-label, multi-center trial would require enrollment of approximately 375 patients with recurrent metastatic melanoma. Patients may have been treated with surgery, adjuvant therapy, and/or biotherapy, but cannot have been treated with chemotherapy. The patients would be randomized on a 2:1 basis: approximately 250 patients will be treated with Allovectin-7<sup>®</sup> and approximately 125 will be treated with their physician's choice of either of two chemotherapy agents, dacarbazine or temozolomide. The primary endpoint would be a comparison of objective response rates at 24 weeks or more after randomization. The study would also evaluate safety and tolerability.

Completion of the SPA allows us to advance in our discussions with potential partners and evaluate which, if any, is best positioned to assist with the further development and commercialization of Allovectin-7<sup>®</sup>.

# IL-2/EP

In October 2004, we exercised an option to establish an exclusive worldwide licensing and supply agreement with Genetronics for the use of its electroporation technology for specified applications. Electroporation involves 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. Our initial application is for enhanced delivery of the plasmid encoding human IL-2 directly into solid tumor lesions. Local administration of the plasmid encoding IL-2 directly into a tumor lesion, when administered with local electroporation, may reduce toxicity and result in local, sustained expression of IL-2 sufficient to provide therapeutic benefit. In 2005, we expect to begin Phase 1 safety testing of intralesional administration of IL-2 pDNA followed by local electroporation in certain patients with metastatic melanoma.

Human recombinant IL-2 has been approved by the FDA for treatment of metastatic melanoma and renal cell carcinoma and can elicit durable clinical responses. However, severe toxicity associated with systemic administration limits its use.

#### About Metastatic Melanoma

The American Cancer Society estimates that approximately 59,580 new diagnoses of, and 7,770 deaths from, melanoma will occur in 2005 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-*a*, 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."

#### DNA Vaccines for Infectious Diseases

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

Vaccines are generally recognized as the most cost-effective approach for infectious disease healthcare. However, the technical limitations of conventional vaccine approaches have constrained the development of effective vaccines for many diseases. Development of vaccines based on conventional methods requires significant infrastructure in research and manufacturing. In addition, the safety risks associated with conventional vaccines may offset the potential benefits. We believe our potential vaccine products should be simpler to manufacture than vaccines made using chemical conjugation of polysaccharides and protein carriers or protein purification and refolding techniques involving mammalian, avian or insect cell, or egg-based, culture procedures and live viruses. In addition, our DNA delivery 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. 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, and 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 highly immunogenic proteins associated with protective antibody and cellular immune responses,
- Our DNA vaccine technologies that have the ability to induce potent cellular immune responses and trigger production of antibodies without the safety concerns that conventional attenuated vaccines have posed for immunocompromised patients, and
- A focused clinical development plan that is designed to allow us to quickly establish proof of concept in transplant patients.

In pursuing a CMV immunotherapeutic vaccine product, we have designed two candidate formulations: a two-component, or bivalent, and a three-component, or trivalent, version of the product, 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. The bivalent vaccine candidate uses plasmid DNA encoding two highly immunogenic proteins of the CMV virus, phosphoprotein 65, or pp65, and glycoprotein B, or gB. The trivalent vaccine candidate also includes a third plasmid encoding the highly immunogenic CMV immediate early 1, or IE1, gene product. In laboratory animal testing, both formulated plasmid DNA vaccine candidates demonstrated potent and specific immune responses against the encoded CMV immunogenic jot both vaccine candidates in laboratory animals, we are now evaluating the safety and immunogenicity of both vaccine formulation candidates in humans. Results from these initial clinical trials will allow us to decide which candidate configuration to advance to a Phase 2 proof-of-concept study.

We announced the initiation of a Phase 1 clinical trial with our bivalent CMV immunotherapeutic vaccine in March 2004. We reported initial safety data from the trial at the Interscience Conference on Antimicrobial Agents and Chemotherapy, or ICAAC, in November 2004. These data showed the bivalent vaccine to be safe and well-tolerated. We announced the initiation of a Phase 1 clinical trial with our trivalent CMV immunotherapeutic vaccine in September 2004.

Subjects in both trials were monitored primarily for safety, with secondary endpoints of immunogenicity. Enrollment in both trials is complete. We expect safety and immunogenicity data from both trials to be presented in April 2005 at the 10th International Cytomegalovirus/Betaherpesvirus Workshop, and to support the selection of a single vaccine formulation to advance into Phase 2 testing in transplant patients.

In addition, we have been awarded approximately \$1.0 million for research and development related to our CMV vaccine program under two grants from the National Institute of Allergy and Infectious Diseases, or NIAID. In 2004, we recognized approximately \$0.7 million in revenues from these grants. In March 2005, we were awarded an additional three-year, \$3.1 million grant by the NIAID. The grant will partially fund the ongoing development of our CMV immunotherapeutic vaccine.

#### About CMV

CMV is a herpes virus, part of the family of viruses that cause genital herpes, cold sores or fever blisters, chicken pox and infectious mononucleosis. Although the body rarely rids itself of CMV, a healthy immune system usually is able to keep the virus in check. As a result, CMV disease rarely occurs in healthy individuals, and reactivation typically occurs only when the immune system is compromised by other disease or drugs. People at greatest risk include bone marrow and solid organ transplant patients who take immunosuppressive drugs, AIDS patients and other immunocompromised individuals, and fetuses and newborns of mothers who become infected during pregnancy.

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

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

#### Anthrax Vaccine

Also 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. Where the others target the single anthrax protein called Protective Antigen, or PA, our bivalent vaccine also targets the anthrax protein called Lethal Factor, or LF.

Preclinical data from the anthrax vaccine program, published in September 2004 in the *Proceedings of the National Academy of Sciences*, Vol. 101, pp 13601-13606, 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 a \$1.0 million, one-year Small Business Technology Transfer Research, or STTR, grant from the NIAID, as announced in 2002. In 2003, we were awarded a three-year, Phase II Small Business Innovation Research, or SBIR, grant from the NIAID of \$5.7 million, which was subsequently increased to \$5.8 million, for additional non-clinical development of our anthrax vaccine candidate. We recognized revenues under these grants of \$2.0 million, \$1.9 million and \$0.5 million in 2004, 2003 and 2002, respectively. In July 2004, we began a Phase 1 clinical trial of our anthrax vaccine candidate at two NIAID-funded Vaccine and Treatment Evaluation Units.

In November 2004, VaxGen Inc., or VaxGen, a U.S. vaccine developer, was awarded a three-year procurement contract under the Project BioShield Act of 2004 to supply 75 million doses of a second-generation anthrax vaccine based on recombinant protein. In January 2005, the FDA granted an Emergency Use

Authorization for the currently approved first-generation anthrax vaccine to be used as protection against inhalation anthrax for certain individuals at heightened risk of exposure due to attack with anthrax.

Based on the award of the procurement contract 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 forseeable future. Therefore, except for the ongoing non-clinical development supported by the SBIR grant, 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 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, 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. We recognized revenues under these agreements of \$8.4 million, \$2.9 million and \$1.0 million in 2004, 2003 and 2002, respectively.

Using clinical supplies provided under these agreements, the VRC began testing in healthy human subjects of an investigational DNA vaccine against HIV in 2002, and of an investigational DNA vaccine against Ebola in 2003. Enrollment in these trials has been completed. Using clinical supplies provided under these agreements, the VRC began testing in healthy human subjects of an investigational DNA vaccine against SARS in December 2004. We also have shipped initial clinical supplies of the West Nile Virus vaccine, which we expect will advance into human testing in early 2005.

In 2003, we secured a license from the NIH for technology used in its Ebola vaccine. Also in 2003, we obtained an option to secure exclusive commercialization rights for a West Nile Virus vaccine being developed in collaboration with the VRC under a Cooperative Research and Development Agreement, or CRADA. In January 2004, we secured a license from the CDC for technology used in a similar DNA vaccine, which was shown in independent tests at the CDC to protect horses from West Nile Virus after a single injection. In February 2005, we signed a letter of intent to enter into a CRADA with the VRC for the development of a therapeutic DNA vaccine against HIV. R. Gordon Douglas, M.D., Chairman of our Board of Directors, is the Director of Strategic Planning at the VRC.

#### International AIDS Vaccine Initiative

In 2002, we entered into an automatically renewing one-year agreement with the IAVI, a not-for-profit entity, to provide clinical trial supplies. 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 and \$0.2 million in 2003 and 2002, respectively. Revenue recognized in 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.

#### Other Infectious Diseases

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 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 in human trials. See "—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. 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 and Merck entered into an agreement, which was subsequently amended, providing Merck with certain exclusive rights to develop and commercialize vaccines using our core DNA delivery technology for certain human diseases. Under the agreement, as amended, Merck licensed preventive and therapeutic human infectious disease vaccines using our core DNA delivery technology. In 2003, under the most recent amendment to the agreement, Merck obtained 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 technology for HIV, hepatitis C virus, and hepatitis B virus.

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 January 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 Phase 1 trials are evaluated.

Merck is obligated to pay fees if certain research milestones are achieved, and royalties on net sales if any covered products are developed and commercialized. For some indications, we may have an opportunity to co-promote product sales. In addition, exercise of the option for each cancer target under the 2003 amendment would result in a license fee payment to us, and further development may lead to milestone and royalty payments to us. No revenues were recognized under the Merck agreement in 2004, 2003 or 2002. Merck has the right to terminate this agreement without cause upon 90 days prior written notice.

Sanofi-Aventis. In December 2004, Sanofi-Synthélabo merged with Aventis to form the Sanofi-Aventis Group, and Aventis Pasteur was subsequently renamed Sanofi Pasteur. In October 2004, Gencell, a wholly-owned subsidiary of Aventis Pharma, was renamed Centelion.

In 2001 and 2002, we merged and amended previous agreements into a new, restructured agreement granting Sanofi Pasteur rights to use our core DNA delivery technology for specific oncology applications. In exchange, Sanofi Pasteur gave up previously licensed rights to develop and commercialize certain infectious disease DNA vaccines.

In 1999, Centelion began testing the DNA delivery of a gene encoding FGF-1, an angiogenic growth factor, in patients with peripheral vascular disease, a severe condition caused by blockage of arteries feeding the foot and lower leg. 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 is currently conducting double-blind, placebo-controlled Phase 2 trials of its FGF-1 plasmid-based therapeutic in the United States and Europe.

The restructured agreement with Sanofi Pasteur and the agreement with Centelion specify that we will receive milestone payments plus royalties if products advance through commercialization. We recognized revenues of \$1.2 million in 2004. under the Sanofi-Aventis agreements. Revenue recognized in 2003 and 2002 was immaterial. Sanofi Pasteur has the right to terminate our restructured agreement without cause upon six months prior written notice. Centelion has the right to terminate our agreement without cause upon 60 days prior written notice.

*Merial.* We entered into a corporate collaboration in 1995 relating to DNA vaccines in the animal health area with Merial, a joint venture between Sanofi-Aventis and Merck. Merial has options to take exclusive licenses to certain of our core DNA delivery technologies to develop and commercialize DNA vaccines to prevent infectious diseases in livestock and companion animals. In 2004, we granted an exclusive license to Merial for use of our core DNA delivery technology in a vaccine to protect certain companion animals against a particular type of cancer. Under the new 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.

We recognized revenues of \$0.3 million and \$1.5 million in 2004 and 2002, respectively, under the Merial agreements. No revenue was recognized in 2003. Merial has the right to terminate these agreements without cause upon 30 days prior written notice.

Human Genome Sciences, Inc. In 2000, we signed an agreement with Human Genome Sciences, Inc. granting reciprocal options to royalty-bearing licenses for up to three gene-based products each. These options expired unexercised in September 2004.

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 September 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. 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 the 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, an affiliate of the Swiss-based company Novartis Animal Health Inc., for use in Canada of our core DNA delivery technology in a vaccine against a disease that affects both wild and farm-raised fish. This vaccine has been sold on a pre-approval basis in support of extensive field trials which have been completed at Canadian fish farms, and we have recognized *de minimus* license fees and royalty revenues on these sales. Data from the trials have been submitted for regulatory review by the Canadian Food Inspection Agency. If it is approved, we believe the Aqua Health vaccine would be the world's first marketed DNA vaccine.

*Invitrogen.* In 1991, we licensed the use of certain proprietary lipids for research products applications to Life Technologies, Inc., or Life Technologies, which was subsequently acquired by Invitrogen in 2000. Invitrogen manufactures and markets these lipid compounds, and pays royalties to us on the sales of the lipids. We recognized \$1.1 million, \$0.9 million and \$1.0 million in 2004, 2003 and 2002, respectively, in royalty revenues under this agreement.

#### Corporate Collaborators—In-licensing

*Genetronics*. In 2003, we entered into an agreement with Genetronics giving us options to worldwide exclusive licenses to use Genetronics' 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 expect to begin 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 Genetronics in 2004 and 2003.

*CytRx*. In 2001, we entered into an exclusive agreement with CytRx which grants to us the rights to use or sublicense CytRx's poloxamer technology to enhance viral or non-viral delivery of polynucleotides in all preventive and therapeutic human and animal health applications, 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.

In 2003, the WARF filed a lawsuit 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 our license agreement. We counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement. In 2004, we settled this matter for \$1.5 million. Pursuant to the settlement and an amendment to the license agreement with the WARF, the lawsuit was dismissed.

University of Michigan. We have licensed from the University of Michigan rights to various U.S. and international patents related to injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin- $7^{\text{®}}$ . Included in this license is a European patent granted and opposed in 2002. We filed a rebuttal response to the opposition in a timely manner. We are currently negotiating with the University of Michigan the return of certain non-U.S. rights under the agreement.

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. A prior malaria vaccine agreement with the ONR had expired. Revenue recognized under this agreement was \$0.2 million and \$0.3 million in 2003 and 2002, respectively. No revenue was recognized in 2004. We do not plan to pursue independent development of malaria vaccines.

### Payments to Others

Under the Merck, Sanofi Pasteur, Centelion, Merial, Corautus and Aqua Health agreements, we would be 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 Genetronics agreements would 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 results 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 other key markets. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We are the assignee of 38 issued U.S. and granted foreign patents having remaining lives ranging from approximately 5 to 15 years, which are listed below:

Patent No.	Description
U.S. Patents	
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	Cytofectin 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 cytofectins
5,994,317	Quaternary cytofectins
5,910,488	Plasmids suitable for gene therapy
5,891,718	Tetracycline inducible/repressible systems
5,861,397	Piperazine based cytofectins
5,707,812	Purification of plasmid DNA during column chromatography
5,703,055	Generation of antibodies through lipid mediated DNA delivery
5,693,622	Expression of exogenous polynucleotide sequences cardiac muscle of a mammal
5,641,665	Plasmids suitable for IL-2 expression
5,589,466	Induction of a protective immune response in a mammal by injecting a DNA sequence
5,580,859	Delivery of exogenous DNA sequences in a mammal
5,576,196	Process for reducing RNA concentration in a mixture of biological material using diatomaceous earth
5,561,064	Production of pharmaceutical-grade plasmid DNA
5,459,127	Cationic lipids for intracellular delivery of biologically active molecules
5,264,618	Cationic lipids for intracellular delivery of biologically active molecules
, ,	
Foreign Patents EP1183231	Cytofectin dimers and methods of use thereof
	Adjuvant compositions for enhancing immune responses to polynucleotide-based vaccines
EP1165140 EP1026253	Expression of exogenous polynucleotide sequences in a vertebrate
	Piperazine based cytofectins
EP0929536	
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
JP 3626127	Plasmids suitable for gene therapy
JP2538474	Cationic lipids for intracellular delivery of biologically active molecules

We are also co-assignee, together with Pasteur Mérieux Sérums et Vaccins, subsequently 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 was maintained after an opposition proceeding and through two Trials for Invalidation, or TFIs, but is still subject to requests for two additional TFIs.

We are also prosecuting 65 pending patent applications in the United States 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. Five 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.

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 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 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<sup>®</sup> 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 injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7<sup>®</sup>.

During 2004 and early 2005, we were issued five U.S. patents and granted six European patents and one Japanese patent related to our core DNA delivery technology, enhancements of that technology, and applications of that technology:

- U.S. Patent 6,670,332, covering a class of cationic lipids useful in gene delivery applications,
- U.S. Patent 6,673,776, covering novel methods of using DNA to deliver biologically active proteins,

- U.S. Patent 6,696,424, covering a class of cationic lipids useful in gene delivery applications,
- U.S. Patent 6,710,035, covering administration of plasmid DNA encoding pathogen-specific antigens to generate immune responses, with or without adjuvants,
- U.S. Patent 6,706,694, covering delivery to the heart of DNA encoding biologically active proteins,
- European Patent 0795015 specifically claiming the composition, manufacture and application of gene-based cancer treatments delivering the cytokine IL-2,
- European Patent 1165140 claiming compositions and methods for gene-based vaccination using immunogens or immunogen-encoding polynucleotides plus the Vaxfectin<sup>™</sup> cationic lipid/co-lipid formulation,
- European Patent 1026253, covering a significant portion of our core technology,
- European Patent 1183231, covering a class of cationic lipids useful in gene delivery applications,
- European Patent 0920497, covering methods of plasmid DNA purification,
- · European Patent 0929536, covering a different class of cationic lipids useful in gene delivery applications, and
- Japanese Patent 3626127, covering the composition, manufacture and application of the Allovectin-7<sup>®</sup> immunotherapeutic.

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 corporate collaborators. We intend to develop and commercialize products to well-defined specialty markets, such as infectious diseases, oncology and other life-threatening diseases. Where appropriate, we intend to rely on strategic marketing and distribution alliances.

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

We produce and supply our own plasmids for all of our research needs and clinical trials and intend to produce sufficient supplies for all foreseeable clinical investigations. In 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, Chiron Corporation, 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, Medarex Inc. and Bristol-Myers Squibb Company, Antigenics, Inc., CancerVax Corporation and Serono S.A., Onyx Pharmaceceuticals, Inc. and Bayer AG, and others are developing treatments for melanoma. MedImmune, Roche, GlaxoSmithKline, ViroPharma Inc. and others have products or development programs for CMV treatment and prevention. 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.

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.

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.

#### **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. Biological products, in addition to being subject to provisions of that 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 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.

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, efficacy, and potency that are necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients.

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, efficacy and potency 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 determine the safety profile, the pattern of drug distribution and metabolism and early evidence of effectiveness. Phase 2 clinical trials are conducted with a larger group of patients afflicted with a target disease to determine preliminary efficacy, optimal dosages and expanded evidence of safety. Phase 3 clinical trials involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease to provide enough data for the statistical proof of safety, efficacy, and potency required by the FDA and other regulatory authorities. For life-threatening diseases, initial human testing generally is done in patients afflicted with 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, 2004, we had 169 full-time employees, including 25 with doctorate degrees. Of these full-time employees, 139 are engaged in, or directly support, research and development and manufacturing activities, and 30 are in general and administrative positions. A significant number of our management and other employees have prior experience with pharmaceutical and biotechnology companies. None of our employees is covered by collective bargaining agreements, and our management considers relations with our employees to be good.

#### **Executive Officers and Other Executives**

Our executive officers and other executives are as follows:

Name	Age <sup>1</sup>	Position
Vijay B. Samant <sup>2</sup>	52	President, Chief Executive Officer and Director
David C. Kaslow, M.D. <sup>2</sup>	46	Chief Scientific Officer
Jill M. Church <sup>2</sup>	43	Vice President, Chief Financial Officer and Secretary
Alain P. Rolland, Pharm.D., Ph.D.	45	Senior Vice President, Product Development
Kevin R. Bracken	56	Vice President, Manufacturing
Robin M. Jackman, Ph.D.	35	Vice President, Business Development

<sup>1</sup> As of December 31, 2004.

<sup>2</sup> 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 15 years of vaccine research experience. Dr. Kaslow joined Merck in February 1999 as Senior Director, Vaccine Research, and was employed by Merck, most recently as Head of the Department of Vaccine Research and Technology, until he joined Vical. From 1986 to 1999, he held various senior research positions at the NIH, including Head of the Recombinant Protein Development Unit and the Malaria Vaccine Development Unit at the Laboratory of Parasitic Diseases. Dr. Kaslow has been awarded numerous professional honors, including the U.S. Public Health Service Outstanding Service Medal. He has published more than 120 scientific papers, and authored more than 20 review articles and book chapters. He holds or co-holds 13 patents. Dr. Kaslow received his M.D. from the School of Medicine at the University of California, San Francisco, in 1983 and his bachelor's degree from the University of California, Davis, in 1979.

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 CIRD, 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.

In January 2005, Thomas G. Evans, M.D., resigned from his position as Vice President, Infectious Diseases Clinical Research.

#### **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 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 are high-dose Allovectin-7<sup>®</sup> for the treatment of metastatic melanoma, which has completed Phase 2 clinical testing, and our vaccines for CMV and anthrax, which are currently in Phase 1 clinical testing. We may not be able to identify and reach agreement with a potential partner for the further development and commercialization of Allovectin-7<sup>®</sup>. Failure to reach agreement with a partner may delay or prevent continued development, significantly increase our development and commercialization expenses, and slow market penetration. We may not, alone or with a potential partner, conduct a Phase 3 trial of Allovectin-7<sup>®</sup>. Endpoints in such a trial may not be achieved, and if achieved, may not establish sufficient safety and efficacy to support product approval. 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 antibody responses in humans. Our anthrax vaccine may not elicit sufficient antibody responses in humans. The additional outside funding needed to support further clinical development of our anthrax vaccine is unlikely under current federal government biodefense program priorities. Additionally, we are in preclinical stages of research and development with product candidates including a solid tumor application of our in-licensed electroporation technology and others.

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.

# 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 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 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 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 FARs 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. We may also be unsuccessful in entering into additional agreements with government agencies.

There are only a limited number of other contractors that could perform under the bulk DNA vaccines manufacturing service contract in the unlikely event that we were unable to perform. The price they might charge could be more than what we would charge based on their capacity, utilization, size of order and other factors. Accordingly, we are unable to estimate a range of potential cost that we could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that we were unable to meet.

We apply for and have received funding from government agencies under STTR and SBIR grants. Eligibility of public companies to receive such grants is under review by the Small Business Administration and may be changed in the future, and there can be no assurance that additional funding from this source will 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 \$23.7 million, \$24.5 million and \$27.9 million for 2004, 2003 and 2002, respectively. As of December 31, 2004, we had incurred cumulative net losses totaling approximately \$138.5 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. For 2005, we have forecast a net loss of between \$23 million and \$26 million. 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. For example, we currently have on file an effective shelf registration statement with the SEC which allows us to issue from time to time an aggregate of up to \$50 million of common or preferred stock, less amounts raised to date. In March 2004, we raised approximately \$18.6 million in gross proceeds pursuant to this registration statement from the sale of approximately 3.4 million shares of our common stock at \$5.50 per share in a registered direct offering to a select group of institutional investors. However, we may not be able to raise additional funds on favorable terms, or at all. In 2004, we entered into an agreement with a leasing company to provide up to \$8.5 million of lease financing through October 31, 2005. The agreement requires a non-interest-bearing cash security deposit in the amount of 60% of the amount of each drawdown. This financing involves restrictive financial covenants, including a requirement that we maintain unrestricted cash and marketable securities of at least \$25 million or obtain a letter of credit from another lender in the amount of outstanding borrowings.

If we are unable to obtain additional funds, we may have to reduce our capital expenditures, scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need will depend on many factors, including:

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

We anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2006.

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

Our product candidates under development and those of our collaborators and licensees are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulations are evolving and uncertain. The regulatory process can take many years and require us to expend substantial resources. For example:

- The FDA has not established guidelines concerning the scope of clinical trials required for gene-based therapeutic and vaccine products,
- The FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of genebased products, and
- Current regulations and guidances are subject to substantial review by various governmental agencies.

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

- Impose costly procedures on our activities,
- · Diminish any competitive advantages that we attain, or
- Negatively affect our results of operations and cash flows.

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. 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 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<sup>®</sup> 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<sup>®</sup> was a significant factor in the patient's death. As another example, we may administer our investigational CMV vaccine to patients who are at risk of CMV reactivation. 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 38 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 TFIs; a recently granted patent in Europe related to our core DNA delivery technology is in the open opposition period; 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 65 pending patent applications in the United States 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. Five 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, three 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; 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 United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary 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 will be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. Moreover, if a competitor were to file a patent application claiming technology also invented by us, we would have to participate in an interference proceeding before the 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 FDA approval faster than we do, or in developing products that are more effective than ours. While we will seek to expand our technological capabilities to remain competitive, research and development by others will seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us. Additionally, even if our product development efforts are successful, and even if the requisite regulatory approvals are obtained, our products may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our products do not achieve market acceptance, we may lose our investment in that product, which could have a material adverse impact on our operations.

See "-Competition," for a discussion of additional risks related to technology-specific and product-specific competitors.

#### 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. We have not had any problem attracting and retaining key personnel and qualified staff. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel.

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

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's cGMP regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we 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 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. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

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

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

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

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

- Government health administration authorities,
- · Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor,

- Private health coverage insurers,
- Managed care organizations, and
- Other organizations.

If we fail to obtain appropriate reimbursement, we could be prevented from successfully commercializing our potential products. There are efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The 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, however the specific nature and degree of impact are not yet known.

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

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

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and minor amounts of low-level radioactive compounds. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials 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 radioactive contamination. Any liability could exceed the limits or fall outside the coverage of our insurance. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

### We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. These risks are inherent in the development and manufacture of chemical and pharmaceutical products. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. To date, no product liability claims have been filed against us. However, if we are sued for any injury caused by our 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. During the three years ended December 31, 2004, 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,
- · Geopolitical developments, natural or man-made disease threats, or other events beyond our control,
- U.S. and foreign governmental regulatory actions,
- · Changes or announcements in reimbursement policies,
- Concern as to the safety of our potential products,
- Period-to-period fluctuations in our operating results,
- Market conditions for life science stocks in general,
- Changes in the collective short interest in our stock,
- Changes in estimates of our performance by securities analysts, and
- Our cash balances, need for additional capital, and access to capital.

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

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

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

Pursuant to the terms of our stockholder rights plan, we have distributed a dividend of one preferred stock purchase right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us prior to the plan's expiration on April 5, 2005, on terms not approved by our board of directors. Our certificate of incorporation and bylaws include other anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written

consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to \$50 million of common stock or preferred stock, of which to date we have issued approximately \$18.6 million of common stock, which yielded approximately \$17.3 million in net proceeds. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

#### ITEM 2. PROPERTIES

We lease approximately 93,600 square feet of manufacturing, research laboratory and office space in northern San Diego, California, at three sites and with three leases. Our newest leased facility has approximately 68,400 square feet of manufacturing, research laboratory and office space. This site allowed us to consolidate most of our operations and offices while increasing our manufacturing capacity for both clinical and commercial production. We intend to relocate our remaining manufacturing operations from our Eastgate Mall facility to our Pacific Center Court facility in 2005.

Location	Use	Owned/Leased	Lease Termination Date	Size (Square Feet)
Pacific Center Court	Manufacturing, research, office	Leased	August 2017	68,400
Eastgate Mall	Manufacturing	Leased	November 2005	14,727
Towne Centre Drive	Research	Leased	November 2009	10,494

### IT EM 3. LEGAL PROCEEDINGS

In 2003, the WARF filed a lawsuit 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 our license agreement. We counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement. In 2004, we settled this matter for \$1.5 million, of which we had paid \$0.5 million as of December 31, 2004, with equal remaining payments due in 2005 and 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 Vical in 1998, and was subsequently opposed by seven companies under European patent procedures. This '529 patent was revoked on formal grounds in 2001 under an initial ruling by the Opposition Division of the EPO. In 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 is opposed,

we may lose part or all of our proprietary protection on our product candidates in Europe. However, we may also use additional issued patents and patent applications that are pending in Europe to protect our core DNA delivery technology.

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

In addition, our core DNA delivery technology is covered by a Japanese patent that was published in 2002 and thereafter revoked by the examining panel at the JPO, on formal and substantive grounds. We filed a rebuttal response to the revocation. Based on our arguments and supporting evidence in that response, the JPO decided to reinstate the patent in 2003. Four TFI requests against this patent 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 in the combined TFI 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 our core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as our clinical-stage Allovectin-7<sup>®</sup> treatment for melanoma, cationic lipid-formulated DNA vaccines such as our investigational anthrax vaccine, and similar pharmaceutical products under development by others. This patent was opposed by two companies. We responded to the oppositions in a timely manner, and are awaiting further action by 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 are awaiting further action by the EPO.

We have licensed from the University of Michigan rights to various U.S. and international patents related to injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7<sup>®</sup>. Included in this license is a European patent granted and opposed in 2002. We filed a rebuttal response to the opposition in a timely manner. We are currently negotiating with the University of Michigan the return of certain non-U.S. rights under the agreement.

We prosecute our intellectual property estate vigorously to obtain the broadest valid scope for our 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, 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, is deemed to be material to our financial condition.

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

Not applicable.

# PART II

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

2004	High	Low
First Quarter	\$8.14	\$4.69
Second Quarter	6.39	4.55
Third Quarter	5.99	4.01
Fourth Quarter	5.28	4.11
2003		
First Quarter	\$3.69	\$2.12
		2.45
Second Quarter	5.12	
Third Quarter	7.80	4.07
Fourth Quarter	6.39	4.45

As of March 1, 2005, there were approximately 416 stockholders of record of our common stock with 23,511,399 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 2004.

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,				
	2004	2003	2002	2001	2000	
		(in thousand	s, except per sh	are amounts)		
Statement of Operations Data:		,		,		
Revenues:						
Contracts and grants	\$ 11,168	\$ 6,012	\$ 3,008	\$ 3,794	\$ 2,593	
Licenses and royalties	3,377	2,066	3,999	7,572	5,027	
Total revenues	14,545	8,078	7,007	11,366	7,620	
Operating expenses:						
Research and development	19,597	18,296	20,104	17,521	14,960	
Manufacturing and production	11,581	8,482	6,270	4,573	3,554	
General and administrative	8,510	6,922	8,061	6,501	5,265	
Write-down of investment <sup>1</sup>	_	482	4,200	-	-	
Total operating expenses	39,688	34,182	38,635	28,595	23,779	
Loss from operations	(25,143)	(26,104)	(31,628)	(17,229)	(16,159)	
Investment income <sup>1</sup>	2,205	2,067	3,984	8,286	9,357	
Interest expense	(795)	(413)	(288)	(297)	(205)	
Net loss before cumulative effect of accounting change	(23,733)	(24,450)	(27,932)	(9,240)	(7,007)	
Cumulative effect of accounting change <sup>2</sup>	_	-	-	-	(1,510)	
Net loss	\$ (23,733)	\$ (24,450)	\$ (27,932)	\$ (9,240)	\$ (8,517)	
Net loss per share (basic and diluted)	\$ (1.05)	\$ (1.22)	\$ (1.39)	\$ (0.46)	\$ (0.43)	
Weighted average shares used in per share calculation	22,695	20,091	20,079	20,032	19,689	
Balance Sheet Data (at end of period):	<b>• • • • • • • • • •</b>	04.510	Ф 111 512	¢ 124.007	¢ 140 144	
Cash, cash equivalents and marketable securities, including restricted	\$ 73,996	\$ 84,518	\$ 111,513	\$ 134,087	\$ 148,144	
Working capital	67,300	76,983	105,672	130,638	145,007	
Total assets	101,226 8,209	110,707	129,426 4,319	154,495	162,903 5,121	
Long-term obligations, less current portion Total stockholders' equity	8,209 82,909	8,662 89,822	/	4,545	150,794	
Total stockholders equity	82,909	09,022	114,307	142,159	130,794	

<sup>1</sup> In 2003 and 2002, we recorded write-downs of \$0.5 million and \$4.2 million, respectively, to shares of stock received under a licensing agreement with Corautus/VGI. We subsequently reclassified these shares as a marketable security. In 2004, we sold our Corautus shares and recognized a \$0.9 million gain.

<sup>2</sup> In 2000, we changed our revenue recognition accounting policy to conform to the requirements of SEC Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*," SAB 101, and reflected this change as a cumulative accounting change in our statement of operations.

# 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.

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. We earn revenue by performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$106.6 million in revenue under these types of agreements. Revenues by source for each of the three years ended December 31, 2004, were as follows (in millions):

Source	2004	2003	2002
NIH contracts	\$ 8.4	\$ 2.9	\$ 1.0
IAVI contract	_	0.9	0.2
Anthrax grants	2.0	1.9	0.5
CMV grants	0.7	-	-
Other contracts and grants	_	0.3	1.3
Total contract and grant revenues	11.1	6.0	3.0
Invitrogen royalties	1.1	0.9	1.0
Sanofi-Aventis licenses	1.2	-	-
Corautus license	0.8	1.1	1.1
Merial license	0.3	-	1.5
Other royalties and licenses	_	0.1	0.4
Total royalty and license revenues	3.4	2.1	4.0
Total revenues	\$14.5	\$ 8.1	\$ 7.0

See "Business—Product Development—DNA Vaccines for Infectious Diseases—NIH Vaccine Research Center," "—International AIDS Vaccine Initiative," and "— Collaboration and Licensing Agreements—Corporate Collaborators—Outlicensing" for a more detailed discussion of the various programs.

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.

Since our inception, we estimate that we have spent approximately \$214 million on research, development, manufacturing and production. Our current independent development focus is on novel DNA vaccines for CMV as well as cancer immunotherapeutics Allovectin-7<sup>®</sup> and IL-2/EP. From inception, we have spent approximately \$56 million on our Allovectin-7<sup>®</sup> program. In 2004, we completed a Phase 2 trial evaluating high-dose, 2 mg, Allovectin-7<sup>®</sup>. We have successfully completed a SPA with the FDA for a Phase 3 trial of high-dose Allovectin-7<sup>®</sup> that would be needed to support submission of a BLA. This and potential future trials would add to the time and cost of development.

Additionally, we are in the early stages of clinical development of vaccine candidates for CMV. Product candidates from these programs and our IL-2/EP program for solid tumors will require significant additional costs to advance through development to commercialization. From inception, we have spent approximately \$17 million on our CMV program, and approximately \$2 million on our IL-2/EP program. 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. See "Business—Product Development—Cancer Therapies" for a more detailed explanation of the status of the Allovectin-7<sup>®</sup> and IL-2/EP programs. See also "Business—Product Development—DNA Vaccines for Infectious Diseases" for more detailed discussions of our CMV and anthrax vaccine programs.

Research, development, manufacturing and production costs by major program, as well as other expenses for research and development and manufacturing, for each of the three years ended December 31, 2004, were as follows (in millions):

Program	2004	2003	2002
Allovectin-7®	\$ 4.9	\$ 5.2	\$ 8.7
CMV	8.9	7.2	1.3
Anthrax	2.7	6.6	1.6
IL-2/EP	2.4	-	_
Other research, development, manufacturing and production	12.3	7.8	14.8
Total research, development, manufacturing and production	\$31.2	\$26.8	\$26.4

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.

# **Critical Accounting Policies**

# Use of Estimates

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

Intangible assets. We capitalize the license fees we pay to acquire access to proprietary technologies if the technologies are expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized to using the straight-line method over the estimated average useful



life of the technology, which is generally ten years. We also capitalize certain costs related to patent applications which have alternative future use in multiple research and development projects. Accumulated costs are amortized using the straight-line method over the estimated economic life of the patent, which is generally 20 years and usually commences at the time the patent application is filed. We review long-lived assets for impairment at least annually, quarterly for intangible assets, and whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount of the assets of the carrying amount of fair value, less costs to sell. Loss of legal ownership or rights to patents or licensed technologies, or significant changes in our strategic business objectives and utilization of the assets, among other things, could give rise to asset impairment.

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

*Clinical trial expenses.* We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the trial site and other external expenses related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the number of treatments for each patient. Treatment periods vary depending on the clinical trial. We make revisions to the clinical trial cost estimates as clinical trials progress. Clinical trial expense was \$0.8 million, \$0.5 million, and \$1.7 million for 2004, 2003, and 2002, respectively. Accrued clinical trial costs were \$0.2 million at December 31, 2004. No material revisions to our previous clinical trial cost estimates were made in the periods presented.

Accruals for potential disallowed costs on contracts We have contracts with agencies of the U.S. government under which we bill for direct and indirect costs incurred. These billed costs are subject to audit by government agencies, such as the NIH. We have established accruals of approximately \$0.5 million at December 31, 2004, to provide for potential disallowed costs. In the event that the final costs allowed are different from what we have estimated, we adjust our estimated accrual, which could also affect our results of operations and cash flow. No material adjustments were made to our previously estimated accruals in the periods presented.

### **Revenue** recognition

We earn revenue by performing services under research and development contracts, grants, and manufacturing contracts, and from licensing our proprietary technologies. 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.

Revenue under research and development contracts, grants, and manufacturing contracts, except for fixed-price contracts, is recognized as the research and development expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met. Revenue from milestones is recognized as agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the agreed-upon passage of time occurs, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured. We do not recognize revenue on manufacturing contract change orders until the service is performed and we have a signed modification for additional funding for the contract. Prior to that time, any costs incurred for change orders on manufacturing contracts are deferred if it is highly probable that we will receive a signed modification. Otherwise, the costs are expensed as incurred. Once the signed modification for additional funding

is received, the deferred costs and any related revenue are both recognized. Advance payments received in excess of amounts earned are classified as deferred revenue.

We also have entered into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used for preclinical and clinical research. Under these contracts, revenue and related expenses are recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met.

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

### **Results of Operations**

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

*Total Revenues.* Total revenues increased \$6.4 million, or 80%, 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 I 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 a marketable security.

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.

### Year Ended December 31, 2003, Compared to Year Ended December 31, 2002

*Total Revenues.* Total revenues increased \$1.1 million, or 15.3%, to \$8.1 million in 2003 from \$7.0 million in 2002. Revenues from our contracts and grants increased to \$6.0 million in 2003 as compared to \$3.0 million in 2002. The increase was primarily related to increased manufacturing contract shipments to the VRC and IAVI along with the recognition of \$1.9 million of grant revenue under an anthrax SBIR grant. License and royalty revenues in 2003 included the recognition of deferred license fees from Corautus, a license payment from Aqua Health and royalty revenue.

Research and Development Expenses. Research and development expenses decreased \$1.8 million, or 9.0%, to \$18.3 million for 2003 from \$20.1 million for 2002. The decrease was due to lower clinical trial and personnel-related costs.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$2.2 million, or 35.3%, to \$8.5 million for 2003 from \$6.3 million for 2002. The increase was primarily due to costs associated with our increased manufacturing capabilities within our new facility and the increase in manufacturing contract shipments in 2003.

General and Administrative Expenses. General and administrative expenses decreased \$1.1 million, or 14.1%, to \$6.9 million for 2003 from \$8.1 million for 2002. The decrease was primarily due to lower personnel costs, including lower incentive-based compensation expense, lower professional fees and lower facilities costs due to sublease loss accruals recorded in 2002.

Write-down of Investment. In 2003 and 2002, we recorded write-downs of \$0.5 million and \$4.2 million, respectively, of our investment in Corautus shares received under a licensing agreement.

Investment Income. Investment income was \$2.1 million in 2003 as compared to \$4.0 million in 2002. Investment income was higher in 2002 primarily due to higher cash, cash equivalents and marketable securities balances in 2002.

Interest Expense. Interest expense was \$0.4 million in 2003 as compared to \$0.3 million in 2002. 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, 2004, we have received approximately \$106.6 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 proceeds of approximately \$219.9 million from the sale of equity securities. As of December 31, 2004, we had working capital of approximately \$67.3 million, compared with \$77.0 million at December 31, 2003. Cash, cash equivalents and marketable securities, including restricted securities, totaled approximately \$74.0 million at December 31, 2003. The declines in our cash, cash equivalents and marketable securities in 2004 were due primarily to cash used to fund our operations, to purchase property and equipment, and to pay our long-term debt obligations, partially offset by net proceeds of \$17.3 million from the sale of common stock under our shelf registration statement.

Net cash used in operating activities was \$21.1 million, \$21.5 million and \$19.1 million in 2004, 2003 and 2002, respectively. The lower net cash used in 2004 as compared to 2003 reflects lower net losses, collections on accounts receivable and increases in accounts payables, offset by increases in deferred revenues. The increase in cash used in 2003 as compared to 2002 included decreases in accounts payable, primarily related to construction payments, offset by higher collections on accounts receivable.

Cash provided by investing activities was \$9.8 million, \$11.1 million and \$9.6 million in 2004, 2003 and 2002, respectively. In 2004, our net sales of marketable securities yielded \$11.0 million compared to \$13.5 million in 2003 and \$11.5 million in 2002. Capital expenditures for 2003 included capital purchases for and improvements to, our new facility.

Cash provided by (used in) financing activities was \$12.4 million, \$(5.6) million and \$(1.7) million in 2004, 2003 and 2002, respectively. Net proceeds from our registered direct stock offering in 2004 provided \$17.3 million of cash. In 2004, we entered into a new lease line with a leasing company and repaid amounts due under an existing capital lease. In addition, the restricted cash requirements under the existing capital lease were significantly reduced as a result of our new lease line.

For 2005, we have forecast a net loss of between \$23 million and \$26 million. We expect that our total net cash used in 2005 may differ from our projected net loss principally because of timing of cash receipts on certain contract work.

We expect to incur substantial additional research and development expenses, manufacturing products and 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 registration statement that we filed with the SEC was declared effective, which allows us to issue from time to time an aggregate of up to \$50 million of common stock or preferred stock, of which approximately \$31.4 million was remaining as of December 31, 2004. We cannot assure that 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 2006.

# **Contractual Obligations**

The following table sets forth our contractual obligations, including all off-balance sheet arrangements, as of December 31, 2004 (in thousands):

	Payments Due by Period				
Contractual Obligation <sup>1</sup>	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Capital lease obligations	\$11,186	\$ 5,088	\$ 5,967	\$ 131	\$ -
Operating lease obligations	43,805	3,727	6,655	7,004	26,419
WARF settlement	1,000	500	500	_	_
Unconditional purchase obligations	417	417	_	_	_
Total contractual obligations	\$56,408	\$ 9,732	\$13,122	\$7,135	\$26,419

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

In 2004, we modified our equipment financing agreement to provide for an additional lease line of up to \$8.5 million through October 31, 2005, with interest rates ranging from 3.0% to 3.2%. A portion of the lease line was used to repay outstanding debt of approximately \$2.2 million under another credit facility. Additional drawdowns will be used to finance equipment purchases. The agreement requires a non-interest-bearing cash security deposit in the amount of 60% of the amount of each drawdown. Financial covenants under the agreement include a requirement that we maintain specified levels of unrestricted cash and marketable securities. In the event of default on this covenant, we would be required to provide an irrevocable letter of credit equal to 100% of the then-outstanding balance of amounts financed.

Under the Merck, Sanofi Pasteur, Centelion, Merial, Corautus and Aqua Health agreements, we would be 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 Genetronics agreements would 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, 2004, we have employment agreements that contain severance arrangements with each of our three executive officers and two 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 \$1.1 million if each executive officer and other executive was terminated at December 31, 2004.

# **Recent Accounting Pronouncements**

For more information on the recent accounting pronouncements impacting our business, see Note 1 of the notes to our financial statements included herewith.

# 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 \$0.5 million lower than the reported fair value of our non-equity investments at December 31, 2004. At December 31, 2004, our unrealized gain on marketable securities was \$0.1 million. We expect lower investment income in 2005 compared with 2004 due to lower investment balances.

The fair market value of floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. Based on our market risk-sensitive instruments outstanding at December 31, 2004, we believe that there were no material market risk exposures to our financial position, results of operations or cash flows as of such date.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

# INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm—Deloitte & Touche LLP Report of Independent Registered Public Accounting Firm—KPMG LLP Balance Sheets Statements of Operations Statements of Stockholders' Equity Statements of Cash Flows Notes to Financial Statements

45

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Vical Incorporated:

We have audited the accompanying balance sheet of Vical Incorporated (the "Company") as of December 31, 2004, and the related statements of operations, stockholders' equity, and cash flows for the year then ended. We also have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that the Company maintained effective internal control over financial reporting as of December 31, 2004, based on *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these financial statements, 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 these financial statements, 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 the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting 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 there 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, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2004, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, 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. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ DELOITTE & TOUCHE LLP

San Diego, California March 11, 2005

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Vical Incorporated:

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

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Vical Incorporated as of December 31, 2003 and the results of its operations and its cash flows for each of the years in the two year period 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)

	Decem	ber 31,
	2004	2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,666	\$ 16,574
Restricted cash equivalents	2,703	2,356
Marketable securities, available-for-sale	53,627	65,588
Receivables and other	3,412	4,688
Total current assets	77,408	89,206
Property and equipment, net	16,277	15,033
Intangible assets, net	5,775	5,870
Other assets	1,766	598
Total assets	\$ 101,226	\$ 110,707
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,970	\$ 5,627
Current portion of capital lease obligations	4,607	3,918
Current portion of note payable	-	341
Current portion of deferred revenue	531	2,337
Total current liabilities	10,108	12,223
Long-term liabilities:		
Long-term capital lease obligations	5,822	7,196
Deferred revenue	-	131
Deferred rent	1,814	1,335
Other liabilities	573	
Total long-term liabilities	8,209	8,662
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized, none issued and outstanding Common stock, \$0.01 par value, 40,000,000 shares authorized, 23,502,374 and 20,092,594 shares issued and outstanding at December 31,	-	-
2004 and 2003, respectively	235	201
Additional paid-in capital	221,341	203,607
Accumulated deficit	(138,517)	(114,784)
Accumulated other comprehensive (loss) income	, í í	· · · · · · · · · · · · · · · · · · ·
	(150)	798
Total stockholders' equity	82,909	89,822
Total liabilities and stockholders' equity	\$ 101,226	\$ 110,707
rotal national stockholders equity	\$ 101,220	φ 110,707

See accompanying notes to financial statements

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

	Y	Year Ended December 31,			
	2004	2003	2002		
Revenues:					
Contract and grant revenue	\$ 11,168	\$ 6,012	\$ 3,008		
License and royalty revenue	3,377	2,066	3,999		
Total revenues	14,545	8,078	7,007		
Operating expenses:	,	.,	.,		
Research and development	19,597	18,296	20,104		
Manufacturing and production	11,581	8,482	6,270		
General and administrative	8,510	6,922	8,061		
Write-down of investment	-	482	4,200		
Total operating expenses	39,688	34,182	38,635		
Loss from operations	(25,143)	(26,104)	(31,628)		
Other income (expense):			(- , )		
Investment income	2,205	2,067	3,984		
Interest expense	(795)	(413)	(288)		
Net loss	\$ (23,733)	\$ (24,450)	\$ (27,932)		
	+ (,)	÷ (=:,::;)	÷ (=;;;==)		
Basic and diluted net loss per share	\$ (1.05)	\$ (1.22)	\$ (1.39)		
Weighted average shares used in computing basic and diluted net loss per share	22,695,349	20,091,436	20,078,591		
	,	.,,,	.,,		

See accompanying notes to financial statements

# VICAL INCORPORATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE THREE YEARS ENDED DECEMBER 31, 2004 (in thousands)

	Common Stock		ficcumulated							
	Number of Shares	An	nount	Additional Paid-in Capital	Oth Comprel Income	nensive	A	ccumulated Deficit		Total ckholders' Equity
Balance at January 1, 2002	20,056	\$	201	\$ 203,543	\$	817	\$	(62,402)	\$	142,159
Net loss	-		-	-		-		(27,932)		(27, 932)
Unrealized gain on marketable securities arising during holding period	-		_	-		283		-		283
Reclassification of realized gain included in net loss	-		-	-		(213)		-		(213)
Comprehensive loss	-		-	_		-		_		(27,862)
Exercise of options to purchase common stock	35		-	9		-		-		9
Non-cash compensation expense related to grant of stock options			-	2		_	. <u> </u>	_		2
Balance at December 31, 2002	20,091		201	203,554		887		(90,334)		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
, r										
Balance at December 31, 2003	20,092	\$	201	\$ 203,607	\$	798	\$	(114,784)	\$	89,822
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	23,502	\$	235	\$ 221,341	\$	(150)	\$	(138,517)	\$	82,909

See accompanying notes to financial statements

# VICAL INCORPORATED STATEMENTS OF CASH FLOWS (in thousands)

	Year Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	\$ (23,733)	\$ (24,450)	\$ (27,932)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,637	3,543	2,736
Write-down of investment	-	482	4,200
Loss on sublease	45	249	720
Write-off of abandoned patents	143	-	-
Compensation expense related to stock options and awards	420	50	2
Deferred rent	479	282	1,052
Changes in operating assets and liabilities:			
Receivables and other	1,174	270	(617)
Other assets	(1,168)	36	(329)
Accounts payable and accrued expenses	(129)	(1,991)	2,361
Deferred revenue	(1,937)	(9)	(1,272)
Net cash used in operating activities	(21,069)	(21,538)	(19,079)
Cash flows from investing activities:	<b>65 5</b> 00	100.051	101.511
Sales of marketable securities—including restricted	65,790	123,371	101,611
Purchases of marketable securities—including restricted	(54,777)	(109,826)	(90,093)
Purchases of property and equipment	(514)	(1,620)	(1,139)
Licensed technology expenditures	-	(80)	-
Patent expenditures	(709)	(744)	(763)
Net cash provided by investing activities	9,790	11,101	9,616
Cash flows from financing activities:			
Proceeds from issuance of common stock	17,348	3	9
Payments on notes payable	(341)	(633)	(657)
Principal payments under capital lease obligations	(4,289)	(2,612)	(1,016)
Sales of restricted cash equivalents	4,857	(2,012)	(1,010)
Purchases of restricted cash equivalents	(5,204)	(2,356)	-
Net cash provided by (used in) financing activities	12,371	(5,598)	(1,664)
	1.002	(1( 025)	(11 107)
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of year	1,092 16,574	(16,035) 32,609	(11,127) 43,736
Cash and cash equivalents at beginning of year	10,574		
Cash and cash equivalents at end of year	\$ 17,666	\$ 16,574	\$ 32,609
Supplemental information:			
Interest paid	\$ 715	\$ 459	\$ 291
Non-cash investing and financing activities:			
Investment accounted for on the cost method, subsequently reclassified to marketable securities available-for-sale, at quoted market value	\$ –	\$ 318	\$ -
Property and equipment acquired under capital lease financing	\$ 3,706	\$ 10,482	\$ 1,798

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 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.

### Issuance of Common Stock

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 \$31.4 million of additional common or preferred stock.

#### 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.

### 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. In the event that the Company meets certain financial covenants for four consecutive quarters the required amount of the letter of credit is reduced by 50%. If the Company meets those same financial covenants for eight consecutive quarters the required amount of the letter of credit is reduced to zero. If the Company fails to meet those same financial covenants in any calendar quarter the requirement for the letter of credit is reduced to



the original amount. The covenants included maintaining a cash balance of \$60.0 million and a market capitalization of \$150.0 million. At December 31, 2004 and 2003 restricted cash equivalents of \$2.7 million and \$2.4 million 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. An impairment loss would be recognized when the sum of the expected future undiscounted net cash flows is less than the carrying amount of the asset. 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. During 2004 the Company expensed approximately \$0.1 million related to a patent which the Company's deemed 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 contracts, 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.

Revenue under research and development contracts, grants, and manufacturing contracts, except for fixed-price contracts, is recognized as the research and development expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met. Revenue from milestones is recognized as agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the passage of time and where the amount of the milestone payment



approximates the value of achieving the milestone, and collection of payment is reasonably assured. The Company does not recognize revenue on manufacturing contract change orders until the service is performed and it has a signed modification for additional funding for the contract. Otherwise, the costs are expensed as incurred. Once the signed modification for additional funding is received, the deferred costs and any related revenue are both recognized upon performance of the service. Advance payments received in excess of amounts earned are classified as deferred revenue.

The Company also has entered into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used for preclinical and clinical research. Under these contracts, revenue and related expenses are recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are 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 services agreement is recognized as revenue over the term of the research and development period. Upfront license payments are only recognized as revenue upon contract signing if the fee is nonrefundable and noncreditable, and if there are no performance obligations remaining. Payments for options on a license to the Company's technology are recognized as revenue over the option period only. Royalty revenue is recognized when earned and when collectibility 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 \$0.5 million and \$0.6 million at December 31, 2004 and 2003, 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. 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 have been computed using the weighted average number of shares of common stock outstanding during each of the years ended December 31, 2004, 2003 and 2002. 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. The number of shares so excluded was 3,941,236, 3,333,693 and 2,910,347, for the years ended December 31, 2004, 2003 and 2002, respectively.

# 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):

	2004	2003	2002
Net loss, as reported	\$(23,733)	\$(24,450)	\$(27,932)
Add stock-based compensation expense included in reported net loss	420	50	2
Less stock-based compensation expense determined under fair value based method for all awards	(3,225)	(3,569)	(4,848)
Pro forma net loss	\$(26,538)	\$(27,969)	\$(32,778)
Basic and diluted net loss per share, as reported	\$ (1.05)	\$ (1.22)	\$ (1.39)
Basic and diluted pro forma net loss per share	\$ (1.17)	\$ (1.39)	\$ (1.63)
Weighted average fair value of stock options	\$ 4.18	\$ 2.45	\$ 5.87
Assumptions:			
Assumed risk-free interest rate	3.10%	2.55%	3.86%
Assumed volatility	78%	80%	82%
Expected option life	4 years	4 years	4 years
Dividend yields	-	-	-

Fair Value of Financial Instruments

The carrying amounts of cash, cash equivalents, restricted cash equivalents, marketable securities, receivables, other assets, accounts payable and accrued expenses at December 31, 2004 and 2003, 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 notes payable and obligations under capital leases at December 31, 2004 and 2003, 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, 2004, 2003 and 2002 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 United States, 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 Statement is effective as of the beginning of the first interim or annual period beginning after June 15, 2005. The Company will adopt SFAS No. 123(R) on July 1, 2005. The Company has not determined the impact of adopting SFAS No. 123(R) on net income and earnings per share. Further the Company does not yet know the impact that any future share-based payment transactions will have on its financial statements.

#### Reclassifications

The Company has reclassified \$0.7 million of purchases of property and equipment which was classified as a current receivable as it was expected to be financed under capital lease obligations from a current receivable to property and equipment in the 2003 balance sheet to conform to the current year presentation. In addition, the Company has segregated its research and development expenses between research and development expenses and manufacturing and production costs for 2003 and 2002 to conform to the current year presentation.

### 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. If an investment is downgraded such that it does not comply with the Company's investment policy or it is put by a credit agency on "Negative Watch" or similar designation the Company will sell the investment immediately and recognize any loss on the transaction in the period in which it occurs.

At December 31, marketable securities, classified as available-for-sale, consisted of the following (in thousands):

2004:	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. government obligations	\$ 35,504	\$ 3	\$ (131)	\$35,376
Corporate bonds	12,762	3 J 7	(13)	12,756
Corporate asset backed securities	5,511	3	(19)	5,495
•				
	\$ 53,777	\$ 13	\$ (163)	\$53,627
2003:	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. government obligations	\$ 46,912	\$ 124	\$ (13)	\$47,023
Corporate bonds	11,230	35	(3)	11,262
Corporate asset backed securities	5,564	11	(9)	5,566
International bond	766	-	(2)	764
Investment in common stock of Corautus	318	655	-	973
	\$ 64,790	\$ 825	\$ (27)	\$65,588

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 as a marketable security. 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, 2004, no individual security has been in an unrealized loss position for more than twelve months.

At December 31, 2004, approximately 95 percent of these securities mature within one year, an additional 4 percent mature within two years, and the remaining 1 percent mature within three years. Net realized gains on sales of available-for-sale securities for the years ended December 31, 2004, 2003 and 2002, were \$0.9 million, \$0.2 million and \$0.2 million, respectively.

# 3. Other Balance Sheet Accounts

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

	2004	2003
Equipment	\$ 19,009	\$ 15,071
Leasehold improvements	12,194	11,976
-		
	31,203	27,047
Less accumulated depreciation and amortization	(14,926)	(12,014)
	\$ 16,277	\$ 15,033

Depreciation and amortization of equipment and leasehold improvements for the years ended December 31, 2004, 2003 and 2002, was \$3.0 million, \$2.9 million and \$2.2 million respectively. These amounts include depreciation related to equipment under capital lease agreements. See note 5 for equipment financing.

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

	2004	2003
Licensed technology rights	\$ 3,830	\$ 3,830
Patent application costs	4,201	3,660
	8,031	7,490
Less accumulated amortization	(2,256)	(1,620)
	\$ 5,775	\$ 5,870

Amortization of licensed technology rights and patent application costs for the years ended December 31, 2004, 2003 and 2002, was \$0.7 million, \$0.6 million and \$0.5 million, respectively. Estimated annual amortization for these assets for each of the years in the period from 2005 to 2009 is \$0.6 million.

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

	2004	2003
Employee compensation	\$1,985	\$ 1,741
Accrued contract liabilities	492	642
Accrued construction liabilities	-	556
Accounts payable	560	406
Accrued royalty	500	_
Other accrued liabilities	1,433	2,282
	\$4,970	\$ 5,627

### 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 \$8.4 million, \$2.9 million and \$1.0 million in 2004, 2003 and 2002, 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 a \$1.0 million, one-year Small Business Technology Transfer Research, or STTR, grant from the National Institute of Allergy and Infectious Diseases, or NIAID, as announced in 2002. In 2003, the Company was awarded a three-year, Phase II Small Business Innovation Research, or SBIR, grant from the NIAID of \$5.7 million, which was subsequently increased to \$5.8 million, for additional non-clinical development of its anthrax vaccine candidate. The Company recognized revenues under these grants of \$2.0 million, \$1.9 million and \$0.5 million in 2004, 2003 and 2002, respectively. In July 2004, the Company began a Phase 1 clinical trial of its anthrax vaccine candidate at two NIAID-funded Vaccine and Treatment Evaluation Units.

In addition, the Company has been awarded approximately \$1 million for research and development related to its CMV vaccine program under two grants from the NIAID. Revenue recognized under these grants was \$0.7 million in 2004. No revenue was recognized in 2003 and 2002.

# 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. A prior malaria vaccine agreement with the ONR had expired. Revenue recognized under this agreement was \$0.2 million and \$0.3 million in 2003 and 2002, respectively. No revenue was recognized in 2004. The Company does not plan to pursue this program independently.

#### Other Contract and Grant Agreements

The Company also received revenue under contract and grant agreements with other entities, including the U.S. government, of which approximately \$1.0 million and \$1.2 million was recognized as revenue in 2003 and 2002, respectively. Revenue recognized in 2004 was immaterial. For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties. See also Note 8 for related party agreements.

### License and Royalty Agreements

#### Merck

In 1991, we and Merck entered into an agreement, which was subsequently amended, providing Merck with certain exclusive rights to develop and commercialize vaccines using our core DNA delivery technology for certain human diseases. Under the agreement, as amended, Merck licensed preventive and therapeutic human infectious disease vaccines using our core DNA delivery technology. In 2003, under the most recent amendment to the agreement, Merck obtained options for rights to use our core DNA delivery technology for three cancer targets. No revenues were recognized under the Merck agreement in 2004, 2003 or 2002.

#### Sanofi-Aventis

In December 2004, Sanofi-Synthélabo merged with Aventis, S.A. to form the Sanofi-Aventis Group, or Sanofi-Aventis, and Aventis Pasteur was subsequently renamed Sanofi Pasteur. In October 2004, Gencell, a wholly-owned subsidiary of Aventis Pharma, was renamed Centelion.

In 2000, Centelion licensed the rights to the Company's core DNA delivery technology for cardiovascular applications using FGF-1. In 2001 and 2002, the Company merged and amended previous agreements into a new, restructured agreement granting Sanofi Pasteur rights to use the Company's core DNA delivery technology for specific oncology applications. In exchange, Sanofi Pasteur gave up previously licensed rights to develop and commercialize certain infectious disease DNA vaccines.

The restructured agreement with Sanofi Pasteur and the agreement with Centelion specify that the Company will receive milestone payments plus royalties if products advance through commercialization. The Company recognized revenues of \$1.2 million in 2004. under the Sanofi-Aventis agreements. Revenue recognized in 2003 and 2002 was immaterial. Sanofi Pasteur has the right to terminate the restructured agreement without cause upon six months prior written notice. Centelion has the right to terminate the agreement without cause upon 60 days prior written notice.

#### Merial

The Company entered into a corporate collaboration in 1995 relating to DNA vaccines in the animal health area with Merial Ltd., or Merial, a joint venture between Sanofi-Aventis and Merck & Co., Inc. or Merck. Merial has options to take exclusive licenses to the Company's core DNA delivery technology to develop and



commercialize DNA vaccines to prevent infectious diseases in livestock and companion animals. In 2004, the Company granted an exclusive license to Merial for use of its core DNA delivery technology in a vaccine to protect certain companion animals against a particular type of cancer. Under the new 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, and \$1.5 million in 2004 and 2002, respectively, under the Merial agreements. No revenue was recognized in 2003. Merial has the right to terminate these agreements without cause on 30 days 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 this agreement was \$0.8 million, \$1.1 million, and \$1.1 million for the years ended December 31, 2004, 2003 and 2002, respectively.

### Aqua Health

In 2003, the Company granted a non-exclusive license to Aqua Health Ltd., or 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. This vaccine has been sold on a pre-approval basis in support of extensive field trials which have been completed at Canadian fish farms, and the Company has recognized *de minimus* license fees and royalty revenues on these sales.

#### Invitrogen Corporation

In 1991, the Company licensed the use of certain proprietary lipids for research products applications to Life Technologies, Inc., or Life Technologies, which was subsequently acquired by Invitrogen Corporation, or Invitrogen, in 2000. Invitrogen manufactures and markets these lipid compounds, and pays royalties to the Company on the sales of the lipids. The Company recognized \$1.1 million, \$0.9 million and \$1.0 million in 2004, 2003 and 2002, respectively, in royalty revenues under this agreement.

#### Other Research and Licensing Agreements

The Company also received revenue under research and licensing agreements with other entities, including the U.S. government, of which approximately \$0.1 million and \$0.4 million was recognized as revenue in 2003 and 2002, respectively. No revenue was recognized in 2004. 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-licensing Agreements**

### Genetronics

In 2003, the Company entered into an agreement with Genetronics giving it options to worldwide exclusive licenses to use Genetronics' proprietary electroporation technology in combination with its DNA delivery technologies for undisclosed targets. In October 2004, the Company exercised options and amended the agreement to include HIV. As part of the agreement, the Company paid *de minimus* option and license fees to Genetronics in 2004 and 2003.

#### CvtRx

In 2001, the Company entered into an exclusive agreement with CytRx which grants to it 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, Sanofi Pasteur, Merial, Centelion, Corautus and Aqua Health agreements. The CytRx and Genetronics agreements would require the Company to make payments if it or its sublicensees advance products through clinical development. Royalty expense for these agreements was \$1.4 million and \$0.2 million in 2004 and 2002, respectively. Royalty expense was immaterial in 2003. See also Note 6.

### 5. Long-term Obligations

Facility Leases

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 the lease or based on changes in the Consumer Price Index subject to certain minimum and maximum annual increases also specified in the lease. The Company is also required to pay taxes, insurance and operating costs under the facilities leases. The Company recognizes level monthly rent for all facility leases over the entire lease period. This deferred 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 \$1.8 million difference between the base rent paid and the level rent expensed through December 31, 2004, is recorded as deferred rent in the balance sheet.

In January 2002, the Company signed a 15-year lease for a new building in San Diego, California. The facility has approximately 68,400 square feet of manufacturing, research laboratory and office space. 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 holds two leases, which were renewed in 2004, at two sites for manufacturing and research space. The Company renewed its lease on approximately 15,000 square feet in its manufacturing facility for one year and approximately 10,000 square feet in its research facility for five years. The Company intends to relocate its remaining operations currently conducted at this manufacturing facility to its new facility in 2005.

Rent expense for the years ended December 31, 2004, 2003 and 2002, was \$3.7 million, \$4.0 million and \$3.7 million, respectively. Rent expense for 2003 and 2002, included \$0.2 million and \$0.5 million, respectively, for the expected loss on space in the Company's older facilities that is vacant or sublet at rental rates less than those incurred by the Company. The expected loss in 2004 was immaterial. In 2002 the Company recorded a \$0.2 million write-down of the unamortized balance of leasehold improvements at the Company's older facilities. Total sublease rental income in 2004 and 2003, was approximately \$0.7 million and \$0.2 million, respectively.

# Equipment Financing

The Company has entered into capital lease agreements that require monthly payments through 2009. The equipment capital leases are secured by substantially all equipment of the Company. The carrying value of the equipment under these agreements at December 31, 2004 and 2003, was \$12.7 million and \$11.6 million, respectively. At December 31, 2004 and 2003, related accumulated depreciation was \$3.8 million and \$3.2 million, respectively.

In December 2004, the Company modified an equipment financing agreement to provide for a lease-line of up to \$8.5 million through October 31, 2005, with interest rates ranging from 3.0% to 3.2%. A portion of the line was used to repay outstanding debt of approximately \$2.2 million under another credit facility. Additional draw downs will be used to finance equipment purchases. The agreement requires a non-interest-bearing cash security deposit in the amount of 60% of the amount of each draw down.

Financial covenants under the agreement require, among other things, that the Company maintain specified levels of unrestricted cash and investments in marketable securities. In the event of default on this covenant, the Company would be required to provide an irrevocable letter of credit equal to 100% of the then outstanding balance of amounts financed.

At December 31, 2004, annual minimum payments due under the Company's facilities and equipment lease obligations are as follows (in thousands):

	Operating Leases	Capital Leases
Years ending December 31,		
2005	\$ 3,727	\$ 5,088
2006	3,286	3,760
2007	3,370	2,207
2008	3,471	123
2009	3,533	8
Thereafter	26,418	-
Total minimum lease payments	\$ 43,805	11,186
Less amount representing interest		(757)
Present value of capital lease payments		10,429
		· · · · ·
Less current portion		(4,607)
Long-term obligations under capital leases		\$ 5,822

# Note Payable

During 2000, the Company entered into a financing agreement with a bank to finance certain leasehold improvements at the bank's prime rate. Under the terms of this financing agreement, outstanding borrowings at June 1, 2001, of \$1.3 million converted to a term loan payable over 42 months. This loan was paid in full as of December 31, 2004.

Notes payable consisted of the following at December 31, 2003 (in thousands):

Note payable to bank, payable in monthly installments of \$31 through 2004, plus interest at the bank's prime rate.	\$ 341
Less current portion	(341)
Notes payable, long-term	\$ -

# 6. Commitments and Contingencies

If the Company fails to satisfy its contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and the Company may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or GFE or other government property in its possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected. Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies.

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 \$0.5 million had been paid as of December 31, 2004, with equal remaining payments due in 2005 and 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. If the '253 patent is opposed, the Company may lose part or all of its proprietary protection on its product candidates in Europe. However, the Company may also use additional issued patents and patent applications that are pending in Europe to protect its core DNA delivery technology.

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

In addition, the Company's core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the Japanese Patent Office, or JPO, on formal and substantive grounds. The Company filed a rebuttal response to the revocation. Based on the Company's arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. 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 into a single action, and in December 2004, ruled in the Company's favor in the combined TFI 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 its clinical-stage Allovectin-7<sup>®</sup> treatment for melanoma, cationic lipid-formulated DNA vaccines such as its 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 awaiting further action by 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 is awaiting further action by the EPO.

The Company has licensed from the University of Michigan rights to various U.S. and international patents related to injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin- $7^{\text{B}}$ . Included in this license is a European patent granted in March 2002, and opposed in December 2002. The Company filed a rebuttal response to the opposition in a timely manner. The Company is currently negotiating with the University of Michigan the return of certain non-U.S. rights under the agreement.

We prosecute our intellectual property estate vigorously to obtain the broadest valid scope for our 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 of the Company.

In addition, the Company has undertaken certain commitments under agreements with its collaborators, and its officers and directors (See note 8). Under license agreements with its collaborators, the Company has agreed to continue to maintain and defend the patent rights licensed to the collaborators.

### 7. Stockholders' Equity

In December 2003, a shelf registration statement filed by the Company with the SEC was declared effective, which allows the Company to issue from time to time an aggregate of up to \$50 million of common or preferred stock, of which approximately \$31.4 million was remaining as of December 31, 2004. Specific terms of any offering under the shelf registration and the securities involved would be established at the time of sale.

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.

### Stock Plan and Directors 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 the fair market value on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to non-employee directors which vest at the next annual meeting, options generally vest 25 percent on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. The plan has also limited the number of options that may be granted to any plan participant in a single calendar year to 300,000 shares.

In 2004, the Company granted 90,500 restricted stock units, or RSUs, to executive and certain other officers. 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. 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, 2004, 2003, and 2002 was approximately \$312,000, \$16,000 and \$51,000, respectively.

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, 2004. It is not anticipated that there will be any future grants under the directors' plan.

The following table summarizes stock option transactions for the Company's stock option plans for the years ended December 31, 2004, 2003 and 2002:

	Shares	Weighted Average Exercise Price	
Outstanding December 31, 2001	2,638,069	\$	15.76
Granted	814,350	\$	8.02
Exercised	(35,000)	\$	0.25
Forfeited	(507,072)	\$	17.06
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

The following table summarizes information about stock options outstanding under the Company's stock option plans at December 31, 2004:

Options Outstanding		<b>Options Exercisable</b>			
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 2.31 - \$ 4.70	821,785	8.3	\$ 3.36	370,991	\$ 3.29
\$ 4.75 - \$ 6.35	910,250	9.1	\$ 5.83	61,256	\$ 5.60
\$ 6.48 - \$11.63	802,217	6.9	\$ 9.20	585,497	\$ 9.25
\$11.75 - \$16.63	888,190	4.4	\$ 15.11	884,660	\$ 15.12
\$16.88 - \$39.25	428,294	4.9	\$ 20.89	428,244	\$ 20.89
\$ 2.31 - \$39.25	3,850,736	6.9	\$ 9.82	2,330,648	\$ 12.57

The number of shares and weighted average price of options exercisable at December 31, 2004, 2003 and 2002, were 2,330,648 shares at \$12.57, 1,794,717 shares at \$14.53 and 1,594,837 shares at \$15.71, respectively. At December 31, 2004, shares available for grant under the Company's stock option plans were 1,026,754.

### 8. Related Parties

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, is also the Director of Strategic Planning at the VRC. For varying periods beginning from November 2000, the VRC has contracted



with Vical for providing regulatory support, manufacturing services, and the production of research and clinical trial supplies. Revenue recognized under these contracts was \$8.4 million, \$2.9 million and \$1.0 million, for the years ended December 31, 2004, 2003 and 2002, respectively. In May 2003, the Company announced a contract to manufacture bulk DNA vaccines for the VRC. In support of this contract, the VRC provided a 500-liter fermenter and related purification equipment in the Company's new manufacturing facility during the term of the contract. Under this agreement, the Company is guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement.

If the Company fails to satisfy its contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and the Company may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or government property in its possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected. There are only a limited number of other contractors that could perform under this contract in the unlikely event that Vical was unable to perform. The price they might charge could be more than what Vical would charge based on their capacity, utilization, size of order and other factors. Accordingly, the Company is unable to estimate a range of potential cost it could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that the Company was unable to meet. Included in "receivables and other" at December 31, 2004 and 2003, is a receivable from the VRC in the amount of \$0.2 million, and \$0.9 million of which \$0.2 million and \$0.6 million, respectively, pertains to equipment reimbursements.

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

Included in "other assets" at December 31, 2004 and 2003, is the long-term portion of notes receivable, representing amounts due from officers and employees of the Company. The loan agreements allow for the notes to be forgiven under certain circumstances over the next three or four years. Imputed interest is applied at the applicable federal rate. The long-term portion was \$0.2 million and \$0.3 million at December 31, 2004 and 2003, respectively. The current portion, included in "receivables and other," was \$0.2 million at December 31, 2004 and 2003.

As of December 31, 2004, the Company had employment agreements with five of its executive and other officers 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 \$1.1 million if each executive officer and other executive was terminated at December 31, 2004. 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 2004 and

\$0.1 million in 2003, including payroll taxes paid by the Company on the officers' behalf. In August 2002 the Company purchased and resold an officers' home and incurred a loss of \$0.1 million. In 2001, the Company made a \$0.3 million, interest free loan to one of the officers'. This loan is forgivable over four years and interest is imputed at the applicable federal rate. In January 2002, the Company entered into another loan agreement with the same officer. The agreement provides for the loan in the amount of \$0.2 million to be repaid after four years and to be secured by a second deed of trust on the residence. Interest, at the applicable federal rate, is due and payable monthly. The loans to officers were entered into before July 2002 which was the implementation date of the Sarbanes Oxley Act of 2002.

### 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:

	2004	2003	2002
Computed "expected" tax benefit	\$(8,069)	\$ (8,313)	\$ (9,497)
State income taxes, net of federal benefit	(1,385)	(2,161)	(1,676)
Tax effect of:			
Change in valuation allowance	7,109	12,865	15,422
Adjustment to prior year credits and			
deferred taxes	590	(1,405)	(3,031)
Effect of change to apportioned state rate	3,355	_	_
Various tax credits	(1,792)	(1,048)	(1,235)
Other	192	62	17
Provision for income taxes	\$ -	\$ -	\$ -

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

	2004	2003
Deferred Tax Assets		
Net operating losses	\$ 45,418	\$ 37,441
Capital loss carryover	1,492	-
Various tax credits	17,023	14,626
Depreciation and amortization	6,648	8,305
Other	306	2,025
Accruals and reserves	777	1,152
Deferred revenue	52	1,057
Total gross deferred tax assets	71,716	64,606
Less valuation allowance	(71,716)	(64,606)
Net deferred tax assets	\$ -	\$ -

As of December 31, 2004 and 2003, the Company had available federal net operating loss carryforwards of approximately \$130.1 million and \$101.2 million, respectively. In addition, the Company had research and development credit and orphan drug credit carryforwards of \$12.3 million as of December 31, 2004, and \$11.0 million as of December 31, 2003, to reduce future federal income taxes, if any. These carryforwards expire from 2004 through 2023 and are subject to review and possible adjustment by the Internal Revenue Service. The Company also has available California state net operating loss carryforwards of approximately \$23.8 million which expire from 2010 to 2014. In addition, the Company has research and development credits and manufactures' investment credits of approximately \$4.7 million and \$4.2 million as of December 31, 2004, and 2003, respectively to reduce future California income tax, if any.



The Company had deferred tax assets of approximately \$71.7 million and \$64.6 million as of December 31, 2004 and 2003, respectively, related primarily to its net operating loss and tax credit carryforwards. A valuation allowance has been recognized to offset the entire amount of the deferred tax asset as it is more likely than not that some or all of the deferred tax asset will not be realized.

The tax benefit associated with the Company's stock incentive plan was \$5.0 million as of December 31, 2004 and 2003, 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<sup>®</sup>, was granted orphan drug designation for the treatment of invasive and metastatic melanoma by the FDA's Office of Orphan Products Development. Orphan drug designation provides certain tax benefits for qualifying expenses. In 2000, another of the Company's product candidates, Leuvectin<sup>®</sup>, was granted orphan drug designation for treatment of renal cell carcinoma. The Company is continuing development of high-dose Allovectin-7<sup>®</sup> for melanoma, but discontinued development of Leuvectin<sup>®</sup> for kidney cancer and prostate cancer and low-dose applications of Allovectin-7<sup>®</sup>.

### 10. Employee Benefit Plans

The Company has a net defined contribution savings plan under section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$0.2 million in each of 2004, 2003 and 2002.

# 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):

2004:	March 31,	June 30,	Sept	ember 30,	Dece	ember 31,
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	\$ (.45)	\$ (.23)	\$	(.21)	\$	(.20)
Weighted average shares used in per share calculation	20,317	23,476		23,479		23,493
2003:	March 31,	June 30,	Sept	ember 30,	Dece	ember 31,
2003: Total revenues	March 31, \$ 908	<b>June 30,</b> \$ 602	Septe \$	ember 30, 4,873	Dece \$	ember 31, 1,695
			<u> </u>			
Total revenues	\$ 908	\$ 602	<u> </u>	4,873		1,695
Total revenues Research and development costs	\$ 908 4,803	\$ 602 5,039	<u> </u>	4,873 4,291		1,695 4,163
Total revenues Research and development costs Total operating expenses	\$ 908 4,803 8,606	\$ 602 5,039 8,069	<u> </u>	4,873 4,291 8,661	\$	1,695 4,163 8,846



# 1TEM 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 under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or 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.

# 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, 2004, 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, 2004.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

# 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 2005 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

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 ACCOUNTING 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, 2004 and 2003

Statements of Operations for the three years ended December 31, 2004

Statements of Stockholders' Equity for the three years ended December 31, 2004

Statements of Cash Flows for the three years ended December 31, 2004

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

# (c) Exhibits

Exhibit Number	Description of Document
3.1(i)(9)	Restated Certificate of Incorporation.
3.1(ii)(9)	Amended and Restated Bylaws of the Company.
4.1(9)	Specimen Common Stock Certificate.
4.2(2)	Rights Agreement dated as of March 20, 1995, between the Company and First Interstate Bank of California.
$10.1(4)^{a}$	Amended and Restated Stock Incentive Plan of Vical Incorporated.
10.2(5) <sup>a</sup>	1992 Directors' Stock Option Plan of Vical Incorporated.
$10.3(15)^{a}$	Form of Indemnity Agreement between the Company and its directors and officers.
10.8(3)	Lease dated December 4, 1987, between the Company and Nexus/GADCoUTC, a California Joint Venture, as amended.
10.9(6) <sup>b</sup>	Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.12(1) <sup>b</sup>	License Agreement dated January 1, 1991, between the Company and Wisconsin Alumni Research Foundation.
10.14(1) <sup>b</sup>	License Agreement dated October 23, 1992, between the Company and the Regents of University of Michigan.
10.16(7)	Research, Option and License Agreement dated September 29, 1994, between the Company and Pasteur Mérieux Sérums & Vaccins (subsequently Sanofi Pasteur).

Exhibit Number	Description of Document
10.17(8)	Amendment dated April 27, 1994, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.19(19) <sup>b</sup>	Amendment dated November 3, 1997, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.20(10)	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/GADCoUTC).
10.22(11) <sup>b</sup>	License Agreement dated February 24, 2000, between the Company and Vascular Genetics Inc., subsequently Corautus Genetics Inc.
10.23(12) <sup>a</sup>	Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.25(13) <sup>a</sup>	Employment Agreement dated September 13, 2001, between the Company and David C. Kaslow.
10.26(14) <sup>b</sup>	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(14)	Lease dated January 30, 2002, between the Company and Kilroy Realty, L.P. a Delaware Limited Partnership.
10.28(14) <sup>a</sup>	Amendment dated February 5, 2002, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.30(15) <sup>b</sup>	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(15) <sup>a</sup>	Amendment dated March 10, 2003, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.32(16) <sup>b</sup>	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(17) <sup>b</sup>	Agreement dated May 6, 2003, between the Company and SAIC-Frederick, Inc.
10.34(18)	Amendment dated March 17, 2004, to Employment Agreement dated November 28, 2000, between the Company and Vijay B. Samant.
10.36(19) <sup>b</sup>	Amendment dated May 20, 2004, to License Agreement dated January 1, 1991, between the Company and the Wisconsin Alumni Research Foundation.
10.37	Letter Agreement dated October 6, 2004 and related documents between the Company and General Electric Capital Corporation
10.38ª	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.
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 Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Jill M. Church, Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

#### **Table of Contents**

Exhibit Number	Description of Document
32.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act of 2002.
32.2	Certification of Jill M. Church, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(1) I (	d have for an end of the Commence of the Statement on Form S 1 (Mar 22 50020) Statement 7, 1002

(1) Incorporated by reference to the Company's Registration Statement on Form S-1 (No. 33-56830) filed on January 7, 1993.

(2) Incorporated by reference to the exhibit of the same number to the Company's Report on Form 10-K for the fiscal year ended December 31, 1994 (No. 0-21088).

(3) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-1 (No. 33-56830) filed on January 7, 1993.

(4) Incorporated by reference to Exhibit 10.1 filed with the Company's Registration Statement on Form S-8 (file No. 333-97019) filed on July 24, 2002.

(5) Incorporated by reference to Exhibit 10.1 filed with the Company's Registration Statement on Form S-8 (No. 333-30181) filed on June 27, 1997.

(6) Incorporated by reference to Exhibit 10.9 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994 (No. 0-21088).

(7) Incorporated by reference to Exhibit A of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994.

(8) Incorporated by reference to Exhibit A of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994 (No. 0-21088).

(9) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.

(10) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999.

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.
 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 Annual Report on Form 10-K for the year ended December 31, 2000.
 (13) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

(14) Incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.

(15) 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.

(16) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.

(17) 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.

(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 March 31, 2004.

(19) 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.

<sup>a</sup> Indicates management contract or compensatory plan or arrangement.

<sup>b</sup> 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.

#### SIGNATURES

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

Date: March 14, 2005

#### VICAL INCORPORATED

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

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

/s/ VIJAY B. SAMANT	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2005	
Vijay B. Samant	(Thicipal Executive Officer)		
/s/ JILL M. CHURCH	Vice President, Chief Financial Officer, and Secretary (Principal Financial and Accounting Officer)	March 14, 2005	
Jill M. Church	(Thepa Thanda and Accounting Officer)		
/s/ R. GORDON DOUGLAS, M.D.	Chairman of the Board of Directors	March 14, 2005	
R. Gordon Douglas, M.D.			
/s/ ROBERT H. CAMPBELL	Director	March 14, 2005	
Robert H. Campbell			
/s/ M. BLAKE INGLE, PH.D.	Director	March 14, 2005	
M. Blake Ingle, Ph.D.			
/s/ GARY A. LYONS	Director	March 14, 2005	
Gary A. Lyons			
/s/ ROBERT C. MERTON, PH.D.	Director	March 14, 2005	
Robert C. Merton, Ph.D.			

**GE CAPITAL CORPORATION** 

Life Science Finance 2050 Martin Avenue Santa Clara, CA 95050 408-986-6886 ph./ 408-980-7722 fax

Barbara Kaiser SVP, Sales

October 6, 2004 Revised: October 22, 2004 Revised: October 27, 2004

CONFIDENTIAL LOAN PROPOSAL FOR

# **Vical Incorporated**

## Vical Incorporated

Mr. Vijay B. Samant President and CEO Ms. Jill M. Church Vice President, Chief Financial Officer Mr. Glen E. Medwid Executive Director and Controller Vical Incorporated 10390 Pacific Center Court San Diego, CA 92121

## Dear Vijay, Jill, and Glen:

General Electric Capital Corporation ("GE Capital") has reviewed the information provided by you in connection with the requested financing for **Vical Incorporated** (referred to as "Vical" or the "Company"). Based on the review to date and subject to the timely receipt of a signed copy of this proposal letter as indicated below, GE Capital is pleased to consider arranging and providing a **\$8,500,000** financing (the "Financing") as outlined in the attached Term Sheet incorporated herein by reference, subject to the general terms and conditions in this proposal letter and the Term Sheet.

GE Capital is one of the largest and most diversified financial service companies in the world with assets exceeding \$300 billion and operations in over 45 countries. We have been actively providing equipment financing for Life Science companies for over a decade. It is our privilege to be a financial partner to hundreds of Life Science companies.

This proposal letter, including the attached Term Sheet, is being provided to the Company on a confidential basis and is merely an indication of interest regarding the Financing transaction on the general terms and conditions outlined herein and should not be construed as a commitment. GE Capital may change the terms of this proposal or cease future consideration of the Financing at any time without liability to GE Capital. The attached Term Sheet does not purport to summarize all of the terms and conditions upon which the overall facilities are to be based, which terms and conditions would be contained fully in final documentation, and indicates only the principal terms and conditions under which the overall financing will be considered.

Company agrees not to utilize this proposal to solicit other offers or to modify, renegotiate or otherwise improve the terms and conditions of any other offer heretofore or hereafter received by the Company. Notwithstanding the foregoing, there is no restriction (either express or implied) on any disclosure or dissemination of the United States federal income tax structure or aspects of the transactions contemplated by this proposal or of any documents executed pursuant hereto. Further, each party hereto acknowledges that it has no proprietary rights to any United States federal income tax elements of this proposal or of the structure contemplated hereby. In addition, none of such persons shall, except as required by law, use the name of, or refer to GE Capital, in any correspondence, discussions, advertisement, press release or disclosure made in connection with the financing without the prior written consent of GE Capital.

By signing below, the Company acknowledges the terms and conditions of this proposal and agrees to pay a Good Faith Deposit of \$42,500. Upon receipt of the executed proposal letter and accompanying Deposit, GE Capital shall commence the investment and credit approval process. If this proposal is approved and accepted by GE Capital, the Good Faith Deposit will be applied to the first rental payment for each funding on a pro rata basis with any unutilized Deposit remaining at the end of the Anticipated Funding Period to be retained by GE Capital as a non-utilization fee. In the

CONFIDENTIAL GE Capital Corporation Life Science Finance

## Vical Incorporated

event the transaction represented by this proposal and any amendment to it is not approved by GE Capital, the Good Faith Deposit (less the cost of credit verification and investigation and any out of pocket expenses incurred such as appraisal fees, legal fees, etc.) shall be promptly returned. Before funding can take place, all proper documentation of title and UCC release from other lenders must be in place and approved by GE Capital.

We thank you for your consideration and look forward to working with you toward completing this transaction.

	Term Sheet
Transaction:	Loan
Borrower:	Vical Incorporated
Lender:	General Electric Capital Corporation, its affiliates or its assignee ("GE Capital")
Loan Amount:	Up to \$8,500,000.
Equipment:	Lab, scientific, and computer equipment, FF&E, and soft cost, per the Company's equipment lists and the attached Addendum A. All equipment must be acceptable to GE Capital and located at Company owned or leased facilities within the continental United States. All equipment will be free and clear of other liens, claims, and encumbrances.
Loan Term and Payment:	<u>Equipment previously-financed by Bank of America (1/1/04 and subsequent) (~ \$2.2MM)</u> : To be combined on one schedule. 33 monthly payments of Principal and Interest @ 3.16081% of financed cost, paid monthly in arrears for each loan schedule, full payout. (3.00% all-in rate)
	<u>Newly-purchased Computer equipment and soft cost (~ \$2.4MM)</u> : 36 payments of Principal and Interest @ 2.90812% of financed cost, paid monthly in arrears for each loan schedule, full payout. (3.00% all-in rate)
	<u>All other newly-purchased equipment (~ \$3.9MM)</u> : 48 payments of Principal and Interest @ 2.22229% of financed cost, paid monthly in arrears for each loan schedule. (3.20% all-in rate.)
Anticipated Funding Period:	November 1, 1004 through October 31, 2005.
Line Mechanics:	Minimum loan fundings will be \$100,000 with no more than one funding per month. (Equipment with different terms may be combined on any schedule.)

CONFIDENTIAL GE Capital Corporation Life Science Finance

3

10/27/04

Vical Incorporated	
	With the exception of the previously-financed equipment, all equipment with invoice dates older than 90 days will be financed at appropriate discount.
	Amortization begins on the first of the month start date. Interim interest will be charged for the period between the funding date and the start date.
Security Deposit:	The Company will provide GE Capital with a non-interest-bearing cash security deposit equivalent to 60% of the financed cost on each schedule. This deposit will be reduced semi- annually (starting 1/1/05) to an amount equivalent to 60% of the remaining principal balance, with appropriate refunds made to the Company.
Covenant:	The financial covenant agreement (12/02) already in place (To wit: Company must maintain unrestricted cash, as defined, of the greater of \$45,000,000 or 12 months' cash needs) will be amended so that Company must maintain the greater of \$25,000,000 or 12 months' cash needs.
	The covenant will be additionally amended so that marketable securities with maturities of up to 36 months (subject to acceptable investment quality) will be considered 'unrestricted cash'.

## **GENERAL TERMS AND CONDITIONS**

Our proposal contains the following provisions and the Loan Payments we propose are specifically based upon these provisions and our assumptions.

- 1. <u>MAINTENANCE AND INSURANCE</u>: All maintenance and insurance (fire and theft, extended coverage and liability) are the responsibility of the Company. Company will be responsible for maintaining in force, all risk damage, and liability insurance in amounts and coverages satisfactory to GE Capital.
- 2. **DOCUMENTATION:** GE Capital's current standard loan documentation for this type of collateralized loan will be used. Any requested changes will be negotiated with GE Capital's internal counsel. (Most of the Company's master documents are already in place.)
- 3. **INDEXING**: The Interest Rate, Payment Factor and corresponding Loan Payments are based on the Federal Reserve 24-, 36and imputed 48-month Constant Maturities Rate (H.15/ "Treasury Rates") for October 4, 2004 (2.65%, 2.93%, and 3.185%, respectively) and will be adjusted effective as of the date of funding of any Financing. The adjustment will be basis-point-forbasis-point for any increase in comparable term treasuries and for any decrease after a 50 basis-point decline.
- 4. **TRANSACTION COSTS**: By execution and return of this proposal letter, the Company will be responsible for (i) all of its closing costs, (ii) all out of pocket fees and expenses incurred by GE

CONFIDENTIAL GE Capital Corporation Life Science Finance

#### Vical Incorporated

Capital in connection with the Financing under consideration including, without limitation, actual out-of-pocket expenses associated with engagement of outside counsel, UCC searches and filings costs, inspection and appraisal fees and similar costs, (iii) the Company will indemnify and hold harmless GE Capital and its affiliates, officers, directors, employees and agents (each a "Indemnified Person") against all claims, costs, damages, liabilities and expenses (each a "Claim") which may be incurred by or asserted against any of them in connection with this letter, the Financing, or the matters contemplated in this proposal letter, and will reimburse each Indemnified Person, upon demand, for any legal or other expenses incurred in connection with investigating, defending or participating in any Claim, or any action proceeding relating to such Claim, and (iv) the Company waives any right to a jury trial in any action or proceeding brought against GE Capital.

- 5. <u>ELECTRONIC PAYMENT SYSTEM</u>: GE Capital's standard payment collection method is through an electronic payment system. An enrollment form will be provided with Loan documentation. (Optional)
- 6. <u>CONFIDENTIALITY</u>: This proposal letter is being provided to the Company on a confidential basis. Except as required by law, neither this proposal nor its contents may be disclosed, except to individuals who are the Company's officers, employees or advisors who have a need to know of such matters and then only on the condition that such matters remain confidential. In addition, none of such persons shall, except as required by law, use the name of, or refer to GE Capital, in any correspondence, discussions, advertisement, press release or disclosure made in connection with the Financing without the prior written consent of GE Capital.
- 7 **EXPIRATION:** This proposal will expire 11/05/04 if not accepted prior to that date.

This proposal expresses GE Capital's willingness to seek internal approval for the transaction contemplated herein. By signing and returning this letter both parties acknowledge that: The above proposed terms and conditions do not constitute a commitment by GE Capital, (ii) GE Capital's senior management may seek changes to the above terms and conditions, and (iii) GE Capital may decline further consideration of this transaction at any point in the approval process. If a commitment were to be given it would be subject to and preceded by a completion of a legal and business due diligence, as well as collateral and credit review and analysis, all with results satisfactory to GE Capital and the closing of any financing would be conditioned upon the prior execution and delivery of final legal documentation and all conditions precedent acceptable to GE Capital and its counsel and no material adverse change in the business condition or prospects of the Company.

I would appreciate the opportunity to discuss this proposal with you at your earliest convenience. Please do not hesitate to contact me at (408) 986-6886 if you have any questions or if I can be of other assistance.

Sincerely,	PROPOSAL ACCEPTED BY:			
	Vical In	l Incorporated		
Barbara Kaiser	Name:	/s/ Vijay B. Samant		
SVP, Sales	Title:	Vijay B. Samant President and CEO		
	Date:			
CONFIDENTIAL GE Capital Corporation Life Science Finance	5		10/27/04	

## Addendum A

## Expected Equipment Composition (by end of term):

Category		Amount	Per	centage
Lab, scientific, & manufacturing equipment	3	\$4,380,000	3	52%
Computer and networking equipment	£	525,000	£	6%
Lab and office furniture, office equipment & similar	£	70,000	£	1%
Soft Cost (TIs, software, GMP validation, tax, freight, & similar, as below):	£	3,525,000	£	41%
Total		\$8,500,000		100%

a) Soft Cost to include remaining TIs for the manufacturing facility (~ \$1.5MM); software and implementation (~ \$570K), external costs of GMP validation of facility and equipment (~ \$1.1MM), tax, freight, and similar (~ \$355K).

b) All other equipment is represented to be "off-the-shelf, non-custom equipment".

CONFIDENTIAL GE Capital Corporation Life Science Finance 6

10/27/04

## AUTHORIZATION FOR RELEASE

## **OF INFORMATION**

The undersigned hereby authorizes past and present depositing institutions, creditors, vendors and suppliers of the undersigned to provide such information pertaining to any loans, leases, lines of credit, account balances, and payment histories of the undersigned to General Electric Capital Corporation as it may request.

## Vical Incorporated

By: /s/ Vijay B. Samant

Vijay B. Samant Title: President and CEO

Date: 11/5/04

CONFIDENTIAL GE Capital Corporation Life Science Finance 7

10/27/04

11/98

## MASTER SECURITY AGREEMENT

dated as of December 15, 2000 ("Agreement")

THIS AGREEMENT is between General Electric Capital Corporation (together with its successors and assigns, if any, "Secured Party"), and VICAL INCORPORATED ("Debtor"). Secured Party has an office at 5150 EI Camino Real, Suite B-21, Los Altos, CA 94022. Debtor is a corporation organized and existing under the laws of the state of Delaware. Debtor's mailing address and chief place of business is 9373 Towne Centre Drive, Suite 100, San Diego, CA 92121.

#### 1. CREATION OF SECURITY INTEREST.

Debtor grants to Secured Party, its successors and assigns, a security interest in and against all property listed on any collateral schedule now or in the future annexed to or made a part of this Agreement ("Collateral Schedule"), and in and against all additions, attachments, accessories and accessions to such property, all substitutions, replacements or exchanges therefor, and all insurance and/or other proceeds thereof (all such property is individually and collectively called the "Collateral"). This security interest is given to secure the payment and performance of all debts, obligations and liabilities of any kind whatsoever of Debtor to Secured Party, now existing or arising in the future, including but not limited to the payment and performance of certain Promissory Notes from time to time identified on any Collateral Schedule (collectively "Notes" and each a "Note"), and any renewals, extensions and modifications of such debts, obligations and liabilities (such Notes, debts, obligations and liabilities are called the "Indebtedness"). Notwithstanding anything to the contrary contained in this Agreement, to the extent that Secured Party asserts a purchase money security interest in any items of Collateral ("PMSI Collateral"): (i) the PMSI Collateral shall secure only that portion of the Indebtedness"), and (ii) no other Collateral shall secure the PMSI Indebtedness.

#### 2. REPRESENTATIONS, WARRANTIES AND COVENANTS OF DEBTOR.

Debtor represents, warrants and covenants as of the date of this Agreement and as of the date of each Collateral Schedule that;

(a) Debtor is, and will remain, duly organized, existing and in good standing under the laws of the State set forth in the preamble of this Agreement, has its chief executive offices at the location specified in the preamble, and is, and will remain, duly qualified and licensed in every jurisdiction wherever necessary to carry on its business and operations;

(b) Debtor has adequate power and capacity to enter into, and to perform its obligations under this Agreement, each Note and any other documents evidencing, or given in connection with, any of the Indebtedness (all of the foregoing are called the **"Debt Documents"**);

(c) This Agreement and the other Debt Documents have been duly authorized, executed and delivered by Debtor and constitute legal, valid and binding agreements enforceable in accordance with their terms, except to the extent that the enforcement of remedies may be limited under applicable bankruptcy and insolvency laws;

(d) No approval, consent or withholding of objections is required from any governmental authority or instrumentality with respect to the entry into, or performance by Debtor of any at the Debt Documents, except any already obtained;

(e) The entry into, and performance by, Debtor of the Debt Documents will not (i) violate any of the organizational documents of Debtor or any judgment, order, law or regulation applicable to Debtor, or (ii) result in any breach of or constitute a default under any contract to which Debtor is a party, or result in the creation of any lien, claim or encumbrance on any of Debtor's property (except for liens in favor of Secured Party) pursuant to any indenture, mortgage, deed of trust, bank loan, credit agreement, or other agreement or instrument to which Debtor is a party;

(f) There are no suits or proceedings pending in court or before any commission, board or other administrative agency against or affecting Debtor which could, in the aggregate, have a material adverse effect on Debtor, its business or operations, or its ability to perform its obligations under the Debt Documents, nor does Debtor have reason in believe that any such suits or proceedings are threatened;

(g) All financial statements delivered to Secured Party in connection with the Indebtedness have been prepared in accordance with generally accepted accounting principles, and since the date of the most recent financial statement, there has been no material adverse change in Debtors financial condition;

(h) The Collateral is not, and will not be, used by Debtor for personal, family or household purposes;

(i) The Collateral is, and will remain, in good condition and repair and Debtor will not be negligent in its care and use;

(j) Debtor is, and will remain, the sole and lawful owner, and in possession of, the Collateral, and has the sole right and lawful authority to grant the security interest described in this Agreement; and

(k) The Collateral is, and will remain, free and clear of all liens, claims and encumbrances of any kind whatsoever, except for (i) liens in favor of Secured Party, (ii) liens for taxes not yet due or for taxes being contested in good faith and which do not involve, in the judgment of Secured Party, any risk of the sale, forfeiture or loss of any of the Collateral, and (iii) inchoate materialmen's, mechanic's, repairmen's and similar liens arising by operation of law in the normal course of business for amounts which are not delinquent (all of such liens are called "**Permitted Liens**").

## 3. COLLATERAL.

(a) Until the declaration of any default, Debtor shall remain in possession of the Collateral; except that Secured Party shall have the right to possess (i) any chattel paper or instrument that constitutes a part of the Collateral, and (ii) any other Collateral in which Secured Party's security interest may be perfected only by possession. Secured Party may inspect any of the Collateral during normal business hours after giving Debtor reasonable prior notice. If Secured Party asks, Debtor will promptly notify Secured Party in writing of the location of any Collateral.

(b) Debtor shall (i) use the Collateral only in its trade or business, (ii) maintain all of the Collateral in good operating order and repair, normal wear and tear excepted, (iii) use and maintain the Collateral only in compliance with manufacturers recommendations and all applicable laws, and (iv) keep all of the Collateral free and clear of all liens, claims and encumbrances (except for Permitted Liens).

(c) Debtor shall not, without the prior written consent of Secured Parry, (i) part with possession of any of the Collateral (except to Secured Party or for maintenance and repair), (ii) remove any of the Collateral from the continental United States, or (iii) sell, rent, lease, mortgage, grant a security interest in or otherwise transfer or encumber (except for Permitted Liens) any of the Collateral.

(d) Debtor shall pay promptly when due all taxes, license fees, assessments and public and private charges levied or assessed on any of the Collateral, on its use, or on this Agreement or any of the other Debt Documents. At its option, Secured Party may discharge taxes, liens, security interests or other encumbrances at any time levied or placed on the Collateral and may pay for the maintenance, insurance and preservation of the Collateral and effect compliance with the terms of this Agreement or any of the other Debt Documents. Debtor agrees to reimburse Secured Party, on demand, all costs and expenses incurred by Secured Party in connection with such payment or performance and agrees that such reimbursement obligation shall constitute Indebtedness.

(e) Debtor shall, at all times, keep accurate and complete records of the Collateral, and Secured Party shall have the right to inspect and make copies of all of Debtor's books and records relating to the Collateral during normal business hours, after giving Debtor reasonable prior notice.

(f) Debtor agrees and acknowledges that any third person who may at any time possess all or any portion of the Collateral shall be deemed to hold, and shall hold, the Collateral as the agent of, and as pledge holder for, Secured Party. Secured Party may at any time give notice to any third person described in the preceding sentence that such third person is holding the Collateral as the agent of, and as pledge holder for, the Secured Party.

#### 4. INSURANCE.

(a) Debtor shall at all times bear the entire risk of any loss, theft, damage to, or destruction of, any of the Collateral from any cause whatsoever.

(b) Debtor agrees to keep the Collateral insured against loss or damage by fire and extended coverage perils, theft, burglary, and for any or all Collateral which are vehicles, for risk of loss by collision, and if requested by Secured Party, against such other risks as Secured Party may reasonably require. The insurance coverage shall be in an amount no less than the full replacement value of the Collateral, and deductible amounts, insurers and policies shall be acceptable to Secured Party. Debtor shall deliver to Secured Party policies or certificates of insurance evidencing such coverage. Each policy shall name Secured Party as a loss payee, shall provide for coverage to Secured Party regardless of the breach by Debtor of any warranty or representation made therein, shall not be subject to co-insurance, and shall provide that coverage may not be canceled or altered by the insurer except upon thirty (30) days prior written notice to Secured Party. Debtor appoints Secured Party as its attorney-in-fact to make proof of loss, claim for insurance and adjustments with insurers, and to receive payment of and execute or endorse all documents, checks or drafts in connection with insurance payments. Secured Party shall not act as Debtors attorney-in-fact unless Debtor is in default. Proceeds of insurance shall be applied, at the option of Secured Party, to repair or replace the Collateral or to reduce any of the Indebtedness.

## 5. REPORTS.

(a) Debtor shall promptly notify Secured Party of (i) any change in the name of Debtor, (ii) any relocation of its chief executive offices, (iii) any relocation of any of the Collateral, (iv) any of the Collateral being lost, stolen, missing, destroyed, materially damaged or worn out, or (v) any lien, claim or encumbrance other than Permitted Liens attaching to or being made against any of the Collateral.

(b) Debtor will deliver to Secured Party Debtors complete financial statements, certified by a recognized firm of certified public accountants, within ninety (90) days of the close of each fiscal year of Debtor. If Secured Party requests, Debtor will deliver to Secured Party copies of Debtors quarterly financial reports certified by Debtors chief financial officer, within ninety (90) days after the close of each of Debtors fiscal quarter. Debtor will deliver to Secured Party copies of all Forms 10-K and 10-Q, if any, within 30 days after the dates on which they are filed with the Securities and Exchange Commission.

#### 6. FURTHER ASSURANCES.

(a) Debtor shall, upon request of Secured Party, furnish to Secured Party such further information, execute and deliver to Secured Party such documents and instruments (including, without limitation, Uniform Commercial Code financing statements) and shall do such other acts and things as Secured Party may at any time reasonably request relating to the perfection or protection of the security interest created by this Agreement or for the purpose of carrying out the intent of this Agreement. Without limiting the foregoing, Debtor shall cooperate and do all acts deemed necessary or advisable by Secured Party to continue in Secured Party a perfected first security interest in the Collateral, and shall obtain and furnish to Secured Party any subordinations, releases, landlord, lessor, or mortgagee waivers, and similar documents as may be from time to time requested by, and in form and substance satisfactory to, Secured Party.

(b) Debtor irrevocably grants to Secured Party the power to sign Debtor's name and generally to act on behalf of Debtor to execute and file applications for title, transfers of title, financing statements, notices of lien and other documents pertaining to any or all of the Collateral; this power is coupled with Secured Party's interest in the Collateral. Debtor shall, if any certificate of title be required or permitted by law for any of the Collateral, obtain and promptly deliver to Secured Party such certificate showing the lien of this Agreement with respect to the Collateral.

(c) Debtor shall indemnify and defend the Secured Party, its successors and assigns, and their respective directors, officers and employees, from and against all claims, actions and suits (including, without limitation, related attorneys' fees) of any kind whatsoever arising, directly or indirectly, in connection with any of the Collateral.

#### 7. DEFAULT AND REMEDIES.

(a) Debtor shall be in default under this Agreement and each of the other Debt Documents if:

(i) Debtor breaches its obligation to pay when due any installment or other amount due or coming due under any of the Debt Documents;

(ii) Debtor, without the prior written consent of Secured Party, attempts to or does sell, rent, lease, mortgage, grant a security interest in, or otherwise transfer or encumber (except for Permitted Liens) any of the Collateral;

(iii) Debtor breaches any of its insurance obligations under Section 4;

(iv) Debtor breaches any of its other obligations under any of the Debt Documents and fails to cure that breach within thirty (30) days after written notice from Secured Party;

(v) Any warranty, representation or statement made by Debtor in any of the Debt Documents or otherwise in connection with any of the Indebtedness shall be false or misleading in any material respect;

(vi) Any of the Collateral is subjected to attachment, execution, levy, seizure or confiscation in any legal proceeding or otherwise, or if any legal or administrative proceeding is commenced against Debtor or any of the Collateral, which in the good faith judgment of Secured Party subjects any of the Collateral to a material risk of attachment, execution, levy, seizure or confiscation and no bond is posted or protective order obtained to negate such risk;

(vii) Debtor breaches or is in default under any other agreement between Debtor and Secured Party;

(viii) Debtor or any guarantor or other obligor for any of the Indebtedness (collectively "Guarantor") dissolves, terminates its existence, becomes insolvent or ceases to do business as a going concern;

(ix) If Debtor or any Guarantor is a natural person, Debtor or any such Guarantor dies or becomes incompetent;

(x) A receiver is appointed for all or of any part of the property of Debtor or any Guarantor, or Debtor or any Guarantor makes any assignment for the benefit of creditors; or

(xi) Debtor or any Guarantor files a petition under any bankruptcy, insolvency or similar law, or any such petition is filed against Debtor or any Guarantor and is not dismissed within forty-five (45) days.

(b) If Debtor is in default, the Secured Party, at its option, may declare any or all of the Indebtedness to be immediately due and payable, without demand or notice to Debtor or any Guarantor. The accelerated obligations and liabilities shall bear interest (both before and after any judgment) until paid in full at the lower of eighteen percent (18%) per annum or the maximum rate not prohibited by applicable law.

(c) After default, Secured Party shall have all of the rights and remedies of a Secured Party under the Uniform Commercial Code, and under any other applicable law. Without limiting the foregoing, Secured Party shall have the right to (i) notify any account debtor of Debtor or any obligor on any instrument which constitutes part of the Collateral to make payment to the Secured Party, (ii) with or without legal process, enter any premises where the Collateral may be and take possession of and remove the Collateral from the premises or store it on the premises, (iii) sell the Collateral at public or private sale, in whole or in part, and have the right to bid and purchase at said sale, or (iv) lease or otherwise dispose of all or part of the Collateral and make it available to Secured Party at a place to be designated by Secured Party, Debtor shall promptly assemble the Collateral and make it available to Secured Party at a place to be designated by Secured Party which is reasonably convenient to both parties. Secured Party may also render any or all of the Collateral unusable at the Debtor's premises and may dispose of such Collateral on such premises without liability for rent or costs. Any notice that Secured Party is required to give to Debtor under the Uniform Commercial Code of the time and place of any public sale or the time after which any private sale or other intended disposition of the Collateral is to be made shall be deemed to constitute reasonable notice if such notice is given to the last known address of Debtor at least five (5) days prior to such action.

(d) Proceeds from any sale or lease or other disposition shall be applied: first, to all costs of repossession, storage, and disposition including without limitation attorneys', appraisers', and auctioneers' fees; second, to discharge the obligations then in default; third, to discharge any other Indebtedness of Debtor to Secured Party, whether as obligor, endorser, guarantor, surety or indemnitor; fourth, to expenses incurred in paying or settling liens and claims against the Collateral; and lastly, to Debtor, if there exists any surplus. Debtor shall remain fully liable for any deficiency.

(e) Debtor agrees to pay all reasonable attorneys' fees and other costs incurred by Secured Party in connection with the enforcement, assertion, defense or preservation of Secured Party's rights and remedies under this Agreement, or if prohibited by law, such lesser sum as may be permitted. Debtor further agrees that such fees and costs shall constitute Indebtedness.

(f) Secured Party's rights and remedies under this Agreement or otherwise arising are cumulative and may be exercised singularly or concurrently. Neither the failure nor any delay on the part of the Secured Party to exercise any right, power or privilege under this Agreement shall operate as a waiver, nor shall any single or partial exercise of any right, power or privilege preclude any other or further exercise of that or any other right, power or privilege. SECURED PARTY SHALL NOT BE DEEMED TO HAVE WAIVED ANY OF ITS RIGHTS UNDER THIS AGREEMENT OR UNDER ANY OTHER AGREEMENT, INSTRUMENT OR PAPER SIGNED BY DEBTOR UNLESS SUCH WAIVER IS EXPRESSED IN WRITING AND SIGNED BY SECURED PARTY. A waiver on any one occasion shall not be construed as a bar to or waiver of any right or remedy on any future occasion.

(g) DEBTOR AND SECURED PARTY UNCONDITIONALLY WAIVE THEIR RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER DEBT DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS BETWEEN DEBTOR AND SECURED PARTY RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED BETWEEN DEBTOR AND SECURED PARTY. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT. ANY OTHER DEBT DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

#### 8. MISCELLANEOUS.

(a) This Agreement, any Note and/or any of the other Debt Documents may be assigned, in whole or in part, by Secured Party without notice to Debtor, and Debtor agrees not to assert against any such assignee, or assignee's assigns, any defense, set-off, recoupment claim or counterclaim which Debtor has or may at any time have against Secured Party for any reason whatsoever. Debtor agrees that if Debtor receives written notice of an assignment from Secured Party, Debtor will pay all amounts payable under any assigned Debt Documents to such assignee or as instructed by Secured Party. Debtor also agrees to confirm in writing receipt of the notice of assignment as may be reasonably requested by assignee.

(b) All notices to be given in connection with this Agreement shall be in writing, shall be addressed to the parties at their respective addresses set forth in this Agreement (unless and until a different address may be specified in a written notice to the other party), and shall be deemed given (i) on the date of receipt if delivered in hand or by facsimile transmission, (ii) on the next business day after being sent by express mail, and (iii) on the fourth business day after being sent by regular, registered or certified mail. As used herein, the term "business day" shall mean and include any day other than Saturdays, Sundays, or other days on which commercial banks in New York, New York are required or authorized to be closed.

(c) Secured Party may correct patent errors and fill in all blanks in this Agreement or in any Collateral Schedule consistent with the agreement of the parties.

(d) Time is of the essence of this Agreement. This Agreement shall be binding, jointly and severally, upon all parties described as the "Debtor" and their respective heirs, executors, representatives, successors and assigns, and shall inure to the benefit of Secured Party, its successors and assigns.

(e) This Agreement and its Collateral Schedules constitute the entire agreement between the parties with respect to the subject matter of this Agreement and supersede all prior understandings (whether written, verbal or implied) with respect to such subject matter. THIS AGREEMENT AND ITS COLLATERAL SCHEDULES SHALL NOT BE CHANGED OR TERMINATED ORALLY OR BY COURSE OF CONDUCT, BUT ONLY BY A WRITING SIGNED BY BOTH PARTIES. Section headings contained in this Agreement have been included for convenience only, and shall not affect the construction or interpretation of this Agreement.

(f) This Agreement shall continue in full force and effect until all of the Indebtedness has been indefeasibly paid in full to Secured Party. The surrender, upon payment or otherwise, of any Note or any of the other documents evidencing any of the Indebtedness shall not affect the right of Secured Party to retain the Collateral for such other Indebtedness as may then exist or as it may be reasonably contemplated will exist in the future. This Agreement shall automatically be reinstated if Secured Party is ever required to return or restore the payment of all or any portion of the Indebtedness (all as though such payment had never been made).

(g) THIS AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF CONNECTICUT (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE EQUIPMENT.

**IN WITNESS WHEREOF,** Debtor and Secured Party, intending to be legally bound hereby, have duly executed this Agreement in one or more counterparts, each of which shall be deemed to be an original, as of the day and year first aforesaid.

SECURED PARTY:

DEBTOR:

General Electric Capital Corporation		VICAL INCORPORATED	
By:	/s/ Barbara B. Kaiser	By:	/s/ MARTHA J. DEMSKI
Name:	Barbara B. Kaiser	Name:	MARTHA J. DEMSKI
Title:	EVP/General Manager	Title:	VICE PRESIDENT/CFO

## CROSS-COLLATERAL AND CROSS-DEFAULT AGREEMENT

General Electric Capital Corporation and LMSI Venture Finance, a division of Phoenixcor, Inc. 5150 El Camino Real, Suite B-21 Los Altos, CA 94022

#### Ladies and Gentlemen:

Reference is made to the following (collectively, the "Accounts"): (a) Master Security Agreement dated December 15, 2000 between V1CAL INCORPORATED ("Debtor") and General Electric Capital Corporation and all related promissory notes, collateral schedules and other documents and (b) Equipment Financing Agreement # 10711 dated October 23, 1900 between Debtor and LMSI Venture Finance, a division of Phoenixcor, Inc. and all related schedules and other documents, all of the foregoing whether now existing or hereafter created. General Electric Capital Corporation and LMSI Venture Finance, a division of Phoenixcor, Inc. are herein individually and collectively referenced to as "Secured Party". Reference is further made to the equipment and other property (the "Collateral") described in or securing the Accounts. In consideration of Secured Party extending additional credit or other consideration to Debtor, the receipt of which is hereby acknowledged. Debtor agrees that all Accounts shall be cross-defaulted and cross-collateralized to the maximum extent possible. Accordingly:

1. Debtor agrees that a default by Debtor under any Account which continues beyond the period of grace, if any, provided therein unless such default has been waived shall constitute an additional event of default under all other Accounts.

2. All presently existing and hereafter acquired Collateral shall secure the payment and performance of all of Debtor's liabilities and obligations to Secured Party of every kind and character, whether joint or several, direct or indirect, absolute or contingent, due or to become due, and whether under presently existing or hereafter created Accounts or otherwise. Debtor further agrees that Secured Party's security interest in the Collateral covered by any Account now held or hereafter acquired by Secured Party shall not be terminated in whole or in part until and unless all indebtedness of every kind, due or to become due, owed by Debtor to Secured Party is fully paid and satisfied. It is further agreed that Secured Party is to retain Secured Party's security interest in all Collateral covered by all Accounts held or acquired by Secured Party, as security for payment and performance under each such Account, notwithstanding the fact that one or more of such Accounts may become fully paid.

3. All rights granted to Secured Party hereunder shall be in addition to and shall in no manner impair or affect Debtor's obligations and Secured Party's rights and remedies under any existing Account, agreement, statute or rule of law.

This Agreement shall run to the benefit of Secured Party's successors and assigns.

Anything above to the contrary notwithstanding, the benefit of the foregoing cross collateral provisions shall apply to the benefit of the Secured Party and any successors or assigns holding an Account (or one or more schedules referenced therein) only to the extent that the Secured Party or such successor or assign is also the holder of another Account (or schedule).

IN WITNESS WHEREOF, this Agreement is executed this <u>12th</u> day of <u>December</u>, 2000

#### VICAL INCORPORATED

By:	/s/ MARTHA J. DEMSKI
Title:	MARTHA J. DEMSKI VICE PRESIDENT/CFO

Acknowledged and Agreed this  $\underline{12^{\pm}}$  day of <u>December</u>, 2000:

#### General Electric Capital Corporation

- By: /s/ Barbara B. Kaiser
- Title: EVP/ General Manager

#### LMSI Venture Finance, a division of Phoenixcor, Inc.

- By: /s/ Barbara B. Kaiser
- Title: EVP/General Manager

## ADDITIONAL COLLATERAL RIDER

This Additional Collateral Rider (this "Rider") is part of that certain Master Security Agreement dated December 15, 2000, and all Collateral Schedules thereto (collectively the "Contract") between **GENERAL ELECTRIC CAPITAL CORPORATION** (the "Secured Party") and **VICAL INCORPORATED** ("Debtor"). Unless otherwise defined herein, all capitalized terms used in this Rider have the meanings set forth in the Contract.

1. As security for the full and faithful performance by Debtor of all of the Indebtedness as defined in the Contract and all other obligations of Debtor to Secured Party now or hereafter in existence, Debtor does hereby grant to Secured Party a security interest in all of Debtor's right, title and interest in and to the following (all hereinafter collectively called the "Additional Collateral"):

All equipment (except computer equipment) and other personal property previously financed under Equipment Financing Agreement #10711, Schedules #20 and subsequent, between Debtor and LMSI Venture Finance, a division of Phoenixcor, Inc., together with all accessories, parts, upgrades, renewals and replacements of, and repairs, improvements and accessions to the equipment assets and any insurance proceeds or revenue derived from the sale or other disposition of the equipment. The foregoing property also secures Secured Party. This lien will stay in effect until all of Debtor's obligations under this new financing are fulfilled.

2. In the event of a default by Debtor under the Contract or under any other obligation to Secured Party, Secured Party shall have all of the rights and remedies of a secured party under the Code with respect to the Additional Collateral in addition to any other rights which it may have under the Contract. Debtor shall have the same obligations with respect to the portion of the Additional Collateral constituting Equipment as it has under the Contract with respect to the Collateral financed under the Contract, including but not limited to the restrictions on moving, transferring, encumbering or giving up possession of, and the obligation to insure, such Additional Collateral constituting Equipment.

3. This agreement shall run to the benefit of Secured Party's successors and assigns. Except as expressly modified hereby, all of the terms and provisions of the Contract shall remain in full force and effect.

IN WITNESS WHEROF, the parties have executed this Rider simultaneously with the Master Security Agreement.

Dated: 12/12/00

## GENERAL ELECTRIC CAPITAL CORPORATION

BY: /s/ Barbara B. Kaiser

## VICAL INCORPORATED

BY: /s/ MARTHA J. DEMSKI

TITLE:: EVP/General Manager

MARTHA J. DEMSKI TITLE:: VICE PRESIDENT/CFO

## AMENDMENT

THIS AMENDMENT is made as of the 15th day of December, 2000, between General Electric Capital Corporation ("Secured Party") and VICAL INCORPORATED ("Debtor") in connection with that certain Master Security Agreement, dated or dated as of December 15, 2000 ("Agreement"). The terms of this Amendment are hereby incorporated into the Agreement as though fully set forth therein. Section references below refer to the section numbers of the Agreement. The Agreement is hereby amended as follows:

## 3. <u>COLLATERAL.</u>

Subsection (c) is hereby amended and replaced with the following:

"(c) Debtor shall not, without the prior written consent of Secured Party, (i) part with possession of any of the Collateral (except to Secured Party or for maintenance and repair), (ii) remove any of the Collateral from the address specified in the Collateral Schedule, or (iii) sell, rent, lease, mortgage, grant a security interest in or otherwise transfer or encumber (except for Permitted Liens) any of the Collateral."

## 5. <u>REPORTS.</u>

Section 5 is hereby amended and replaced with the following:

## 5. REPORTS.

(a) Debtor shall promptly notify Secured Party of (i) any change in the name of Debtor, (ii) any relocation of its chief executive offices or its state of organization, (iii) any relocation of any of the Collateral, which relocation may not be made unless Debtor has obtained the prior written consent of Secured Party, (iv) any of the Collateral being lost, stolen, missing, destroyed, materially damaged or worn out, or (v) any lien, claim or encumbrance other than Permitted Liens attaching to or being made against any of the Collateral.

(b) Debtor will deliver to Secured Party financial statements as follows. If Debtor is a privately held company, then Debtor agrees to provide monthly financial statements, certified by Debtor's president or chief financial officer including a balance sheet, statement of operations and cash flow statement within 30 days of each month end and its complete audited annual financial statements, certified by a recognized firm of certified public accountants, within 120 days of fiscal year end or at such time as Debtor's Board of Directors receives the audit. If Debtor is a publicly held company, then Debtor agrees to provide quarterly and annual audited statements, certified by a recognized firm of certified public accountants, within 10 days after the statements are provided to the Securities and Exchange Commission ("SEC"). All such statements are to be prepared using generally accepted accounting principles ("GAAP") and, if Debtor is a publicly held company, are to be in compliance with SEC requirements."

## 7. DEFAULT AND REMEDIES.

Section 7(a)(viii) is hereby amended and replaced with the following:

(viii) Debtor or any guarantor or other obligor for any of the Indebtedness (collectively "Guarantor") dissolves. Terminates its existence, becomes insolvent, ceases to do business as a going concern, or, without the prior written consent of Secured Party, (A) Debtor sells all or substantially all of its assets, or sells assets which constitute, or are an integral part of, the primary intellectual property of Debtor, or sells all or substantially all of the assets of the division of Debtor purchasing or using the Collateral, if applicable, or (B) Debtor becomes a party to any consolidation or merger where the Debtor is not the surviving entity, or (C) the current stockholders of Debtor sell or transfer more than 50% of the outstanding voting stock of Debtor, or, (D) if Debtor is a publicly held company, any person or group of persons (within the meaning of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) shall have acquired beneficial ownership (within the meaning of Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act) of 20% or more of the outstanding voting stock of Debtor:

TERMS USED, BUT NOT OTHERWISE DEFINED HEREIN SHALL HAVE THE MEANINGS GIVEN TO THEM IN THE AGREEMENT. EXCEPT AS EXPRESSLY AMENDED HEREBY, THE AGREEMENT SHALL REMAIN IN FULL FORCE AND EFFECT. IF THERE IS ANY CONFLICT BETWEEN THE PROVISIONS OF THE AGREEMENT AND THIS AMENDMENT, THEN THIS AMENDMENT SHALL CONTROL.

**IN WITNESS WHEREOF,** the parties hereto have executed this Amendment simultaneously with the Agreement by signature of their respective authorized representative set forth below.

General Electric Capital Corporation		VICAI	VICAL INCORPORATED		
By:	/s/ Barbara B. Kaiser	By:	/s/ MARTHA J. DEMSKI		
Name:	Barbara B. Kaiser	Name:	MARTHA J. DEMSKI		
Title:	EVP/General Manager	Title:	VICE PRESIDENT/CFO		

## FINANCIAL COVENANTS ADDENDUM NO. 001 TO MASTER SECURITY AGREEMENT DATED AS OF December 15, 2000

THIS ADDENDUM (this "Addendum") amends and supplements the above referenced agreement (the "Agreement"), between General Electric Capital Corporation (together with its successors and assigns, if any, "Secured Party") and Vical Incorporated ("Debtor") and is hereby incorporated into the Agreement as though fully set forth therein. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Note and Security Agreement.

The Agreement is hereby amended by adding the following:

#### FINANCIAL COVENANTS.

(a) Debtor shall, at all times during the term of the Agreement, comply with the following:

Maintain minimum Unrestricted Cash (as defined below) at the greater of (1) \$45,000,000 or (2) an amount equal to twelve (12) months of Cash Needs (as defined below). If this covenant is violated, Debtor will provide Secured Party within ten (10) days of such occurrence an irrevocable letter of credit equal to 100% of the remaining principal balance under the new line of credit approved in November 2002 and the extended portion of the prior line of credit with the exception of up to \$400,000 to be funded prior to December 31,2002. The form of letter of credit and the bank upon which it is drawn must be acceptable to Secured Party.

Unrestricted Cash shall be defined as cash on hand plus investments in marketable securities with maturities of less than fourteen (14) months, excluding (i) cash pledged to other parties and any contingent liability associated with similar cash covenants under leases, loans or other financial arrangements and (ii) all long-term debt not owed to or subordinated to Secured Party.

Cash Needs shall be defined as cash burn for the immediately preceding three (3) months multiplied by a factor of 4.0

(b) COMPLIANCE REPORTS. Debtor's Authorized Representative shall certify that Debtor is in compliance with the requirements of subsection (a) above. Such notification and certification shall be provided within thirty (30) days after the end of each fiscal month (the "Compliance Date"), reflecting such information as of the end of such fiscal month. If Debtor fails timely to provide such notification and compliance certificates, within fifteen (15) days after the Compliance Date, such failure shall automatically be deemed a default under the Agreement without notice or other act by Secured Party. The reports required under this section are in addition to and not a substitute for the reports required under the REPORTS Section of the Agreement.

Except as expressly modified hereby, all terms and provisions of the Note and Security Agreement shall remain in full force and effect. This Addendum is not binding nor effective with respect to the Note and Security Agreement until executed on behalf of Secured Party and Debtor by authorized representatives of Secured Party and Debtor.

**IN WITNESS WHEREOF,** Debtor and Secured Party have caused this Addendum to be executed by their duly authorized representatives as of the date first above written.

Secure	d Party:	Debtor	:	
Genera	l Electric Capital Corporation	Vical I	ncorporated	
By:	/s/ Diane Hernandez	By:	/s/ MARTHA J. DEMSKI	
Name:	Diane Hernandez	Name:	MARTHA J. DEMSKI	
Title:	Vice President	Title:	VICE PRESIDENT/CFO	
		Attest		
		By:	/s/ Janilyn Cullins	
		Name:	Janilyn Cullins	

#### **AMENDMENT NO. 1**

to

## FINANCIAL COVENANTS ADDENDUM NO. 001 TO MASTER SECURITY AGREEMENT DATED AS OF DECEMBER 15, 2000

THIS AMENDMENT NO. 1 is made as of the  $9^{\pm}$  day of December 2004, between General Electric Capital Corporation ("Secured Party") and Vical Incorporated ("Debtor") in connection with that Financial Covenants Addendum No. 001 ("Addendum") to that certain Master Security Agreement, dated as of December 15, 2000 ("Agreement"). The terms of this Amendment No. 1 are hereby incorporated into the Addendum as though fully set forth therein. Secured Party and Debtor mutually desire to amend the Agreement as set forth below. Section references below refer to the section numbers of the Addendum. The Addendum is hereby amended as follows:

Section (a) is hereby amended and replaced with the following:

"(a) Debtor shall, at all times during the term of the Agreement, comply with the following:

Maintain minimum Unrestricted Cash (as defined below) at the greater of (i) \$25,000,000 or (ii) an amount equal to twelve (12) months of Cash Needs (as defined below). If this covenant is violated, Debtor will provide Secured Party within ten (10) days of such occurrence an irrevocable letter of credit equal to 100% of the remaining principal balance of all financings subsequent to 1/1/03. The form of letter of credit and the bank upon which it is drawn must be acceptable to Secured Party.

Unrestricted Cash shall be defined as cash on hand plus investments in marketable securities with maturities of less than or equal to thirty-six (36) months, subject to investment quality satisfactory to Secured Party, excluding (i) cash pledged to other parties and any contingent liability associated with similar cash covenants under leases, loans or other financial arrangements and (ii) all long-term debt not owed to or subordinated to Secured Party.

Cash Needs shall be defined as Cash Burn (as defined below) for the immediately preceding three (3) months multiplied by a factor of 4.0.

Cash Burn is defined as the sum of net income plus non-cash charges for the most recent 3 months ended divided by 3, minus current portions of long-term debt divided by 12."

TERMS USED, BUT NOT OTHERWISE DEFINED HEREIN SHALL HAVE THE MEANINGS GIVEN TO THEM IN THE ADDENDUM AND THE FINANCING AGREEMENT. EXCEPT AS EXPRESSLY AMENDED HEREBY, THE ADDENDUM SHALL REMAIN IN FULL FORCE AND EFFECT. IF THERE IS ANY CONFLICT BETWEEN THE PROVISIONS OF THE ADDENDUM AND THIS AMENDMENT NO. 1, THEN THIS AMENDMENT NO. 1 SHALL CONTROL.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 on December 16, 2004.

## GENERAL ELECTRIC CAPITAL CORPORATION

By: /s/ Diane Earle

Name: Diane Earle

Title: Senior Vice President

VICAL INCORPORATED

By: /s/ Jill M. Church

Name: Jill M. Church

Title: VP and CFO

#### SECURITY DEPOSIT PLEDGE AGREEMENT (Loan)

This Security Deposit Pledge Agreement (this "Agreement") is made and entered into as of the <u>9</u><sup>th</sup> day of December 2004, by and between Vical Incorporated, a Delaware corporation with its principal place of business at 10390 Pacific Center Court, San Diego, CA 92121 ("Debtor") and General Electric Capital Corporation, a Delaware corporation, with its principal place of business at 83 Wooster Heights Road, Danbury, CT 06810 ("Secured Party").

In consideration of, and as an inducement for Secured Party to lend funds to Debtor under the Master Security Agreement, dated as of December 15, 2000, and Collateral Schedule and Promissory Note #4124419-028 and subsequent, thereunder (the "Master Security Agreement and all Collateral Schedules and Promissory Notes thereto being referred to as the "Loan"), and to secure the payment and performance of all of Debtor's obligations under the Loan, Debtor hereby deposits and pledges with Secured Party a security deposit in the amount of sixty- percent (60.00%) of the loan amount financed on each Promissory Note (the "Deposit"). Such pledge to be upon the terms and conditions set forth below:

1. Debtor delivers the Deposit to Secured Party to secure Debtor's performance of its obligations under the Loan.

2. The Deposit deposited with Secured Party will not accrue interest. Secured Party may commingle the Deposit with its other funds.

3. Provided there has been no material adverse change in Debtor's operations that impacts its financial condition, Secured Party shall continuously reduce the security deposit to sixty percent (60.00%) of the aggregate outstanding principal balance of the associated Promissory Notes on a semi-annual basis, commencing January 1, 2005. Notwithstanding the foregoing, the Deposit shall not exceed the aggregate outstanding principal balance of the associated Promissory Notes at any time.

4. After any default by Debtor under the Loan and while the same is continuing, upon, or at any time after said default, Secured Party may apply the Deposit towards the satisfaction of Debtor's obligations under the Loan and the payment of all reasonable costs and expenses incurred by Secured Party as a result of such default, including but not limited to, reasonable costs of repossessing equipment and reasonable attorneys' fees. Such application shall not excuse the performance at the time and in the manner prescribed of any obligation of Debtor or cure a default of Debtor. Upon the application by Secured Party of any amount of the Deposit pursuant to the terms of this paragraph, Debtor shall be obligated to immediately deposit with Secured Party an amount sufficient to cause the Deposit to equal the amount first set forth above.

5. Secured Party shall have no duty to first commence an action against or seek recourse from Debtor, in the event of a default under the Loan, before enforcing the provisions of, and proceedings under the provisions of this Agreement. The obligations of Debtor under this Agreement shall be absolute and unconditional and shall remain in full force and effect without regard to, and shall not be released or discharged or in any way affected by:

(a) any amendment or modification of or supplement to the Loan;

- (b) any exercise or non-exercise of any right, remedy or privilege under or in respect to this Agreement, the Loan, or any other instrument provided for in the Loan, or any waiver, consent, explanation, indulgence or actions or inaction with respect to any such instrument; or
- (c) any bankruptcy, insolvency, reorganization, arrangement, readjustment, composition, liquidation or similar proceeding of Debtor.

6. Upon the termination of the Loan and the satisfaction of all of the obligations of Debtor thereunder, Secured Party shall promptly and without further request or action on the part of any party deliver to Debtor the Deposit (less any portion of same cashed, sold, assigned or delivered pursuant to and under the conditions specified in paragraph 4 hereof), and this Agreement shall thereupon be without further effect.

7. Secured Party may with written notice to Debtor, assign this Agreement. Debtor agrees that if Debtor receives written notice of an assignment from Secured Party, Debtor will pay all amounts due hereunder to such assignee or as instructed by Secured Party. Debtor also agrees to confirm in writing receipt of the notice of assignment as may be reasonably requested by assignee. Debtor hereby waives and agrees not to assert against any such assignee any defense, set-off, recoupment claim or counterclaim which Debtor has or may at any time have against Secured Party for any reason whatsoever.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

SECURED PARTY:		DEBTO	DR:
General Electric Capital Corporation		Vical I	ncorporated
By:	/s/ Diane Earle	By:	/s/ Jill M. Church
Name:	Diane Earle	Name:	Jill M. Church
Title:	Senior Vice President	Title:	VP and CFO

## VICAL INCORPORATED DELAYED ISSUANCE STOCK PURCHASE GRANT NOTICE (Amended and Restated Stock Incentive Plan)

Vical Incorporated (the "*Company*"), pursuant to its Amended and Restated Stock Incentive Plan of Vical Incorporated (the "*Plan*"), hereby awards to Employee a right to purchase the number of Shares set forth below (the "*Award*"). This Award shall be evidenced by a Delayed Issuance Stock Purchase Agreement (the "*Award Agreement*"). This Award is subject to all of the terms and conditions as set forth herein and in the applicable Award Agreement, the Plan, and the Employee's Delayed Issuance Stock Purchase Election Agreement (the "*Election Agreement*"), all of which are attached hereto and incorporated herein in their entirety.

Employee:	
Date of Grant:	
Number of Shares subject to Award:	
Purchase Price per Share:	
Total Purchase Price:	

Vesting Schedule: 25% of the Shares subject to the Award vest on the first anniversary following the Date of Grant and 1/16<sup>th</sup> of the Shares shall vest at the end of each three-month period following such first anniversary, provided in each case that the Employee's Service has not terminated prior to that date.

Additional Terms/Acknowledgements: The undersigned acknowledges receipt of, and understands and agrees to, this Grant Notice, the Award Agreement and the Plan. Employee further acknowledges that as of the Date of Grant, this Grant Notice, the Award Agreement, the Election Agreement and the Plan set forth the entire understanding between Employee and the Company regarding the acquisition of Shares and supersede all prior oral and written agreements on that subject with the exception of (i) awards previously granted and delivered to Employee under the Plan, and (ii) the following agreements only:

#### **OTHER AGREEMENTS:**

VICAL INCORPORATED		Employee:		
By:				
	Signature		Signature	
Title:		Date:		
Date				
ATTACHME	NTS: Award Agreement and Election Agreement			

## ATTACHMENT I Award Agreement

#### AMENDED AND RESTATED STOCK INCENTIVE PLAN OF VICAL INCORPORATED DELAYED ISSUANCE STOCK PURCHASE AGREEMENT

Pursuant to the Delayed Issuance Stock Purchase Grant Notice ("Grant Notice") and this Delayed Issuance Stock Purchase Agreement ("Agreement") (collectively, the "Award"), Vical Incorporated (the "Company") has awarded you a Delayed Issuance Stock Purchase right pursuant to Section 6 of the Amended and Restated Stock Incentive Plan of Vical Incorporated (the "Plan") for the number of Shares as indicated in the Grant Notice. Defined terms not explicitly defined in this Delayed Issuance Stock Purchase Agreement but defined in the Plan or the Grant Notice shall have the same definitions as in such documents.

The details of your Award are as follows.

1. PURCHASE PRICE. The Purchase Price for each Share shall be \$.01.

2. VESTING. Subject to the limitations contained herein, your Award shall vest as provided in the Grant Notice, provided that vesting shall cease upon the termination of your Service. Any Shares covered by this Delayed Issuance Stock Purchase Agreement that have not vested shall be forfeited upon the termination of your Service.

**3. DIVIDENDS.** You shall be entitled to receive cash payments equal to any cash dividends and other distributions paid with respect to a corresponding number of Shares covered by your Award, provided that if any such dividends or distributions are paid in Shares, the Fair Market Value of such Shares shall be converted into additional Shares covered by the Award, and further provided that such additional Shares shall be subject to the same forfeiture restrictions and restrictions on transferability as apply to the Awards with respect to which they relate.

4. DISTRIBUTION OF SHARES OF COMMON STOCK. The Company shall deliver to you a number of Shares of the Company's Stock equal to the number of vested Shares subject to your Award, including any additional Shares received pursuant to Section 3 above, on the date or dates that you elect (the "Settlement Date"). If such deferral election is made, the Committee shall, in its sole discretion, establish the rules and procedures for such payment deferrals, including, without limitation, rules and procedures as may be required to cause the delivery of Shares to comply with the distribution requirements of Section 409A of the Code.

5. NUMBER OF SHARES. In the event of a subdivision of the outstanding Stock, a declaration of a dividend payable in Shares, a declaration of a dividend payable in a form other than Shares in an amount that has a material effect on the value of Shares, a combination or consolidation of the outstanding Stock into a lesser number of Shares, a recapitalization, a spinoff, a reclassification or a similar occurrence, the Committee shall make appropriate adjustments in the number of Shares covered by your Award.

6. EFFECT OF CHANGE IN CONTROL. Upon the occurrence of a Change in Control, outstanding Shares covered by your Award which have not theretofore vested shall become

immediately and fully vested, and the Company shall deliver to you a number of Shares of the Company's Stock equal to the number of Shares subject to your Award, including any additional Shares pursuant to Section 2 above, as soon as practicable following such Change in Control.

7. SECURITIES LAW COMPLIANCE. You may not be issued any Shares under your Award unless the Shares are either (i) then registered under the Securities Act or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

**8. RESTRICTIVE LEGENDS.** The Shares issued under your Award shall be endorsed with appropriate legends, if any, determined by the Company.

**9. TRANSFERABILITY.** Your Award is not transferable, except by will or by the laws of descent and distribution. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Shares pursuant to Section 4 of this Agreement.

10. AWARD NOT A SERVICE CONTRACT. Your Award is not an employment or service contract, and nothing in your Award shall be deemed to create in any way whatsoever any obligation on your part to continue in the service of the Company or a Subsidiary, or on the part of the Company or a Subsidiary to continue such service. In addition, nothing in your Award shall obligate the Company or a Subsidiary, their respective stockholders, boards of directors or Employees to continue any relationship that you might have as an Employee of the Company or a Subsidiary.

11. UNSECURED OBLIGATION. Your Award is unfunded, and as a holder of vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue Shares pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the Shares purchased pursuant to this Agreement until such Shares are issued to you pursuant to Section 4 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between the Agreement and the Company or any other person.

#### **12.** WITHHOLDING OBLIGATIONS.

(a) On or before the time you receive a distribution of Shares pursuant to your Award, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from, at the Company's election, the Shares, payroll and any other amounts payable to you and otherwise agree to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or a Subsidiary, if any, which arise in connection with your Award.

(b) Unless the tax withholding obligations of the Company and/or any Subsidiary are satisfied, the Company shall have no obligation to issue a certificate for such Shares.

13. NOTICES. Any notices provided for in your Award or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Any notice shall have been deemed given when actually delivered.

14. **HEADINGS.** The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

15. AMENDMENT. This Agreement may be amended only by a writing executed by the Company and you which specifically states that it is amending this Agreement. Notwithstanding the foregoing, this Agreement may be amended solely by the Committee by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that no such amendment adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Committee reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Delayed Issuance Stock Purchase which is then subject to restrictions as provided herein.

#### 16. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the

result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. GOVERNING PLAN DOCUMENT. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control; *provided, however*, that Section 4 of this Agreement shall govern the timing of any such distribution of Shares under your Award, and *provided further, however*, that Section 5 of this Agreement shall govern the timing of any such distribution in the event of a Change in Control. The Committee shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretations and application of the Plan as are consistent therewith and to interpret or revoke any such rules. All actions taken and all interpretations and determinations made by the Committee shall be final and binding upon you, the Company, and all other interested persons. No member of the Committee shall be personally liable for any action, determination, or interpretation made in good faith with respect to the Plan or this Agreement.

18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of the Delayed Issuance Stock Purchase subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating the Employee's benefits under any employee benefit plan sponsored by the Company or any Subsidiary except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Subsidiary's employee benefit plans.

**19. CHOICE OF LAW.** The interpretation, performance and enforcement of this Agreement shall be governed by the law of the state of California without regard to such state's conflicts of laws rules.

20. RESOLUTION OF DISPUTES. To ensure rapid and economical resolution of any disputes that may arise under the Plan and this Agreement with respect to your Award, you and the Company agree that any and all disputes, claims, or controversies of any nature whatsoever arising from or regarding the interpretation, performance, enforcement or breach of the Plan and this Agreement with respect to your Award (excluding, however, any dispute that may arise with respect to clause (ii) of Section 3 of this Agreement) shall be resolved, to the fullest extent allowed by law, by confidential, final and binding arbitration conducted by Judicial Arbitration and Mediation Services, Inc. ("JAMS") in San Diego, California, under the then-existing JAMS rules, using a single arbitrator. The arbitration shall be completed within six (6) months from the date the demand for arbitration is filed with JAMS, provided that the arbitrator may extend such date for good reason as determined in his sole discretion. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. Nothing in this Agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. The arbitrator, and not a court, shall be authorized to determine whether the provisions of this Section 18 apply to a dispute, controversy or claim sought to be resolved in accordance with these arbitration

procedures. Notwithstanding the foregoing, neither party shall be permitted to initiate a demand for arbitration until it has participated in a nonbinding mediation conducted by JAMS, after providing notice to the other party. Both parties shall participate in such a mediation within fortyfive (45) days of delivery of such notice. If the parties cannot mutually agree upon a mediator within ten (10) days of such notice, then a mediator shall be designated by JAMS.

**21. SEVERABILITY.** If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement effective as of the day and set forth below.

EMPLOYEE

VICAL INCORPORATED

Date:

Date:

By:

## ATTACHMENT II Election Agreement

#### VICAL INCORPORATED DELAYED ISSUANCE STOCK PURCHASE ELECTION AGREEMENT

Please complete this Election Agreement and return a signed copy to Jill Church, Chief Financial Officer of Vical Incorporated (the "Company") by \_\_\_\_\_\_, 2005.

# NOTE: THIS ELECTION AGREEMENT MUST BE COMPLETED AND RETURNED WITHIN 30 DAYS OF THE DATE OF GRANT AS INDICATED ON YOUR DELAYED ISSUANCE STOCK PURCHASE GRANT NOTICE. IF THE INTERNAL REVENUE SERVICE DETERMINES THAT THIS ELECTION FORM MUST BE COMPLETED PRIOR TO THE GRANT DATE, THEN THIS ELECTION SHALL BE VOID AND THE SHARES WILL BE ISSUED ON THE DATE OR DATES UPON WHICH THEY VEST.

Defined terms not explicitly defined in this Election Agreement but defined in the Plan, your Delayed Issuance Stock Purchase Agreement or your Grant Notice shall have the same definitions as in such documents.

Name:
-------

SS #:

#### INSTRUCTIONS

In making this election, the following rules apply:

- You may elect a Settlement Date that occurs after the date of vesting. The "Settlement Date" is the date as of which you will receive the vested Shares associated with the Delayed Issuance Stock Purchase that you elected to defer below. Unless you timely elect otherwise on this Election Agreement, the Shares will be issued to you on the date or dates upon which they vest as indicated on your Grant Notice.
- You may elect up to four different Settlement Dates related to the Delayed Issuance Stock Purchase, in increments of 25%. For example, if you have 10,000 Shares covered by your Delayed Issuance Stock Purchase, you may elect up to four different Settlement Dates one Settlement Date related to each increment of 2,500 Shares.
- The vested Shares will be transferred to you on February 1 (or, if February 1 is not a business day, the first business day thereafter) of the year in which you select to defer receipt of the Shares, unless you specifically select a different Settlement Date in that year.
- This Election Agreement is **irrevocable**.
- If no Settlement Date is elected, then the issuance of vested Shares will occur upon the vesting date(s) indicated on your Grant Notice.
- Notwithstanding any provision in this Election Form or your Grant Notice, Award Agreement or the Plan to the contrary, the issuance of the vested Shares shall be made in a manner that complies with the requirements of Code Section 409A, which may include, without limitation, deferring the payment of such benefit for six (6) months after your termination of Service, provided however, that nothing in this paragraph shall require the payment of benefits to you earlier than they would otherwise be payable under the Award.

## **DEFERRAL ELECTION**

I hereby irrevocably elect to defer receipt of the Shares associated with the above-referenced Delayed Issuance Stock Purchase until the following date(s) and in the following increment(s). I acknowledge that only vested Shares will be issued to me and that the Settlement Date may occur after vesting. (CHOOSE ONE ALTERNATIVE BELOW)

#### ALTERNATIVE #1 (ON VESTING DATE):

□ I elect to have my vested Shares issued to me on the vesting date(s) indicated on my Grant Notice.

#### ALTERNATIVE #2: (SPECIFIED DATE(S) — CHECK BOXES THAT APPLY)

I elect to have my vested Shares issued to me on the following dates, in the following amounts:

A.	Number	Month	Day	Year
B.	Number	Month	Day	Year
C.	Number	Month	Day	Year
D.	Number	Month	Day	Year

E. D Notwithstanding the election that I made in A-D above, I elect to have my vested Shares issued to me on the following date, in the event such date occurs prior to the date(s) selected above (check boxes that apply):

□ \_\_\_\_ days following my Termination of Service

□ Immediately upon a Change in Control

□ Upon the earlier of a Change in Control or <u>days</u> following my Termination of Service

## ALTERNATIVE #3 (SPECIFIED EVENT – CHECK ONE BOX):

I elect to have my vested Shares issued to me on the following event (check boxes that apply):

□ \_\_\_\_ days following my Termination of Service

□ Upon the earlier of a Change in Control or \_\_\_\_ days following my Termination of Service

## Manner of Transfer

*All* of the Shares you are entitled to receive on the Settlement Date specified in this Election Agreement will be transferred to you on or as soon as practicable after such Settlement Date.

#### Terms and Conditions

By signing this form, you hereby acknowledge your understanding and acceptance of the following:

- 1. **Company Right to Early Transfer**. Notwithstanding any election made herein, the Company or any Subsidiary reserves the right to transfer to you all of the vested and then unissued Shares associated with the Delayed Issuance Stock Purchase subject to this Election Agreement at any time following the termination of your employment with the Company or any Subsidiary.
- 2. Withholding. The Company shall have the right to deduct from all deferrals or payments hereunder, any federal, state, or local tax required by law to be withheld.
- 3. **Nonassignable**. Your rights and interests under this Election Agreement may not be assigned, pledged, or transferred other than as provided in the Amended and Restated Stock Incentive Plan of Vical Incorporated.
- 4. **Termination of this Agreement**. The Company reserves the right to terminate this Agreement at any time. In such case, Shares that you purchased pursuant to your Agreement may be issued to you immediately.
- 5. **Bookkeeping Account**. The Company will establish a bookkeeping account to reflect the number of Shares that you acquired pursuant to your Delayed Issuance Stock Purchase and the Fair Market Value of such Shares that are subject to this Election Agreement.
- 6. Stock Certificates. Share certificates (each, a "Certificate") evidencing the issuance of the Shares pursuant to your Delayed Issuance Stock Purchase shall be issued to you as of the applicable Settlement Dates (or such earlier date payment is to be made pursuant to this Election Agreement) and shall be registered in your name. Subject to the withholding requirements outlined above, Certificates representing the unrestricted Shares will be delivered to you as soon as practicable after the Settlement Date.
- 7. **Change in Control.** As used in this Election Agreement, "Change in Control" shall have the meaning contained in the Plan; *provided however*, that a distribution upon a Change in Control shall only occur if such distribution complies with the distribution requirements of Code Section 409A and the regulations promulgated thereunder.
- 8. Governing Law. This Agreement shall be construed and administered according to the laws of the State of California.

By executing this Election Agreement, I hereby acknowledge my understanding of and agreement with all the terms and provisions set forth in this Election Agreement.

Employee

Date:

VICAL INCORPORATED

By: \_\_\_\_\_\_Name: \_\_\_\_\_\_Title: \_\_\_\_\_\_Date: \_\_\_\_\_

## 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, and No. 333-107581 on Form S-8 of our report dated March 11, 2005 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, 2004.

/s/ DELOITTE & TOUCHE LLP San Diego, California March 11, 2005

## **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 Form S-8 of Vical Incorporated of our report dated February 6, 2004, with respect to the balance sheet of Vical Incorporated as of December 31, 2003 and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2003, which report appears in the December 31, 2004 annual report on Form 10-K of Vical Incorporated.

/s/ KPMG LLP

San Diego, California March 11, 2005 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;
  - 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 14, 2005

By: /s/ VIJAY B. SAMANT

Vijay B. Samant Chief Executive Officer I, Jill M. Church, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Vical Incorporated;
- 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;
  - 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 14, 2005

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, 2004, 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 14, 2005

/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, 2004, 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 14, 2005

/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.