

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 1996, or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 0-21088

VICAL INCORPORATED  
(Exact name of registrant as specified in its charter)

DELAWARE 93-0948554  
(State or other jurisdiction of (IRS Employer Identification No.)  
incorporation or organization)

9373 TOWNE CENTRE DRIVE, SUITE 100, SAN DIEGO, CA 92121  
Address of principal executive offices

(619) 453-9900  
Registrant's telephone number including area code

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, Par Value \$0.01  
Preferred Stock Purchase Rights, Par Value \$0.01 (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  X No  \_\_\_\_\_

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the National Association of Securities Dealers Automated Quotation National Market System on February 28, 1997, was \$233,226,333.

The number of shares of Common Stock outstanding as of February 28, 1997, was 15,426,574.

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DOCUMENTS INCORPORATED BY REFERENCE

(To the Extent Indicated Herein)

Registrant's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Registrant's 1997 Annual Meeting of Stockholders to be held on June 10, 1997, is incorporated by reference in Part III, Items 10 (as to directors), 11, 12 and 13 of this Form 10-K.

ITEM 1. BUSINESS

OVERVIEW

Vical discovers and develops non-viral, gene-based pharmaceutical product candidates for human therapy. Gene transfer is an approach to the treatment and prevention of genetic and acquired diseases in which genes are introduced into cells in an effort to produce specific proteins needed to selectively correct or modulate disease conditions. The Company and its collaborators have developed core technologies that allow direct transfer of specific genes into cells in vivo (inside the body). The Company believes that its non-viral, gene-based drug therapy approach may offer safer and more cost-effective treatment opportunities for many diseases as well as novel treatment alternatives for certain diseases that are currently poorly addressed.

Except for the historical information contained herein, the matters discussed in this Annual Report on Form 10-K are forward-looking statements that involve risks and uncertainties, including the timely and successful development of candidate products, receipt of necessary regulatory approvals and commercial acceptance of products, the obtaining of proprietary protection for any such products, the impact of competitive products and pricing and reimbursement policies, changing market conditions and the other risks detailed throughout this Form 10-K. Actual results may differ materially from those projected. These forward-looking statements represent the Company's judgment as of the date of the filing of this Form 10-K. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

The key discoveries leading to Vical's proprietary direct gene transfer technology were that, under certain conditions, some muscle tissues are able to absorb genetic material directly and subsequently express a desired protein for periods ranging from weeks to several months. From these basic findings the Company has developed yield increases and productivity improvements that have led to what is referred to as "naked DNA" reagents for gene transfer. In addition, the Company is developing other technologies that may allow the delivery of DNA directly into certain non-muscle tissues, including the use of lipid molecules (cytofectins) that facilitate direct absorption of DNA into cells. The active ingredients of products under development at Vical consist of highly purified, well-defined gene sequences produced by conventional fermentation processes. The Company believes that the broad applicability, ease of manufacturing and potential cost effectiveness of its gene-based drug therapy approach may provide it with competitive advantages for commercialization.

Vical is concentrating its research and development activities in: oncology, infectious diseases and metabolic disorders. Currently, the Company is developing its cancer and metabolic disorder product candidates internally, while developing vaccines for infectious diseases primarily in collaboration with corporate partners.

PRODUCT DEVELOPMENT PROGRAMS

Vical is applying its direct gene transfer technology to the following therapeutic areas:

ONCOLOGY

The Company is developing a product candidate, Allovectin-7, for the treatment of various solid tumors. Allovectin-7 is a gene-based product candidate intended for direct injection into tumor lesions of cancer patients. The product contains a gene that encodes a foreign tissue antigen (HLA-B7) which, when injected into tumors, is intended to cause the malignant cells to bear this antigen on their surface. If this foreign antigen is expressed, the Company believes that the patient's immune system, which previously failed to recognize the tumor cells as abnormal, may attack and destroy the cancer cells as if they were foreign tissue.

After a small pilot trial conducted by the Company's collaborator, Dr. Gary Nabel of the University of Michigan, Vical initiated Phase I/II clinical trials with approximately 15 patients for each of three advanced cancer

indications: renal cell carcinoma, melanoma, and colorectal carcinoma. The trials were designed primarily to test the safety of Allovectin-7 at varying dosage levels and to assess HLA-B7 gene transfer and expression. Upon completion of the trials in June 1995, the Company concluded that the gene transfer was successful in the majority

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of patients, the treatment appeared to be safe and well-tolerated, and measurable tumor shrinkage was observed in 7 of 14 patients with advanced melanoma. In September 1995, Vical commenced multi-center Phase II clinical testing of Allovectin-7 in five tumor types: melanoma, renal cell carcinoma, colorectal carcinoma, breast carcinoma and non-Hodgkin's lymphoma. Treatment of more than 100 patients was completed in December 1996, and initial results are expected to be presented in 1997. In October 1996, Vical commenced additional multi-center Phase II clinical testing of Allovectin-7 in approximately 40 advanced melanoma patients. In addition, Allovectin-7 is being evaluated, either alone or in combination with approved cancer therapeutic agents, in several other Phase I/II clinical trials.

In April 1995, Vical initiated clinical testing of Leuvectin, its second gene-based product candidate intended for direct injection into tumor lesions of cancer patients. Leuvectin contains a gene that encodes the potent immunostimulator, IL-2, and a lipid material to facilitate gene uptake. The Company expects that Leuvectin, when injected into tumors, will cause the malignant cells to produce and secrete IL-2 in the vicinity of the tumor lesion. The Company believes that local expression of IL-2 will stimulate the patient's immune system to attack and destroy the tumor cells. Recombinant IL-2 protein is a Food and Drug Administration ("FDA")-approved anti-cancer agent for the treatment of advanced renal cell carcinoma. It has been investigated widely as a cancer immunotherapeutic agent, but is frequently associated with serious side effects. Because Vical's gene-based product candidate is designed to deliver IL-2 only at the site of tumor lesions, Leuvectin may provide similar efficacy with fewer side effects than systemic protein-based therapy.

The initial Phase I/II clinical trials were designed primarily to test the safety of Leuvectin at varying dosage levels and to assess IL-2 gene transfer and expression. Upon completion of the trials in February 1996, the Company concluded that the gene transfer was effective in the majority of patients, the treatment appeared to be safe and well-tolerated, and measurable tumor shrinkage was observed in 5 of 23 patients with various types of advanced malignancies. In October 1996, the Company initiated additional multi-center Phase I/II clinical testing of higher doses of Leuvectin in approximately 45 patients with advanced melanoma, renal cell carcinoma, and soft-tissue sarcoma.

In September 1996, Vical entered into a collaboration with Dr. Ronald Levy of Stanford University Medical Center to develop a naked DNA anti-idiotypic vaccine, Vaxid, against low-grade non-Hodgkin's B-cell lymphoma. This type of lymphoma is characterized by a slow growth rate and excellent initial response to chemotherapy or radiotherapy; however, a regular pattern of relapse to a diffuse aggressive lymphoma generally occurs for which no curative therapy has been identified. Vaxid is a DNA plasmid that encodes the patient-specific idiotypic of the B-cell tumor immunoglobulin. The Company believes that immunization of post-chemotherapy patients with Vaxid could result in the elimination of residual disease and the prevention of the relapse of disease. Vaxid is currently under preclinical development and may enter clinical trials in the second half of 1997.

#### INFECTIOUS DISEASE VACCINES

Preventive Vaccines. Vical and its collaborators have generated preclinical data demonstrating that direct intramuscular injection of specific genes can induce a potent, specific and prolonged immune response to infectious disease-causing agents. In preclinical models, a direct injection of genes for antigens of influenza resulted in both antibody-mediated and cell-mediated immunity that was protective across widely divergent strains of influenza. Thus, it may be possible, using Vical's naked DNA vaccine technology, to develop a new generation of preventive vaccine products effective against a variety of microorganism strains. Additional studies by Vical, its collaborators and several independent laboratories have extended these findings to preclinical models for over a dozen infectious diseases, suggesting a wide array of potential targets for Vical's naked DNA vaccine technology.

In May 1991, Vical entered into a commercial collaborative agreement with Merck & Co., Inc. ("Merck") to undertake research and development in the area of infectious disease preventive vaccines. As of April 1995, Merck had exercised its options to exclusive licenses to use Vical's naked DNA technology for development of vaccines directed against seven human infectious disease

targets: influenza, HIV, herpes, hepatitis B, hepatitis C, human papilloma and tuberculosis. Merck initiated a Phase I clinical trial with a preventive DNA vaccine candidate for influenza in April 1996, and is expected to present initial results in 1997. Merck has indicated that a preventive DNA vaccine candidate for herpes simplex may enter a clinical trial in 1997.

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In September 1994, the Company entered into a collaborative agreement with Pasteur Merieux Serums & Vaccins, subsequently renamed Pasteur Merieux Connaught ("PMC"), covering the use of Vical's proprietary naked DNA technology for developing up to five new vaccine products directed against cytomegalovirus, respiratory syncytial virus, Lyme disease, helicobacter pylori and malaria. As of December 31, 1996, PMC had added a new target, herpes zoster, exercised four of the options, and extended one option. See "--Collaboration and Licensing Agreements-- Corporate Partners--Merck & Co., Inc." and "--Pasteur Merieux Connaught."

Independently, the Company is conducting research on preventive vaccines for the Epstein-Barr virus (EBV) and chlamydia.

Therapeutic Vaccines. Vical is also developing gene-based therapeutic vaccines that are intended to stimulate the immune system to eliminate already-existing infections. For these product opportunities, the Company is focusing on the treatment of chronic viral infections, including hepatitis B and herpes.

#### THERAPEUTIC PROTEINS FOR METABOLIC DISORDERS

Vical's direct gene transfer technology may also permit the development of sustained-release alternatives to chronically administered therapeutic proteins. Delivering therapeutic proteins by way of direct gene injection may represent a cost-effective, more convenient and, possibly safer, mode of administration than using the protein itself. The Company has entered into a collaborative agreement with Genzyme Corporation ("Genzyme") for the treatment of cystic fibrosis. See "--Collaboration and Licensing Agreements--Corporate Partners--Genzyme Corporation."

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Vical's product development programs are summarized in the following table:

<TABLE>  
<CAPTION>

Project Development Rights(2)	Target Indication(s)	Development Status(1)	
<S> ONCOLOGY Allovectin-7	<C> Breast Carcinoma Colorectal Carcinoma Melanoma Non-Hodgkin's Lymphoma Renal Cell Carcinoma	<C> Phase II Clinical Trials	<C> Vical
	Head and Neck Carcinoma	Phase I/II Clinical Trial	Vical
Leuvectin	Melanoma Renal Cell Carcinoma Other Solid Tumors	Phase I/II Clinical Trials	Vical

Vaxid	Non-Hodgkin's B-Cell Lymphoma	Preclinical	Vical
INFECTIOUS DISEASES			
Preventive Vaccines	Influenza Hepatitis B Hepatitis C Herpes Simplex HIV Human Papilloma Virus Tuberculosis	Phase I Research/Preclinical Development	Merck
	Cytomegalovirus Helicobacter Pylori Herpes Zoster Lyme Disease Malaria Respiratory Syncytial Virus	Research/Preclinical Development	PMC
Therapeutic Vaccines	Chlamydia Epstein-Barr Virus	Research	Vical
	Hepatitis B Herpes Simplex	Research	Vical
Animal Health Vaccines Merieux	Various	Research	Rhone Merck
THERAPEUTIC PROTEINS			
Cystic Fibrosis Transmembrane Regulator (CFTR)	Cystic Fibrosis	Phase I/II	Genzyme
Hormones	Metabolic Disorders	Research	Vical

</TABLE>

- (1) As denoted in the table, "Research" indicates research related to identification and synthesis of lead compounds. "Preclinical Development" indicates that a specific compound is undergoing toxicology testing and manufacturing scale-up, among other things, in preparation for filing an IND. In Phase I, trials are conducted with a small number of healthy volunteers to determine the safety profile, the pattern of drug distribution and metabolism. In Phase II, trials are conducted with a larger group of patients afflicted with a target disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In the case of products for life-threatening diseases, the initial human testing is generally done in patients rather than in healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such studies may provide results traditionally obtained in Phase II trials. Such trials are frequently referred to as "Phase I/II" trials. See "--Government Regulation."
- (2) See "--Collaboration and Licensing Agreements--Corporate Partners."

## TECHNOLOGY

### GENE TRANSFER OVERVIEW

Gene transfer is an approach to the treatment and prevention of genetic and acquired diseases in which genes are introduced into cells to direct the production of specific proteins needed to selectively correct or modulate disease conditions. A typical human cell contains thousands of different proteins essential to cellular structure, growth and function. Proteins are produced by the cell according to a set of genetic instructions encoded by the DNA, which contains all the information necessary to control the cell's biological processes. DNA is organized into segments called genes, with each gene containing the information required to produce a specific protein. Production of the protein encoded by a particular gene is known as gene expression. The aberrant expression of even a single gene can severely alter a cell's normal function, frequently resulting in a disease condition.

A variety of methods have been developed to transfer genes into cells. The most common approach used to date relies on viral gene transfer. The use of viruses takes advantage of the natural ability of these organisms to insert their own genes into a host cell and use the host's metabolic machinery to produce proteins essential for the survival and function of the virus. In gene transfer applications, viruses are genetically modified to replace certain viral genes with desired genes and inhibit the ability of the virus to

reproduce and infect other cells. The most widely tested viral gene transfer systems to date have been based on retroviruses. Successful application of retroviral gene transfer processes entails two specific technical requirements. First, the viral DNA carrying the gene of interest must become stably integrated into the DNA of the host cell. Such integration results in a permanent genetic alteration of the modified cell and of all daughter cells resulting from cell division of the parent cell. Second, the viral DNA modified with a specific gene generally must be administered to the cells *ex vivo* (outside the body). Once the DNA is incorporated, the cells must be expanded in number, cleansed of contaminants, and then reintroduced into the patient. More recently, several companies and academic institutions have begun testing viral gene transfer systems based on other types of viruses, especially adenoviruses, which may be suitable for direct administration to patients. While more convenient to administer, these systems may, however, be hampered by the development of an immune response against the viral components of the products which may prevent effective repeat administrations.

#### VICAL'S DIRECT GENE TRANSFER TECHNOLOGY

Vical has developed a direct, non-viral gene transfer technology which it believes will potentially allow a safer and more cost-effective method of gene therapy in a number of therapeutic applications. Vical and its collaborators are developing core technologies to allow the non-viral delivery of genes into cells directly *in vivo*. The initial observation that led to Vical's direct gene transfer approach was that, under certain conditions, some tissues, specifically myocardial (heart) and peripheral striated skeletal muscle tissues, are able to directly absorb genetic material into cells and subsequently express the desired protein for periods ranging from weeks to several months. In addition, the Company is developing other proprietary gene transfer methods to allow the delivery of genes directly into certain non-muscle tissues, including the use of lipid molecules (cytoflectins) that facilitate direct absorption of genes into cells.

Vical's direct gene transfer approach involves the design and construction of plasmids, DNA segments whose ends are attached together to form a highly stable closed loop. These plasmids contain the gene encoding the protein of interest as well as short segments of DNA, or flanking sequences, that control the rate and location of protein expression. These plasmids can be manufactured through conventional fermentation and purification techniques, and in some applications will be formulated with a cytoflectin.

Vical's gene-based products are intended to be administered to patients by different techniques depending on the therapeutic application and the target tissue. For many applications, direct intramuscular injection of a pure plasmid DNA in an aqueous solution may suffice. For delivery to non-muscle tissues, the Company anticipates that the plasmids will generally be formulated with a cytoflectin.

Cytoflectins are proprietary lipid substances that Vical is developing specifically as drug delivery vehicles for its direct gene transfer technology. These lipid molecules are positively charged, which allows them to bind effectively to negatively charged molecules of DNA. The resulting cytoflectin-DNA complex can be delivered in an

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aqueous solution to tissues *in vivo* using a syringe or a catheter. Cytoflectins are capable of delivering DNA to the interior of the target cell while allowing the DNA to evade metabolic processes that normally degrade internalized material. Cytoflectins appear to be superior for the *in vivo* delivery of DNA, as compared with other lipid-based vehicles (e.g., liposomes), in which there is rapid degradation of the genetic material following ingestion by cells.

The Company believes that the potential benefits of Vical's direct gene transfer technology may include:

- Convenience. Vical's gene-based drug therapy is intended to be directly administered to patients similar to conventional pharmaceuticals.
- Safety. Vical's anticipated products will contain no viral structural components that may induce an unwanted immune response or infection.
- Ease of Manufacturing. Vical's products are expected to be manufactured using conventional fermentation techniques and standardized purification procedures.
- Cost-Effectiveness. The Company believes that its direct gene transfer technology will prove more cost-effective than gene transfer

systems requiring ex vivo manipulation of cells on a patient-by-patient basis. In addition, in certain clinical situations, administering a gene-based drug consisting of DNA encoding a particular protein may prove to be more cost-effective than administering a therapeutically effective dose of the protein itself. This is because the DNA, once introduced into the body, is intended to stimulate the production of a therapeutic protein over a prolonged period of time.

#### ONCOLOGY

Cancer is a disease in which certain cells grow uncontrolled by the body's normal self-regulatory mechanisms. Traditional chemotherapy seeks to control cancer by killing rapidly dividing cells. However, a number of non-malignant cells in the body, such as intestinal epithelium and bone marrow cells, are also rapidly dividing and hence are highly susceptible to chemotherapy. Thus, doses sufficient to eradicate the cancer often cannot be administered without life-threatening side effects.

A therapeutic approach that selectively kills tumor cells would be far superior to currently available therapies. One such approach would be the generation of a specific immune response capable of recognizing cancer cells as foreign. It is generally believed that the immune system is capable of selectively recognizing cancer cells as abnormal and destroying them. However, the vast majority of cancers arise spontaneously in patients with an otherwise normal immune system. This observation suggests that cancer cells somehow escape the normal immune defense mechanisms or that the cytotoxic T lymphocytes ("CTLs") response is not powerful enough to kill all of the abnormal cells. A variety of methods have been used to augment the immune response against tumor cells, including the administration of natural immune-enhancing proteins such as IL-2, either alone or in combination with other agents. These methods have shown encouraging results in some patients with certain tumor types but suffer from serious side effects.

In collaboration with Dr. Gary J. Nabel of the University of Michigan, Vical scientists are developing a novel approach to cancer immunotherapy by seeking to induce a strong local immune response to tumor cells. Vical's approach is based on direct injection into the tumor of a gene encoding a human histocompatibility antigen ("HLA"). Vical has formulated a complex called Allovectin-7 containing the gene for a particular antigen, called HLA-B7, and a lipid material to facilitate gene uptake. After injection, the gene encoding HLA-B7 enters cancer cells at the injection site, and causes the cells to begin producing the HLA-B7 protein. This in turn would be expected to trigger a potent CTL response against the tumor cells, similar to the rejection of donor organs in transplant recipients.

After a small pilot trial conducted by Dr. Nabel, Vical initiated Phase I/II clinical trials with approximately 15 patients for each of three advanced cancer indications: renal cell carcinoma, melanoma, and colorectal carcinoma. The trials were designed primarily to test the safety of Allovectin-7 at varying dosage levels and to assess HLA-B7 gene transfer and expression. Upon completion of the trials in June 1995, the Company concluded that:

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- Direct gene transfer into different tumor types and a variety of lesion sites was well-tolerated;
- The HLA-B7 gene was transferred and protein could be detected for several weeks in greater than 80 percent of biopsies from treated patients;
- Measurable tumor shrinkage was observed in 7 of 14 patients with advanced melanoma; 3 of these 7 were in clinical partial remission, and as of January 1997, one patient had been in complete remission for a period of 33 months;
- No significant differences were observed in gene expression or tumor responses to 10, 50, or 250 ug doses.

In September 1995, Vical commenced multi-center Phase II clinical testing of Allovectin-7 in five tumor types: melanoma, renal cell carcinoma, colorectal carcinoma, breast carcinoma and non-Hodgkin's lymphoma. Treatment of more than 100 patients was completed in December 1996, and initial results are expected to be presented in 1997. In October 1996, Vical commenced additional multi-center Phase II clinical testing of Allovectin-7 in approximately 40 advanced melanoma patients. In addition, Allovectin-7 is being evaluated, either alone or in combination with approved cancer therapeutic agents, in several other Phase I/II clinical trials.

In April 1995, Vical initiated clinical testing of Leuvectin, its second gene-based product candidate intended for direct injection into tumor lesions of cancer patients. Leuvectin contains a gene that encodes the potent immunostimulator, IL-2, and a lipid material to facilitate gene uptake. The Company expects that Leuvectin, when injected into tumors, will cause the malignant cells to produce and secrete IL-2 in the vicinity of the tumor lesion. The Company believes that local expression of IL-2 will stimulate the patient's immune system to attack and destroy the tumor cells. Recombinant IL-2 protein is an FDA-approved anti-cancer agent for the treatment of advanced renal cell carcinoma. It has been investigated widely as a cancer immunotherapeutic agent, but is frequently associated with serious side effects. Because Vical's gene-based product candidate is designed to deliver IL-2 only at the site of tumor lesions, Leuvectin may provide similar efficacy with fewer side effects than systemic protein-based therapy.

The initial Phase I/II clinical trials were designed primarily to test the safety of Leuvectin at varying dosage levels and to assess IL-2 gene transfer and expression. Upon completion of the trials in February 1996, the Company concluded that:

- Direct injection at varying doses and gene transfer into different tumor types and a variety of lesion sites was well-tolerated;
- The IL-2 gene was transferred and protein could be detected in more than 75 percent of biopsies from treated patients;
- Measurable tumor shrinkage was observed in 5 of 23 patients with various types of advanced malignancies;

In October 1996, the Company initiated additional multi-center Phase I/II clinical testing of higher doses of Leuvectin in approximately 45 patients with advanced melanoma, renal cell carcinoma, and soft-tissue sarcoma.

In September 1996, Vical entered into a collaboration with Dr. Ronald Levy of Stanford University Medical Center to develop a naked DNA anti-idiotypic vaccine, Vaxid, against low-grade non-Hodgkin's B-cell lymphoma. This type of lymphoma is characterized by a slow growth rate and excellent initial response to chemotherapy or radiotherapy; however, a regular pattern of relapse to a diffuse aggressive lymphoma occurs for which no curative therapy has been identified. Clinical studies involving administration of either monoclonal anti-idiotypic antibodies or patient-specific B-cell lymphoma idiotypic protein have resulted in prolonged remissions; however, these therapies are limited by the time and effort required to produce the drug product. Vaxid is a DNA plasmid that encodes the patient-specific idiotypic of the B-cell tumor immunoglobulin. In preclinical studies, Dr. Levy showed that the injection into mice of a murine B-cell lymphoma idiotypic plasmid results in strong anti-idiotypic immune responses and significant protection against tumor challenge. Based on these preclinical studies and additional studies conducted at Vical, the Company believes that immunization of post-chemotherapy patients with Vaxid could result in the elimination of residual disease and the prevention of the relapse of disease. Vaxid is currently under preclinical development and may enter a clinical trial in the second half of 1997.

#### INFECTIOUS DISEASES

Preventive Vaccines. Vical's naked DNA technology may address two deficiencies of traditional preventive vaccine approaches: (i) the inability to predict the random changes in the strains of various infectious agents and (ii) the need for safe formulations (adjuvants) that accentuate a humoral response or that elicit sufficient cell-mediated responses. The Company's scientists have shown in animal experiments that the intramuscular injection of a plasmid encoding a protein common to all strains of the influenza virus stimulates both humoral and cell-mediated responses against the virus itself and the virus-infected cells. The immune response is potent, specific and requires no adjuvant formulation. For over a year following vaccination, animals were shown to have higher survival rates from an otherwise lethal dose of inhaled influenza virus as compared with untreated control animals. Improved survival rates were also observed in treated animals that were exposed to a lethal dose of a different strain of influenza. This observed cross-strain protection, if reproducible in humans, will offer a key advantage compared with conventional influenza vaccines, which must be specifically designed and manufactured to combat a particular strain of a prevalent influenza virus. Thus, Vical's direct gene transfer technology may be universal, not requiring frequent re-design or product modification for each new viral strain.

Additional studies by Vical and its collaborators have extended these findings to other models of infectious diseases for which there are no



currently approved vaccines, such as human papilloma virus, herpes and malaria. Further, the Company believes Vical's potential vaccine products should be simpler to manufacture, requiring conventional bacterial fermentation, whereas many vaccines are made using cumbersome and labor-intensive techniques involving difficult tissue culture procedures and the use of live viruses. Merck holds exclusive licenses to use Vical's naked DNA technology for development of vaccines directed against seven human infectious disease targets: influenza, HIV, herpes, hepatitis B, hepatitis C, human papilloma and tuberculosis. Merck initiated a Phase I clinical trial with a preventive DNA vaccine candidate for influenza in April 1996, and is expected to present initial results in 1997. Merck has indicated that a preventive DNA vaccine candidate for herpes simplex may enter a clinical trial in 1997. In September 1994, the Company entered into a commercial collaborative agreement with PMC covering the use of Vical's proprietary naked DNA technology for developing up to five new vaccine products directed against cytomegalovirus, respiratory syncytial virus, Lyme disease, helicobacter pylori and malaria. In 1996, PMC added herpes zoster as a sixth target indication. As of December 31, 1996, PMC held licenses for four of the indications and options for the remaining two. See "-- Collaboration and Licensing Agreements--Corporate Partners--Merck & Co., Inc." and "-- Pasteur Merieux Connaught."

Independently, the Company is conducting research on preventive vaccines for the Epstein-Barr virus (EBV) and chlamydia.

**Therapeutic Vaccines.** The Company believes that by stimulating cell-mediated immunity, its direct gene transfer approach may prove beneficial to patients suffering from chronic viral diseases where current therapeutic alternatives are inadequate. Such diseases include herpes and hepatitis B. The Company is conducting research to evaluate the feasibility of its direct gene transfer approach in the treatment of herpes and hepatitis B in relevant animal models.

#### THERAPEUTIC PROTEINS

Vical's direct gene transfer technology may permit the development of alternatives to therapeutic protein administration. The major shortcomings of some therapeutic proteins are their short duration of action and the side effects associated with high levels of circulating protein after intravenous administration. By direct injection of genes into muscles, a sustained-release of low levels of the therapeutic proteins may be achieved. This may reduce side effects and the need for repeated dosing, effectively using the muscle as a "protein factory." Vical is initially focusing on the production of highly potent proteins which are required in small amounts to produce therapeutic effects, such as certain immunomodulatory proteins, blood clotting factors, and other therapeutic proteins. If Vical's technology can successfully demonstrate therapeutic effect with these proteins, this approach could prove useful with other proteins.

Cystic fibrosis is the most common fatal recessive genetic disease in the Caucasian population. It is estimated that about 30,000 Americans have cystic fibrosis, and the disease occurs in approximately 1 in 2,500 live

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births. The disease is caused by a defect in the function of a specific protein, cystic fibrosis transmembrane conductance regulator (CFTR). This protein functions as a chloride channel in the cell membrane, and the defect results in the buildup of mucus in the lungs of cystic fibrosis patients. Cystic fibrosis gene therapy is aimed at restoring chloride channel function by introducing the gene coding for CFTR into a patient's airway cells. In 1993, Vical entered into a collaborative research and option agreement with Genzyme to evaluate the use of, and which granted an option to license, the Company's cytofectins as non-viral vectors in gene therapy for the treatment of cystic fibrosis. In 1996, Genzyme exercised the option. See "--Collaboration and Licensing Agreements--Corporate Partners--Genzyme Corporation."

#### COLLABORATION AND LICENSING AGREEMENTS

The Company's strategy for the research, development and commercialization of its potential products requires entering into various arrangements with corporate, academic and government collaborators, licensors, licensees and others, and is dependent upon the subsequent success of these outside parties in performing their responsibilities. Although the Company believes parties to any such arrangements would have an economic motivation to succeed in performing their contractual responsibilities, the amount and timing of resources to be devoted to these activities may not be within the control of the Company. There can be no assurance that such parties will perform their obligations as expected or that the Company will derive any revenue from such arrangements. In addition, there can be no assurance that the collaborators

will not be pursuing alternative technologies as a means for developing treatments for the diseases targeted by these collaborative programs.

The Company has entered into, and expects to enter into, additional research collaborations, licensing agreements and corporate collaborations. In addition to the agreements summarized below, Vical has entered into or is currently conducting on-going negotiations with potential corporate partners. However, there can be no assurance that the Company will be able to negotiate acceptable collaborative agreements, or that its existing collaborative agreements will be successful.

#### CORPORATE PARTNERS

Merck & Co., Inc. In May 1991, the Company entered into a research collaboration and license agreement with Merck (the "Merck Agreement") to develop vaccines to prevent infection and/or disease in humans utilizing Vical's intramuscular delivery technology. In connection with the Merck Agreement, Vical has granted Merck a worldwide exclusive license to preventive vaccines using Vical's technology against seven human infectious diseases: influenza, HIV, herpes simplex, hepatitis B, hepatitis C, human papilloma and tuberculosis. In 1996, Merck initiated a Phase I clinical trial with a preventive DNA vaccine candidate for influenza and is expected to present initial results in 1997. Merck has indicated that a preventive DNA vaccine candidate for herpes simplex may enter a clinical trial in 1997. In connection with the Merck Agreement, Merck has paid the Company \$11.6 million to date at December 31, 1996. In connection with certain of these payments, Vical was required to pay 10 percent of certain payments received by the Company under the Merck Agreement to Wisconsin Alumni Research Foundation ("WARF"). A small portion of any future milestone or royalty payments received by Vical under the Merck Agreement would also be owed to WARF. See "--Research Institutions--Wisconsin Alumni Research Foundation." In addition, Merck also has certain rights to therapeutic uses of preventive vaccines developed under the Merck Agreement. Merck is obligated to pay additional fees upon successful completion of certain research milestones with respect to the products developed under the Merck Agreement and royalties on net sales by Merck of such products, if any such products are developed and marketed.

In May 1992, Vical entered into a separate agreement with Merck pursuant to which the Company granted Merck a worldwide exclusive license to certain Vical technology to develop vaccines for the prevention of a veterinary infectious disease.

Pasteur Merieux Connaught. In September 1994, the Company entered into a collaborative agreement with the vaccine manufacturer PMC (the "PMC Agreement") covering the use of Vical's proprietary naked DNA technology for developing up to five new vaccine products. The following vaccine targets are included: (i) cytomegalovirus (CMV); (ii) respiratory syncytial virus (RSV); (iii) Lyme disease; (iv) helicobacter pylori; and, (v) malaria. With respect to malaria, see "--Research Institutions--Naval Medical Research Institute." In 1996, a sixth option target, herpes zoster, was added. The PMC Agreement includes a research collaboration and options

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for PMC to take exclusive licenses to Vical's naked DNA vaccine technology for each of the six vaccine targets. To maintain the options, PMC is required to pay Vical annual research payments. For licensed options, PMC will have to make milestone and royalty payments to Vical. PMC has exercised four such options at December 31, 1996, and extended an option. PMC will make research payments to Vical for expenses incurred by Vical in performing certain clinical and preclinical work. Through December 31, 1996, Vical had received \$5,950,000 under this agreement. If Vical were to receive milestone or royalty payments from PMC, Vical would be required to pay 10 percent of certain payments to WARF. See "--Research Institutions--Wisconsin Alumni Research Foundation."

Genzyme Corporation. In October 1993, Vical entered into a collaborative research and option agreement with Genzyme to evaluate the use of Vical's proprietary cytofectins as non-viral vectors in gene therapy for the treatment of cystic fibrosis. The agreement includes a multi-year research collaboration and an option for Genzyme to take an exclusive worldwide license for the use of Vical's cytofectins in the field of cystic fibrosis treatment. Vical also granted Genzyme a four year right of first offer to use Vical's cytofectin technology in other lung disorders. In 1996, Genzyme exercised the option. Through December 31, 1996, Vical had received \$2,300,000 from Genzyme under this agreement. The license agreement includes provisions for research, milestone and royalty payments to Vical.

Baxter Healthcare Corporation. In December 1993, Vical entered into a collaborative research and option agreement with Baxter to evaluate the use of Vical's proprietary gene-based pharmaceutical technology for the treatment of hemophilia. Through the termination of this agreement in December 1996, the Company received \$1.1 million from Baxter.

Rhone Merieux. The Company entered into a corporate alliance in March 1995 relating to DNA vaccines in the animal health area with Rhone Merieux, a leading manufacturer and marketer of animal health products worldwide. The agreement includes options for Rhone Merieux to take exclusive licenses to Vical's direct injection technology and the cytofectin technology to develop and commercialize certain gene-based products for use in the prevention of infectious diseases in domesticated animals. If Rhone Merieux exercises its license options, cash payments and royalties on net sales would be due to the Company. If Vical were to receive milestone or royalty payments from Rhone Merieux, Vical would be required to pay 10 percent of certain payments to WARF. See "--Research Institutions--Wisconsin Alumni Research Foundation." In 1996, the agreement was extended to March 1998.

#### RESEARCH INSTITUTIONS

The University of Michigan. In September 1992, the Company entered into a license agreement with the University of Michigan ("Michigan") pursuant to which the Company obtained the exclusive license (subject to Michigan's retaining the right to grant non-exclusive, non-royalty bearing licenses to the United States government and the Howard Hughes Medical Institute) to products utilizing technology related to the use of genetically altered heart muscle cells in the treatment or prevention of certain diseases in return for certain license fees and royalty payments. The Company's rights to certain gene transfer technology developed by Dr. Jeffrey Leiden while at Michigan are governed by this agreement. In October 1996, the Company notified Michigan of its intent to terminate this agreement effective April 1997.

In October 1992, Vical entered into a second license agreement with Michigan pursuant to which the Company obtained the exclusive license (subject to Michigan's retaining the right to grant non-exclusive, non-royalty bearing licenses to the United States government and the Howard Hughes Medical Institute) to products for the prevention and treatment of disease utilizing certain technology relating to the introduction of recombinant nucleic acid products into cancer cells and cells of the vasculature by catheterization in return for certain license fees and royalty payments. The Company's rights to certain gene transfer technology developed by Drs. Gary and Elizabeth Nabel at Michigan are governed by this agreement.

Wisconsin Alumni Research Foundation. Under a research agreement entered into in 1989, scientists at the University of Wisconsin, Madison, and at Vical co-invented a core technology related to intramuscular naked DNA administration. Effective January 1, 1991, Vical entered into a license agreement with WARF whereby WARF granted to the Company the exclusive license to its interest in that technology (except as to the United

States government which may hold non-exclusive licenses to certain technology developed with government funds). As consideration for the license grant, Vical paid WARF, the designated patent and licensing organization for the University of Wisconsin, an initial license fee upon execution of the agreement and has committed to pay WARF a royalty on sales of the products incorporating the licensed technology and a percentage of up-front license payments from third parties. Under certain circumstances, Vical is obligated to pay \$5,000 annually to WARF from 1995 until the termination of the agreement.

The University of Chicago. In September 1992, Vical entered into a sponsored research agreement with The University of Chicago ("Chicago") pursuant to which the Company agreed to pay Chicago an annual research fee for a four year period for research to be conducted under the direction of Dr. Jeffrey Leiden in the area of gene therapy using cardiac and skeletal muscles. The agreement was extended for a fifth year and will end in September 1997.

Naval Medical Research Institute. In November 1993, Vical entered into a Cooperative Research and Development Agreement ("CRADA") with the Naval Medical Research Institute ("NMRI"), a laboratory operated under the command of the United States Navy, for research in the area of vaccines for the prevention of malaria. Under the CRADA, the Company and NMRI are each contributing research materials and expertise towards the appropriate testing of candidate DNA-based malaria vaccines in laboratory animals and, if warranted, human subjects. Each party funds its own activities. Vical has licensed the right to commercialize any vaccine product that emerges from research under the CRADA to PMC, subject to the right of the U.S. government to use any such vaccine for government purposes only. In September 1995, Vical and NMRI were awarded a grant from the Department of Defense that was to provide up to \$1,000,000 per year for up to three years to support further development of a malaria vaccine

based on Vical's naked DNA vaccine technology. The agreement commenced in the first quarter of 1996. As a result of subsequent federal budget cuts, funding for the grant has been capped at \$1,000,000 total and the agreement is expected to end June 30, 1997.

#### ACCESS TO PROPRIETARY GENES AND PROTEINS

A number of the genetic sequences or proteins encoded by certain of those sequences that the Company expects to use or is currently investigating in its clinical trials or may use in its other gene-based products are or may become patented by others. As a result, the Company may be required to obtain licenses under such patents in order to conduct certain research, to manufacture or to market products that contain proprietary genetic sequences. There can be no assurance that such licenses will be available on commercially reasonable terms, if at all.

#### PATENTS AND PROPRIETARY RIGHTS

Patents and other proprietary rights are important to the Company's business. The Company's policy is to file patent applications to protect technology, inventions and improvements to its inventions that are considered important to the development of its business. The Company also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain its competitive position. To date, the Company has filed or participated as licensee in the filing of a number of patent applications in the United States relating to the Company's technology, as well as foreign counterparts of certain of these applications in many countries. The Company has filed a series of patent applications to cover direct gene transfer for immunization and for delivering therapeutic proteins to patients. Other patent applications have been filed that cover specific gene sequences and formulations comprising the Company's gene-based product candidates as well as methods for producing pharmaceutical grade DNA. Certain of these patents have been issued by the U.S. Patent and Trademark Office ("PTO"). See table below. Several other such applications are still pending in the United States, and corresponding foreign applications have been filed. No assurance can be given that the claims will issue in their present form, if at all. Other patent applications seek to cover several families of cytofectin molecules and their uses in gene delivery. Patents covering the composition of matter of certain of these molecules and their uses were issued by the PTO and several foreign counterparts are pending. Under its agreement with Michigan, the Company is the exclusive licensee of several patent applications related to gene therapy applications in cardiovascular disease and cancer. One such patent, claiming a kit for site-specific gene delivery using catheters, was issued by the PTO. Several other applications relating to the Company's business are also pending.

In December 1996, the Company was issued two U.S. patents covering methods of direct gene transfer for delivering therapeutic proteins and for inducing immune responses, respectively. As of December 31, 1996, the Company or its exclusive licensors had received seven U.S. patents covering various aspects of its proprietary technology. These patents are summarized below:

<TABLE>  
<CAPTION>

U.S. Patent -----	Technology Covered -----
<S>	<C>
5,589,466	Direct administration of naked DNA for immunization
5,580,859	Direct administration of naked DNA for protein expression
5,576,196	Process to reduce RNA during DNA production
5,561,064	Process to manufacture pharmaceutical-grade DNA
5,459,127	Use of cationic lipids to deliver genes in vivo
5,328,470	Catheter to facilitate intravascular gene transfer
5,264,618	Cationic lipid compositions to facilitate gene transfer in vivo

</TABLE>

The patent positions of pharmaceutical and biotechnology firms, including the Company, are uncertain and involve complex legal and factual questions for which important legal principles are largely unresolved. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued. Consequently, the Company does not know whether any patent applications will result in the issuance of patents or, if any patents are issued, whether those patents will provide significant proprietary protection or will be circumvented or invalidated. Since patent

applications in the United States are maintained in secrecy until patents issue or foreign counterparts, if any, publish, and, since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, the Company cannot be certain that it or any licensor was the first creator of inventions covered by pending patent applications or that it or such licensor was the first to file patent applications for such inventions. Moreover, the Company might have to participate in interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to the Company, even if the eventual outcome were favorable to the Company. There can be no assurance that the Company's patents, if issued, would be held valid or enforceable by a court or that a competitor's technology or product would be found to infringe such patents.

A number of pharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to the Company's business. Some of these technologies, applications or patents may conflict with the Company's technologies or patent applications. Such conflict could limit the scope of the patents, if any, that the Company may be able to obtain or result in the denial of the Company's patent applications. In addition, if patents that cover the Company's activities are issued to other companies, there can be no assurance that the Company would be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technology.

In addition to patent protection, the Company also relies upon trade secret protection for its confidential and proprietary information. There can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to the Company's trade secrets or disclose such technology or that the Company can meaningfully protect its trade secrets.

It is the Company's policy to require its employees, consultants, members of its Scientific Advisory Board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with the Company. These agreements provide that all confidential information developed or made known during the course of the relationship with the Company is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for the Company, utilizing property of the Company or relating to the Company's business and conceived or completed by the individual during employment, shall be the exclusive property of the Company to the extent permitted by applicable law. There can be no assurance, however, that these agreements will provide meaningful protection of the Company's trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information.

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#### COMMERCIALIZATION AND MANUFACTURING

Because of the broad potential applications of its technology, Vical intends to develop and commercialize products both on its own and through corporate partners. The Company intends to develop and market products to well-defined specialty markets, such as oncology, infectious diseases and metabolic disorders. Where appropriate, the Company intends to rely on strategic marketing and distribution partners for manufacturing and marketing products addressing diseases treated by primary care physicians. There can be no assurance that the Company will be able to reach satisfactory arrangements with such distribution partners or that any such arrangements will be successful.

The Company believes its DNA plasmids can be produced in commercial quantities in bacterial cells through traditional fermentation and purification techniques. The separation and purification of plasmid DNA is a relatively straightforward procedure because of the inherent biochemical differences between plasmid DNA and the majority of other bacterial components. In addition, the Company's cytofectin formulations consist of lipid components that are synthesized chemically using traditional, readily scaleable, organic synthesis procedures.

Vical currently produces supplies of product for Phase I/II and Phase II clinical trials and intends to produce sufficient supplies for additional clinical investigations. The Company may also choose to rely in part on outside organizations to manufacture its product candidates for expanded clinical trials under close supervision and utilizing the Company's proprietary processes. There can be no assurance that the Company will be able to contract for manufacturing capabilities on acceptable terms.

#### COMPETITION

The field of gene-based drug development is new and rapidly evolving, and it is expected to continue to undergo significant and rapid technological change. Rapid technological development could result in the Company's potential products or technologies becoming obsolete before the Company recovers a significant portion of its related research, development and capital expenditures. The Company will experience competition both from other companies in the field and from companies which have other forms of treatment for the diseases targeted by the Company. The Company is aware of several development stage and established enterprises, including major pharmaceutical and biotechnology firms, which are exploring gene-based drugs or are actively engaged in research and development in areas including both viral gene transfer and other methods of gene insertion. The Company may also experience competition from companies that have acquired or may acquire technology from companies, universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may materially and adversely affect Vical. See "--Patents and Proprietary Rights."

Certain competitors and potential competitors of the Company have substantially greater product development capabilities and financial, scientific, marketing and human resources than the Company. Other companies may succeed in developing products earlier than the Company, obtaining FDA approvals for such products more rapidly than the Company, or developing products that are more effective than those proposed to be developed by the Company. While the Company will seek to expand its technological capabilities to remain competitive, there can be no assurance that research and development by others will not render the Company's technology or products obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by the Company, or that any therapy developed by the Company will be preferred to any existing or newly developed technologies.

The Company's competitive position will be affected by the disease indications addressed by the Company's and its competitors' potential products, the timing of market introduction for such potential products and the stage of development of other technologies under development to address such disease indications. Accordingly, the Company's and its competitors' proprietary positions, their ability to complete clinical trials of their potential products on a timely basis and their ability to obtain timely regulatory approvals to market such potential products are likely to be significant competitive factors for the Company. Other important competitive factors will include the efficacy, safety, reliability, availability and price of the Company's and its competitors' potential products and the ability of the Company and its competitors to secure sufficient capital resources for the often substantial period between technological conception and commercial sales.

#### GOVERNMENT REGULATION

Any products developed by the Company will require regulatory clearances prior to clinical trials and additional regulatory clearances prior to commercialization. New human gene therapy products are expected to be subject to extensive regulation by the FDA and comparable agencies in other countries. The precise regulatory requirements with which the Company will have to comply are uncertain at this time due to the novelty of the human gene products and therapies currently under development. The Company believes that its potential products will be regulated either as biological products or as new drugs. New drugs are subject to regulation under the Federal Food, Drug and Cosmetic Act, and biological products, in addition to being subject to certain provisions of that Act, are regulated under the Public Health Service Act. Both statutes and the regulations promulgated thereunder govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and other promotional practices involving biologics or new drugs, as the case may be. FDA approval or other clearances must be obtained before clinical testing, and before manufacturing and marketing, of biologics or new drugs. At the FDA, the Center for Biological Evaluation and Research ("CBER") is responsible for the regulation of new biologics and the Center for Drug Evaluation and Research ("CDER") is responsible for the regulation of new drugs.

Obtaining FDA approval has historically been a costly and time-consuming process. Generally, in order to gain FDA premarket approval, a developer first must conduct preclinical studies in the laboratory and in animal model systems to gain preliminary information on an agent's efficacy and to identify any major safety concerns. The results of these studies are submitted as a part of an application for an investigational new drug ("IND"), which the FDA must review and allow before human clinical trials of an investigational drug can start. The IND includes a detailed description of the clinical investigations to be undertaken.

In order to commercialize any products, the Company must sponsor and file an IND for each proposed product and will be responsible for initiating

and overseeing the clinical studies to demonstrate the safety, efficacy and potency that are necessary to obtain FDA approval of any such products. Clinical trials are normally done in three phases. In Phase I, trials are conducted with a small number of healthy volunteers to determine the safety profile, the pattern of drug distribution and metabolism. In Phase II, trials are conducted with a larger group of patients afflicted with a target disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of safety and efficacy required by the FDA and other regulatory authorities. In the case of products for life-threatening diseases, the initial human testing is generally done in patients rather than in healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such studies may provide results traditionally obtained in Phase II clinical trials. Such trials are frequently referred to as "Phase I/II" clinical trials.

The FDA receives reports on the progress of each phase of clinical testing, and it may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients. Human gene therapy products are a new category of therapeutics, and there can be no assurance as to the length of the clinical trial period or the number of patients the FDA will require to be enrolled in the clinical trials in order to establish to its satisfaction the safety, efficacy and potency of human gene therapy products.

After completion of clinical trials of a new product, FDA marketing approval must be obtained. If the product is regulated as a biologic, CBER will require the submission and approval of a Biologic License Application ("BLA") or a Product License Application ("PLA"), and an Establishment License Application ("ELA") before commercial marketing of the biologic is permitted. If the product is classified as a new drug, the Company must file a New Drug Application ("NDA") with CDER and receive approval before commercial marketing of the drug. The NDA, BLA, or PLA/ELA must include results of product development activities, preclinical studies and clinical trials in addition to detailed manufacturing information. The review and approval processes require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. NDAs and BLA/ELAs submitted to the FDA can take, on average, two to five years to receive approval after filing. If questions arise during the FDA review process, approval can take more than five years. Notwithstanding the submission of relevant data, the FDA may ultimately decide that the NDA, BLA, or PLA/ELA does not satisfy its regulatory criteria for approval and require additional 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

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civil or criminal sanctions. In addition, after marketing clearance is secured, the manufacturing facility for the Company's products will be subject to periodic inspections for Good Manufacturing Practices 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 National Institutes of Health ("NIH") have established guidelines for research involving recombinant DNA molecules, which are utilized by the Company and certain of its collaborators in their research. These guidelines apply to all recombinant DNA research which is conducted at or supported by the NIH. Under current guidelines, proposals to conduct clinical research involving gene therapy which is conducted at institutions supported by the NIH must be reviewed and allowed by the NIH. The NIH review is a public process and usually involves review and approval by the Recombinant DNA Advisory Committee ("RAC") of the NIH.

In both domestic and foreign markets, sales of the Company's products, if any, will be dependent in part on the availability of reimbursements from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. If the Company succeeds in bringing one or more products to market, there can be no assurance that these products will be considered cost-effective, that reimbursement will be available, or if available, that the payor's reimbursement policies will not adversely affect the Company's ability to sell its products on a profitable basis.

The Company is also 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

the Company's research work. The extent of government regulation which might result from any future legislation or administrative action cannot be accurately predicted.

#### HUMAN RESOURCES

As of February 28, 1997, Vical had 93 full-time employees, 23 of whom hold degrees at the doctorate level. Of these employees, 71 are engaged in, or directly support, research and development activities, and 22 are in administrative and business development positions. A significant number of the Company's management and professional employees have had prior experience with pharmaceutical and biotechnology companies. None of the Company's employees is covered by collective bargaining agreements, and management considers relations with its employees to be good.

#### PRODUCT LIABILITY EXPOSURE

The use of any products produced by the Company could expose the Company to product liability claims. The Company currently carries insurance against such claims for clinical trials only. There can be no assurance that the Company has sufficient coverage, or that sufficient coverage can be acquired at a reasonable cost. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of products developed by the Company. A product liability claim or recall could have a material adverse effect on the business or financial condition of the Company.

#### RISK FACTORS

The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time.

**UNCERTAINTY OF PRODUCT DEVELOPMENT AND CLINICAL TESTING:** Existing preclinical and clinical data on the safety and efficacy of gene therapy are limited, and the results of preclinical studies do not necessarily predict safety or efficacy in humans. The Company has not yet completed the development of any products and the Company's potential products currently under development will require significant additional research and development efforts prior to commercial use. There can be no assurance that further research and development will be successful, that any of the Company's potential products will prove to be safe and effective in clinical trials, or that any commercially successful products utilizing the Company's technology will ultimately be developed by the Company or its collaborators. Even if developed, these potential products may not receive regulatory approval or be successfully commercialized.

**HISTORY OF OPERATING LOSSES:** The Company has not generated revenues from the commercialization of any products and expects to incur substantial net operating losses for the next several years. There can be no assurance that the Company will ever achieve product revenues or profitable operations.

**ADDITIONAL FINANCING REQUIREMENTS AND ACCESS TO CAPITAL:** Additional funding will be required to conduct research and development, preclinical studies and clinical trials necessary to bring the Company's potential products to market and to establish manufacturing and marketing capabilities. Insufficient funds may require the Company to scale back or eliminate some or all of its research and development programs or to license third parties to commercialize products the Company would otherwise seek to develop itself. No assurance can be given that additional financing will be available when needed or on terms acceptable to the Company.

**LENGTHY APPROVAL PROCESS AND UNCERTAINTY OF GOVERNMENT REGULATORY REQUIREMENTS:** Given that gene therapy is a new technology and has not been extensively tested in patients, the regulatory requirements governing gene therapy products and related clinical procedures are uncertain and are subject to substantial review by various governmental regulatory authorities. This regulatory review may result in extensive delay in the regulatory approval process. Such requirements ultimately imposed could adversely affect the Company's ability to clinically test, manufacture or market products. There can be no assurance that the Company will be able to obtain the necessary approvals for clinical



trials or for manufacturing or marketing of any products.

**PATENTS AND PROPRIETARY RIGHTS; ACCESS TO PROPRIETARY GENES AND PROTEINS:** To date, the Company has filed or participated as licensee in the filing of a number of patent applications in the United States relating to the Company's technology, as well as foreign counterparts of certain of these applications in many countries. The Company intends to file applications as appropriate for patents covering both its products and processes. There can be no assurance that patents will issue from any of these applications or, if patents do issue, that claims allowed will be sufficient to protect the Company's technology. The Company's success will depend in part on its ability to obtain patent protection for its products and processes both in the United States and other countries. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions, and therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. In addition, there can be no assurance that any patents issued to the Company or to licensors of the Company's technology will not be challenged, invalidated, or circumvented, or that the rights granted thereunder will provide proprietary protection or commercial advantage to the Company.

The commercial success of the Company will also depend in part on the Company not infringing patents issued to competitors and not breaching the technology licenses that might cover technology used in the Company's products. It is uncertain whether any third-party patents will require the Company to alter its products or processes, obtain licenses, or cease certain activities. A number of the genetic sequences or proteins encoded by certain of those sequences that the Company is currently investigating in its clinical trials or may use in other of its gene-based products are or may become patented by others. As a result, the Company may be required to obtain licenses under such patents in order to test, use or market products that contain proprietary genetic sequences or encode proprietary proteins. There can be no assurance that the Company will be able to obtain any such license on commercially favorable terms, if at all. Failure by the Company to obtain a license to any technology that it

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may require to commercialize its products may have a material adverse impact on the Company. Litigation, which could result in substantial cost to the Company, may also be necessary to enforce any patents issued to the Company or to determine the scope and validity of third-party proprietary rights. Should any of its competitors have prepared and filed patent applications in the United States which claim technology also invented by the Company, the Company may have to participate in interference proceedings declared by the PTO in order to determine priority of invention and, thus, the right to a patent for the technology in the United States, all of which could result in substantial cost to the Company to determine its rights. The Company also relies on protecting its proprietary technology in part through confidentiality agreements with its corporate collaborators, employees, consultants and certain contractors. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach, or that the Company's trade secrets will not otherwise become known or be independently discovered by its competitors. See "Business - Collaboration and Licensing Agreements-Access to Proprietary Genes and Proteins" and "-Patents and Proprietary Rights."

**DEPENDENCE ON OTHERS:** The Company's strategy for development and commercialization of certain of its products entails entering into various arrangements with corporate collaborators, licensors, licensees, and others. There can be no assurance that such parties will perform their obligations as expected or that any revenues will be derived from such arrangements, that any of the Company's current strategic arrangements will be continued, or that the Company will be able to enter into future collaborations.

**COMPETITION AND TECHNOLOGICAL CHANGE:** The gene therapy field is new and rapidly evolving, and it is expected to continue to undergo significant and rapid technological change. There can be no assurance that competitors will not succeed in developing technologies and products that are more effective than any which are being developed by the Company or which would render the Company's technology and products obsolete or non-competitive or result in treatments or cures superior to any therapy developed by the Company, or that any therapy developed by the Company will be preferred to any existing or newly developed technologies.

**LACK OF COMMERCIAL SCALE MANUFACTURING OR MARKETING CAPABILITIES:** The Company does not currently have the resources or capability to manufacture or market any of its proposed products by itself on a commercial scale, and large scale manufacturing of such products has not been demonstrated. Initially, the Company may be dependent on corporate partners, licensees or other entities for commercial scale manufacturing and marketing of its products. Should the Company decide to establish a commercial scale manufacturing facility, the

Company will require substantial additional funds and personnel and will be required to comply with extensive regulations applicable to such a facility. There can be no assurance that the Company will be able to enter into any arrangements for the manufacturing or marketing of its products or to obtain additional capital to conduct such activities independently.

UNCERTAINTY OF PRODUCT PRICING, REIMBURSEMENT AND RELATED MATTERS: The Company's ability to earn sufficient returns on its products may depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other organizations. If purchasers or users of the Company's products are not entitled to adequate reimbursement for the cost of using such products, they may forego or reduce such use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and there can be no assurance that adequate third party coverage will be available.

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HAZARDOUS MATERIALS AND ENVIRONMENTAL MATTERS: The Company produces limited quantities of clinical trial supplies. The Company's research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result, and any such liability could exceed the resources of the Company. There can be no assurance that the Company will not be required to incur significant costs to comply with current or future environmental laws and regulations nor that the operations, business or assets of the Company will not be materially or adversely affected by current or future environmental laws or regulations.

VOLATILITY OF STOCK PRICE AND ABSENCE OF DIVIDENDS: The market price of the Company's Common Stock has been and is likely to be highly volatile. Announcements by the Company or others regarding its existing and future collaborations, results of clinical trials, scientific discoveries, technological innovations, regulatory actions, patents or proprietary rights, concern as to the safety of the Company's products, period to period fluctuations in the Company's operating results, market conditions for life science stocks in general and other factors not within the control of the Company may have a significant adverse effect on the market price of the Common Stock. The Company has never paid cash dividends on its Common Stock and does not anticipate paying any cash dividends in the foreseeable future.

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EXECUTIVE OFFICERS

The executive officers of the Company are as follows:

<TABLE>  
<CAPTION>

NAME	AGE	POSITION
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<S>	<C>	<C>
Alain B. Schreiber, M.D.	41	President, Chief Executive Officer and Director
Martha J. Demski, M.B.A.	44	Vice President, Chief Financial Officer, Treasurer and Secretary
Jon A. Norman, Ph.D.	48	Vice President, Research
George J. Gray	50	Vice President, Operations
Robert H. Zaugg, Ph.D.	47	Vice President, Business Development

</TABLE>

ALAIN B. SCHREIBER, M.D. has been President, Chief Executive Officer and a director of the Company since May 1992. Prior to joining the Company, Dr. Schreiber held various executive level positions at Rhone-Poulenc Rorer Inc., a pharmaceutical company, from July 1985 to April 1992, lastly as Senior Vice President of Discovery Research. From October 1982 to June 1985, Dr. Schreiber served as Biochemistry Department Head at Syntex Research. He received his undergraduate degree and M.D. from the Free University of Brussels, after which he was awarded a fellowship in immunology at the Weizmann Institute.

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

JON A. NORMAN, PH.D. joined the Company in January 1993 as Vice President, Research. From 1986 until joining the Company, Dr. Norman was the Group Leader/Section Head for the Departments of Pharmacology and Biochemistry at Bristol-Myers Squibb Corporation, a pharmaceutical company. He was a Senior Research Scientist at Ciba-Geigy Corporation, a pharmaceutical company, from 1981 to 1986. Dr. Norman received his B.A. and M.A. from the University of California at Santa Barbara and his Ph.D. in Biochemistry from the University of Calgary, after which he was awarded a fellowship at the Friederich Miescher Institute in Basel, Switzerland.

GEORGE J. GRAY joined the Company in October 1992 as Vice President, Operations. Prior to that time he was at Rhone-Poulenc Rorer Inc. where he held various positions since 1975, lastly as Director, Discovery Research Ventures, US/UK from January 1990 to October 1992, and prior to that as Director, Project Management from January 1988 to December 1989. Mr. Gray received a B.A. from George Washington University.

ROBERT H. ZAUGG, PH.D. joined the Company in July 1991 as the Senior Director, Business Development and has served as the Vice President of Business Development since January 1994. Prior to joining the Company, Dr. Zaugg served as Director of Business Development & Licensing for Triton Biosciences from 1988 to 1991 and in various business development positions with Sandoz Pharmaceuticals Corporation from 1982 to 1988. He holds a B.A. from the University of California at Los Angeles, a Ph.D. in Biochemistry from Northwestern University and an M.B.A. from New York University. He was awarded a post-doctoral fellowship in immunology at the Massachusetts Institute of Technology.

The executive officers are elected annually by the Board of Directors.

#### SCIENTIFIC ADVISORY BOARD

Vical's Scientific Advisory Board ("SAB") consists of academic and industrial experts in the fields of direct gene transfer, infectious diseases, biology and pharmacology, immunology, oncology and genetic engineering. The Company meets with members of the SAB on an ad hoc basis to discuss research and development strategies, and certain members communicate with the Company's scientists frequently to discuss the details of specific projects. All SAB members own shares or have been granted options to acquire Common Stock of the Company. Each SAB member has entered into a consulting agreement specifying the terms and scope of the advisory relationship with the Company, which provides that the consultant will not consult or otherwise provide services to any other Company engaged in gene therapy without the prior consent of Vical. The Company does not believe that termination of any individual consulting agreement would materially affect its business. All of the SAB members are employed by employers other than the Company and may have other commitments to, or consulting or advisory contracts with, other entities which may compete for such members' time with their obligations to the Company.

ITEM 2. PROPERTIES

The Company currently leases approximately 38,000 square feet of laboratory and office space in San Diego, California at three sites and with three leases. The leases terminate in 1999 and 2001 and contain varying renewal options. Total current monthly rental on the facilities, including common area maintenance costs, is approximately \$90,000.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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

Not applicable.

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PART II

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

The Company's common stock is traded on the Nasdaq National Market under the symbol "VICL." The following table presents quarterly information on the price range of high and low sales prices for the Common Stock on the Nasdaq National Market for the periods indicated since January 1, 1995.

<TABLE>  
<CAPTION>

	HIGH	LOW
<S>	----	---
	<C>	<C>
January 1 - March 31, 1995	\$9.00	\$6.50
April 1 - June 30, 1995	10.75	6.50
July 1 - September 30, 1995	14.50	8.75
October 1 - December 31, 1995	12.875	8.50
January 1 - March 31, 1996	20.00	11.50
April 1 - June 30, 1996	22.00	13.00
July 1 - September 30, 1996	16.625	10.375
October 1 - December 31, 1996	21.25	12.75

</TABLE>

As of February 28, 1997, there were approximately 579 stockholders of record of the Company's common stock with 15,426,574 shares outstanding. The Company has never declared or paid any dividends and does not expect to pay any dividends in the foreseeable future.

## ITEM 6. SELECTED FINANCIAL DATA

<TABLE>  
<CAPTION>

	YEAR ENDED DECEMBER 31,				
	1996	1995	1994	1993	1992
	(in thousands, except per share and share amounts)				
<S>	<C>	<C>	<C>	<C>	<C>
STATEMENT OF OPERATIONS DATA:					
Revenues:					
Contract revenue . . . . .	\$ 1,061	\$ 900	\$ 1,005	\$ 1,206	\$
License/royalty revenue . . .	5,679	5,402	4,509	1,623	
Sale of technology . . . . .	--	--	--	3,148	
	6,740	6,302	5,514	5,977	
Expenses:					
Research and development . . . .	11,318	8,997	8,336	6,163	
General and administrative . . .	3,168	2,902	2,615	1,989	
Loss from operations . . . . .	(7,746)	(5,597)	(5,437)	(2,175)	
Interest income . . . . .	2,773	1,687	1,159	873	
Interest expense . . . . .	108	73	80	63	
Net loss . . . . .	\$ (5,081)	\$ (3,983)	\$ (4,358)	\$ (1,365)	\$
Net loss per share . . . . .	\$ (.33)	\$ (.29)	\$ (.34)	\$ (.12)	\$
Shares used in per share calculation .	15,382,848	13,504,790	12,831,585	11,065,357	8,498,742

</TABLE>

<TABLE>  
<CAPTION>

	YEAR ENDED DECEMBER 31,				
	1996	1995	1994	1993	1992
	(in thousands)				
<S>	<C>	<C>	<C>	<C>	<C>
BALANCE SHEET DATA:					
Cash, cash equivalents and marketable securities . . . . .	\$ 46,846	\$ 52,528	\$ 27,339	\$ 32,538	\$
Working capital . . . . .	46,315	51,541	25,956	30,920	
Total assets . . . . .	52,440	55,118	30,324	35,123	
Long-term obligations . . . . .	1,617	339	527	447	
Stockholders' equity . . . . .	48,365	53,264	27,852	32,446	

</TABLE>

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

OVERVIEW

Vical was incorporated in April 1987 and since that time has devoted substantially all of its resources to its research and development programs. To date, the Company has not received revenues from the sale of products. No assurance can be given that the Company will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. As of December 31, 1996, the Company's accumulated deficit was approximately \$24.6 million.

Vical expects to incur substantial operating losses for at least the next several years due to significant increases in research and development expenses. The increases are expected to result from costs of preclinical studies and clinical trials for the Company's product candidates, increased patent and regulatory costs, and associated increases in personnel. Losses may fluctuate from quarter to quarter as a result of differences in the timing of expenses incurred and the revenues received from collaborative agreements. Such fluctuations may be significant.

When used in this discussion, the words "expects," "anticipated" and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks and uncertainties which could cause actual results to differ materially from those projected. Readers are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date hereof. The Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

RESULTS OF OPERATIONS

The Company had revenues of \$6.7 million for the year ended December 31, 1996, compared with \$6.3 million in 1995 and \$5.5 million in 1994. Revenues in 1996 resulted from research and license income from: the PMC collaboration in the amount of \$2.7 million, the Merck Agreement in the amount of \$1.5 million, the Genzyme collaboration in the amount of \$1.3 million, and several other agreements in the amount of \$1.2 million. Revenue from the PMC agreement in 1996 was primarily the result of PMC's payment of licensing and option fees, and the addition of a new option, as well as the payment of fees for the Company's performance of certain clinical and preclinical work. The Merck revenue resulted from milestone payments due under the Merck agreement. The Genzyme collaboration income was the result of Genzyme exercising its option to license the Company's technology for the treatment of cystic fibrosis as well as payments for the Company's performance of certain research and preclinical work. Revenues in 1995 resulted from research and license income from the Merck Agreement in the amount of \$3.6 million, from the PMC collaboration in the amount of \$1.3 million and under several other agreements in the amount of \$1.4 million. Revenue in 1995 from the Merck Agreement resulted primarily from the exercise by Merck of remaining options to license Vical's technology to develop preventive vaccines against certain human disease targets and the recognition of revenue from previously received payments. PMC renewed its options to acquire rights to use Vical's technology against certain disease targets and exercised one such option in 1995. Revenues in 1994 resulted from research and license income from the Merck Agreement in the amount of \$2.7 million, from the PMC collaboration in the amount of \$1.2 million and under other agreements in the amount of \$1.6 million. The Merck revenues included recognition of previously received payments as well as payments received in 1994 to exercise options to license Vical's technology for use against two vaccine targets, hepatitis C and human papilloma virus, to extend the exclusive option to license Vical's technology for use with the hepatitis B and herpes simplex vaccine targets, and to acquire an option to an exclusive license to use Vical's proprietary gene-based vaccine technology for development of a tuberculosis vaccine.

Research and development expense increased to \$11.3 million in 1996 from \$9.0 million in 1995 and \$8.3 million in 1994. This increase in research and development expense was generally due to expansion of the Company's research and development activities and preclinical and clinical efforts that resulted in staffing increases and increased expenditures on laboratory supplies. During 1996, the Company incurred expenses of approximately \$1.2 million with the commencement and progression of the multi-center Phase I/II and Phase II clinical trials of Leuvectin and Allovectin-7 respectively. Such costs are expected to continue to increase in 1997 and thereafter as the Company's preclinical and clinical trial activities increase.

General and administrative expense increased to \$3.2 million in 1996 from \$2.9 million in 1995 and \$2.6 million in 1994. These increases were due primarily to additional staffing and related expenses, as well as increased business development efforts. General and administrative expenses are expected to continue to increase as research and development activities expand.

Prior to its initial public offering in March 1993, the Company recorded deferred compensation for the difference between the price of stock sold and options granted and the deemed fair market value of the Common Stock at the time of sale or grant. Deferred compensation and related amortization expense as of and for the year ended December 31, 1996, amounted to approximately \$1.0 million and \$158,000, respectively. Deferred compensation was fully amortized at December 31, 1996.

Interest income increased to \$2.8 million in 1996 compared with \$1.7 million in 1995 and \$1.2 million in 1994. These increases are primarily due to changes in cash balances as a result of the completion of a follow-on offering of common stock in September 1995, increases in payments received under collaborative agreements and changes in the overall interest rates earned on cash balances. Interest expense fluctuated to \$107,000 in 1996 from \$73,000 in 1995 and \$80,000 in 1994 due to changing capital lease obligations to finance equipment needs and the addition of a debt instrument in 1996.

Vical expects to incur substantial operating losses over the next several years due to anticipated significant increases in research and development expenses. Increases in costs are expected to result from the aforementioned preclinical efforts and clinical trials for the Company's proposed products, increased patent and regulatory costs and associated increases in personnel. Losses may fluctuate from quarter to quarter as a result of differences in the timing of expenses incurred and the revenues received from collaborative agreements. Such fluctuations may be significant.

#### LIQUIDITY AND CAPITAL RESOURCES

Since its inception, Vical has financed its operations primarily through private placements of preferred stock, three public offerings of common stock, and revenues from collaborative agreements. As of December 31, 1996, the Company had working capital of approximately \$46.3 million compared with \$51.5 million at December 31, 1995. Cash and marketable securities totaled approximately \$46.8 million at December 31, 1996, compared with \$52.5 million at December 31, 1995.

The Company expects to incur substantial additional research and development expense including continued increases in personnel and costs related to preclinical testing and clinical trials. The Company's future capital requirements will depend on many factors, including the rate of scientific progress in its 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 and enforcing patent claims, competing technological and market developments, the cost of manufacturing scale-up, commercialization activities and arrangements and other factors not within the Company's control. The Company intends to seek additional funding through research and development relationships with suitable potential corporate collaborators and/or through public or private financings. There can be no assurance that additional financing will be available on favorable terms, if at all.

If additional financing is not available, Vical anticipates that its available cash and existing sources of funding will be adequate to satisfy its operating needs through 1998.

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#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and supplementary data of the Company required by this item are set forth at the pages indicated in Item 14(a)(1).

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

Not applicable.

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#### PART III

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

DIRECTORS

The directors of the Company are as follows:

NAME - ----	AFFILIATION -----
Alain B. Schreiber, M.D.	Vical Incorporated
Robert C. Bellas, Jr.	Morgenthaler Ventures
M. Blake Ingle	Canji, Inc. (retired)
Patrick F. Latterell	Venrock Associates
Fred A. Middleton	Sanderling Venture Partners, Inc.
Dale A. Smith	Baxter International Inc. (retired)
Philip M. Young	U.S. Venture Partners

The information required by this item (with respect to Directors) is incorporated by reference from the information under the caption "Election of Directors" contained in the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Company's 1997 Annual Meeting of Stockholders to be held on June 10, 1997 ("Proxy Statement").

The required information concerning Executive Officers of the Company is contained in Part I of this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

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PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS  
ON FORM 8-K

(A) (1) FINANCIAL STATEMENTS

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

Financial Statements

Report of Independent Public Accountants	F-1
Balance Sheets at December 31, 1996 and 1995	F-2
Statements of Operations for the three years ended December 31, 1996	F-3
Statements of Stockholders' Equity for the three years ended December 31, 1996	F-4
Statements of Cash Flows for the three years ended December 31, 1996	F-5
Notes to Financial Statements	F-6

(2) FINANCIAL STATEMENT SCHEDULES



Schedules 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 with each management contract or compensatory plan or arrangement required to be filed are identified. See paragraph (c) below.

(B) REPORTS ON FORM 8-K

No reports on Form 8-K were filed during the quarter ended December 31, 1996.

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(C) EXHIBITS

<TABLE>  
<CAPTION>

EXHIBIT  
-----  
NUMBER  
-----

DESCRIPTION OF DOCUMENT  
-----

<S>	<C>
3(i)(11)	Restated Certificate of Incorporation.
3(ii)(11)	Amended and Restated Bylaws of the Company.
3.2(i)(2)	Certificate of Designation, Rights and Preferences of Series A Participating Stock of Vical Incorporated.
4.1(11)	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)#	1992 Stock Plan of Vical Incorporated.
10.2(5)#	1992 Directors' Stock Option Plan of Vical Incorporated.
10.3(3)	Form of Indemnity Agreement between the Company and its directors and officers.
10.4(3)#	Employment Agreement dated April 17, 1992, between the Company and Dr. Alain B. Schreiber.
10.5(3)#	Employment Agreement dated August 20, 1992, between the Company and Mr. George J. Gray.
10.6(3)#	Employment Agreement dated November 2, 1992, between the Company and Dr. Jon A. Norman.
10.7(3)	Stock Purchase Agreement dated February 20, 1992.
10.8(3)	Lease dated December 4, 1987, between the Company and Nexus/GADCo.-UTC, a California Joint Venture, as amended.
10.9(6)*	Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.10(3)*	Agreement dated as of January 6, 1993, between the Registrant and Vestar, Inc.
10.11(7)*	License and Development Agreement dated February 21, 1992, between the Company and ISIS Pharmaceuticals, Inc.
10.12(1)*	License Agreement dated January 1, 1991, between the Company and Wisconsin Alumni Research Foundation.
10.13(1)*	License Agreement dated September 17, 1992, between the Registrant and the

Regents of University of Michigan.

10.14(1)*	License Agreement dated October 23, 1992, between the Company and the Regents of University of Michigan.
10.15(8)#	Employment Agreement dated February 21, 1994, between the Company and Ms. Martha J. Demski.
10.16(9)	Research, Option and License Agreement dated September 29, 1994, between the Company and Pasteur Merieux Serums & Vaccins.
10.17(10)	Amendment dated April 27, 1994, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
11	Schedule re: Computation of net loss per share.
23.1	Consent of Arthur Andersen LLP.
24	Power of Attorney (see page 32).

</TABLE>

- 
- (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 Exhibits 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 (No. 33-81602) filed on July 15, 1994.

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- (5) Incorporated by reference to Exhibit 10.1 filed with the Company's Registration Statement on Form S-8 (No. 33-87972) filed on December 29, 1994.
- (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 10.3 of ISIS Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 1992, as amended (No. 0-19125).
- (8) 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, 1993 (No. 0-21088).
- (9) Incorporated by reference to Exhibit A of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994.
- (10) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994 (No. 0-21088).
- (11) 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.

\* The Company has received confidential treatment of certain portions of these agreements.

# Indicates management contract or compensatory plan or arrangement.

The financial statement schedules of Vical Incorporated required by this item are set forth at the pages indicated in Item 14(a)(2).

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on February 28, 1997.

VICAL INCORPORATED

By: s/ Alain B. Schreiber  
-----  
Alain B. Schreiber, M.D.  
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.

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alain B. Schreiber and Martha J. Demski, and each of them, his or her attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Report and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each said attorneys-in-fact, or substitute or substitutes, may do or cause to be done by virtue hereof.

s/ Alain B. Schreiber ----- Alain B. Schreiber	President, Chief Executive Officer and Director	February 28, 1997
s/ Martha J. Demski ----- Martha J. Demski	Vice President, Finance Chief Financial Officer Secretary and Treasurer	February 28, 1997
s/ Robert C. Bellas ----- Robert C. Bellas	Director	February 28, 1997

s/ Fred A. Middleton	Director	February 28, 1997
-----		
Fred A. Middleton		
s/ Philip M. Young	Director	February 28, 1997
-----		
Philip M. Young		
s/ Patrick F. Latterell	Director	February 28, 1997
-----		
Patrick F. Latterell		
s/ Dale A. Smith	Director	February 28, 1997
-----		
Dale A. Smith		
s/ M. Blake Ingle	Director	February 28, 1997
-----		
M. Blake Ingle		

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Vical Incorporated:

We have audited the accompanying balance sheets of Vical Incorporated, a Delaware corporation, as of December 31, 1996 and 1995, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 1996. 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 generally accepted auditing standards. 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, 1996 and 1995, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1996, in conformity with generally accepted accounting principles.

ARTHUR ANDERSEN LLP

San Diego, California  
January 31, 1997

VICAL INCORPORATED  
BALANCE SHEETS

<TABLE>  
<CAPTION>

	December 31,	
	1996	1995
	-----	-----
<S>	<C>	<C>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents (Note 2)	\$ 12,609,277	\$ 7,174,128
Marketable securities - available-for-sale (Note 2)	34,237,314	45,353,638
Receivables and other	1,925,995	528,089
	-----	-----
Total current assets	48,772,586	53,055,855
	-----	-----
Property and Equipment (Note 5):		
Equipment	4,635,432	3,218,315
Leasehold improvements	1,235,199	517,846
	-----	-----
	5,870,631	3,736,161
Less--Accumulated depreciation and amortization	(3,607,724)	(3,044,110)
	-----	-----
	2,262,907	692,051
	-----	-----
Patent costs (Note 1)	1,091,687	835,410
Other assets	312,900	534,188
	-----	-----
	\$ 52,440,080	\$ 55,117,504
	=====	=====
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses (Note 4)	\$ 810,384	\$ 528,297
Current portion of capital lease obligations (Note 5)	455,681	307,485
Deferred revenue (Note 3)	1,191,304	679,167
	-----	-----
Total current liabilities	2,457,369	1,514,949
	-----	-----
Long-Term Obligations:		
Long-term obligations under capital leases (Note 5)	976,164	338,514
Notes payable (Note 5)	641,320	-
	-----	-----
Total long-term obligations	1,617,484	338,514
	-----	-----
Commitments (Note 5)		
Stockholders' Equity (Note 6):		
Common stock, \$.01 par value--40,000,000 shares authorized-- 15,396,582 and 15,364,265 shares issued and outstanding in 1996 and 1995, respectively	153,966	153,643
Additional paid-in capital	72,904,472	72,728,484
Deferred compensation	-	(158,427)
Unrealized gain (loss) on marketable securities (Note 2)	(48,785)	104,176
Accumulated deficit	(24,644,426)	(19,563,835)
	-----	-----
Total stockholders' equity	48,365,227	53,264,041
	-----	-----
	\$ 52,440,080	\$ 55,117,504
	=====	=====

</TABLE>

See accompanying notes.

<TABLE>  
<CAPTION>

	Year ended December 31,		
	1996	1995	1994
<S>	<C>	<C>	<C>
Revenues (Note 3):			
Contract revenue	\$ 1,060,557	\$ 899,547	\$ 1,005,278
License/Royalty revenue	5,679,542	5,402,018	4,508,794
	-----	-----	-----
	6,740,099	6,301,565	5,514,072
Expenses:			
Research and development	11,317,908	8,997,001	8,335,954
General and administrative	3,168,331	2,902,176	2,614,825
	-----	-----	-----
	14,486,239	11,899,177	10,950,779
	=====	=====	=====
Loss from operations	(7,746,140)	(5,597,612)	(5,436,707)
Other income (expense):			
Interest income	2,772,845	1,687,380	1,159,484
Interest expense	(107,296)	(73,219)	(80,645)
	-----	-----	-----
Net loss	\$ (5,080,591)	\$ (3,983,451)	\$ (4,357,868)
	=====	=====	=====
Net loss per share (Note 1)	\$ (0.33)	\$ (0.29)	\$ (0.34)
	=====	=====	=====
Shares used in per share calculation	15,382,848	13,504,790	12,831,585
	=====	=====	=====

</TABLE>

See accompanying notes.

F-3

VICAL INCORPORATED  
STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE THREE YEARS ENDED DECEMBER 31, 1996

<TABLE>  
<CAPTION>

Total	Common Stock		Additional	Deferred	Unrealized Gain (Loss) on	Accumulated
	Shares	Amount	Paid-in Capital	Compensation	Marketab Securities	Deficit
Stockholders' Equity						
	-----	-----	-----	-----	-----	-----
<S>	<C>	<C>	<C>	<C>	<C>	<C>
BALANCE, December 31, 1993	12,828,819	\$ 128,288	\$44,182,216	(\$642,288)	\$ -	(\$11,222,516)
\$32,445,700						
Repurchase of common stock at \$.16 per share (797)	(4,434)	(44)	(2,223)	1,470	-	-
Stock option exercises 3,854	21,329	213	3,641	-	-	-
Deferred compensation 234,017	-	-	-	234,017	-	-
Unrealized gain (loss) on marketable securities	-	-	-	-	(472,708)	-

(472,708)							
Net loss	-	-	-	-	-	-	-
(4,357,868)	(4,357,868)						
-----							
BALANCE, December 31, 1994	12,845,714	128,457	44,183,634	(406,801)	(472,708)	(15,580,384)	
27,852,198							
Issuance of common stock							
at \$12.25 per share	2,500,000	25,000	28,524,733	-	-	-	
28,549,733							
Repurchase of common stock							
at \$.16 per share	(449)	(4)	(123)	43	-	-	
(84)							
Stock option exercises	19,000	190	20,240	-	-	-	
20,430							
Deferred compensation	-	-	-	248,331	-	-	
248,331							
Unrealized gain (loss) on							
marketable securities	-	-	-	-	576,884	-	
576,884							
Net loss	-	-	-	-	-	-	
(3,983,451)	(3,983,451)						
-----							
BALANCE, December 31, 1995	15,364,265	153,643	72,728,484	(158,427)	104,176	(19,563,835)	
53,264,041							
Stock option exercises	32,317	323	175,988				
176,311							
Deferred compensation				158,427			
158,427							
Unrealized gain (loss) on							
marketable securities					(152,961)		
(152,961)							
Net loss							
(5,080,591)	(5,080,591)						
-----							
BALANCE, December 31, 1996	15,396,582	\$ 153,966	\$72,904,472	\$ -	\$ (48,785)	\$ (24,644,426)	
\$48,365,227							
=====							

</TABLE>

See accompanying notes.

F-4

VICAL INCORPORATED  
STATEMENTS OF CASH FLOWS

<TABLE>

<CAPTION>

	Year ended December 31,		
	1996	1995	1994
	-----	-----	-----
<S>	<C>	<C>	<C>
OPERATING ACTIVITIES:			
Net loss	\$ (5,080,591)	\$ (3,983,451)	\$ (4,357,868)
	-----	-----	-----
Adjustments to reconcile net loss to net cash provided			
from (used in) operating activities:			
Depreciation and amortization	620,033	509,375	493,868
Compensation expense related to stock purchases	158,427	248,331	234,017
Write-off of abandoned patent application costs	3,247	220,440	180,314
Changes in operating assets and liabilities:			
Receivables and other	(1,397,906)	33,902	49,841
Accounts payable and accrued expenses	282,087	(24,400)	156,105
Deferred revenue	512,137	(350,000)	(516,249)
Other	-	43	1,470

Net cash provided from (used in) operating activities	(4,902,566)	(3,345,760)	(3,758,502)
INVESTING ACTIVITIES:			
Marketable securities	10,963,363	(19,701,751)	5,834,655
Capital expenditures	(980,709)	(40,322)	(503,261)
Other assets	221,288	171,888	171,481
Patent expenditures	(269,682)	(356,135)	(283,326)
Net cash provided from (used in) investing activities	9,934,260	(19,926,320)	5,219,549
FINANCING ACTIVITIES:			
Principal payments under capital lease obligations	(414,176)	(387,958)	(354,495)
Proceeds from notes payable	641,320	-	-
Issuance of common stock, net	176,311	28,570,036	1,587
Net cash provided from (used in) financing activities	403,455	28,182,078	(352,908)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,435,149	4,909,998	1,108,139
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,174,128	2,264,130	1,155,991
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 12,609,277	\$ 7,174,128	\$ 2,264,130
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest Paid	\$ 107,296	\$ 73,219	\$ 80,645
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Equipment acquired under capital leases	\$ 1,200,022	\$ 144,355	\$ 509,549

</TABLE>

See accompanying notes.

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VICAL INCORPORATED  
NOTES TO FINANCIAL STATEMENTS  
December 31, 1996

1. Summary of Significant Accounting Policies

Organization and Business Activity

Vical Incorporated (the "Company"), a Delaware corporation, was incorporated in 1987. Vical discovers and develops non-viral, gene-based pharmaceutical product candidates for human gene therapy.

All of the Company's potential products are in research and development. No revenues have been generated from the sale of any of such products, nor are any such revenues expected for at least the next several years. The products currently under development by the Company will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercial use. There can be no assurance that the Company's research and development efforts will be successful and that any of the Company's potential products will prove to be safe and effective in clinical trials. Even if developed, these products may not receive regulatory approval or be successfully introduced and marketed at prices that would permit the Company to operate profitably. The Company expects to continue to incur substantial losses for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable at all or on a sustained basis.

Use of Estimates

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



#### Property and Equipment

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

#### Patent Costs

The Company capitalizes certain costs related to patent applications. Accumulated costs are amortized over the estimated economic lives of the patents using the straight-line method, commencing at the time the patents are issued. Costs related to patent applications are written off to expense at the time such costs are deemed to have no continuing value.

#### Research and Development Costs

All research and development costs are expensed as incurred.

#### Revenue Under Collaborative Agreements

Revenue under collaborative agreements is generally recognized over the term of the agreement or on the achievement of certain milestones. Advance payments received in excess of amounts earned are classified as deferred revenue.

#### Net Loss Per Share

Net loss per share for the three years ended December 31, 1996, has been computed using the weighted average number of shares of common stock outstanding during the periods. Common equivalent shares are excluded as the effect would be antidilutive.

#### Income Taxes

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109 ("SFAS 109"), "Accounting for Income Taxes."

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#### New Accounting Standard

In January 1996, the Company adopted Statement of Financial Accounting Standards No. 123 ("SFAS 123"), "Accounting for Stock-Based Compensation." The Company has elected to adopt the alternative disclosure provisions of SFAS 123 and therefore will not be recording stock-based compensation using fair value accounting as defined under SFAS 123.

## 2. Cash Equivalents and Marketable Securities

The Company invests its excess cash in debt instruments of financial institutions, corporations with strong credit ratings, and in U.S. government obligations. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. Cash equivalents are short-term, highly liquid investments with original maturities of less than three months. Cash equivalents at December 31, 1996 and 1995, consist primarily of \$12,560,988 and \$5,959,870, respectively, in commercial paper and money market funds.

In January 1994, the Company adopted Statement of Financial Accounting Standards No. 115 ("SFAS 115"), "Accounting for Certain Investments in Debt and Equity Securities." The provisions of SFAS 115 require that the Company's marketable securities be classified as available-for-sale and that unrealized holding gains or losses are recorded as a separate component of stockholders' equity. Realized gains or losses are calculated based on the specific identification method.

At December 31, 1996, marketable securities consisted of the following:

<TABLE>

<CAPTION>

	Amortized Cost	Market Value	Unrealized Gain (Loss)
	-----	-----	-----
<S>	<C>	<C>	<C>
U.S. Government Obligations	\$ 25,421,815	\$ 25,395,811	\$ (26,004)
Commercial Paper	8,864,284	8,841,503	(22,781)
Total Marketable Securities	\$ 34,286,099	\$ 34,237,314	\$ (48,785)
	=====	=====	=====

</TABLE>

Approximately 55% of these securities mature within one year of December 31, 1996, and the remaining 45% mature within two years of December 31, 1996.

At December 31, 1995, marketable securities consisted of the following:

<TABLE>  
<CAPTION>

	Amortized Cost	Market Value	Unrealized Gain (Loss)
<S>	<C>	<C>	<C>
U.S. Government Obligations	\$ 28,637,937	\$ 28,731,446	\$ 93,509
Commercial Paper	16,611,525	16,622,192	10,667
Total Marketable Securities	\$ 45,249,462	\$ 45,353,638	\$ 104,176

</TABLE>

### 3. Significant Contracts and License Agreements

#### Pasteur Merieux Connaught

In September 1994, the Company entered into an agreement with Pasteur Merieux Connaught ("PMC") that includes a research collaboration and options for PMC to take exclusive licenses to Vical's "naked" DNA vaccine technology for each of five vaccine targets. In order to maintain the options, PMC will be required to pay Vical option fees as specified in the agreement. In addition, Vical shall be paid an annual research fee through September 1998 by PMC for expenses incurred in performing certain preclinical work as defined in the agreement. PMC renewed options and exercised an option in 1995. In 1996, PMC exercised three options, extended one option, and added a new option. Through December 31, 1996, Vical has received \$5,950,000 of which \$2,746,000, \$1,287,500, and \$1,225,000 was recognized as income in 1996, 1995, and 1994, respectively. The agreement provides for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales. Under a separate agreement Vical is obligated to pay a third party 10 percent of certain payments received by the Company under the PMC agreement.

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#### Genzyme Corporation

In October 1993, the Company entered into an option agreement with Genzyme Corporation ("Genzyme"). The Company granted Genzyme a three year option to obtain exclusive worldwide license rights related to the use of the Company's cytofectin technology in the treatment of cystic fibrosis. Vical also granted Genzyme a right of first offer to use the Company's cytofectin technology in other lung disorders. In 1996, Genzyme exercised the option, resulting in a \$1,000,000 payment to Vical. Through December 31, 1996, Vical received \$2,300,000 from Genzyme of which \$1,300,000, \$400,000 and \$475,000 has been recognized as income in 1996, 1995, and 1994, respectively. The agreement also provides for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

#### Merck & Co., Inc.

In May 1991, the Company entered into a collaborative research, development, and commercialization agreement with Merck & Co., Inc. ("Merck"), which provides Merck with certain exclusive rights to develop and commercialize certain preventive human infectious disease vaccines incorporating the Company's naked DNA vaccine technology. A second collaborative agreement was signed in May 1992 granting Merck exclusive rights to develop and commercialize the Company's naked DNA vaccine technology for an animal disease application. In 1993, Merck exercised its right under the 1991 agreement to extend its option to vaccines developed against five specific infectious disease targets in return for the payment to Vical of \$1,250,000. In 1994, Merck acquired the option to an exclusive license to use the Company's naked DNA vaccine technology for the development of a tuberculosis vaccine. In 1994, Merck also exercised its options to license the Company's technology for use with two vaccine targets and extended its option to vaccines developed against two other specific diseases. For these 1994 transactions, the Company received \$2,300,000. In 1995, Merck exercised its remaining options. The Company received approximately \$2,950,000 for these transactions in 1995. In 1996, the Company received a \$1,000,000 payment from Merck upon the initiation of a Phase I clinical trial of an experimental DNA vaccine against influenza virus, one of the seven infectious disease targets covered by the agreement. Also in 1996, Vical accrued a \$500,000 payment from Merck in conjunction with the issuance of the patent technology covering the agreement. The payment was subsequently received in 1997. Through December 1996, the Company had received a total of \$11,630,000 under these agreements of which \$1,500,000, \$3,562,500, and \$2,665,000 has been recognized as revenues in 1996, 1995, and 1994,

respectively. Both agreements provide for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales. Under a separate agreement the Company is obligated to pay a third party 10 percent of certain payments received by the Company under the Merck agreements.

#### Baxter Healthcare Corporation

In December 1993, the Company entered into a collaborative research and renewable option agreement with Baxter Healthcare Corporation ("Baxter"). The Company granted Baxter an option to obtain an exclusive worldwide license to the Company's direct DNA injection technology for use in the treatment of hemophilia. Baxter renewed the option agreement in 1995. Through the termination of this agreement in December 1996, the Company had received \$1,100,000 from Baxter of which \$91,667, \$300,000, and \$666,667 has been recognized as income in 1996, 1995, and 1994, respectively.

#### 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 \$1,102,000, \$752,000, and \$483,000 was recognized as revenue during the years ended December 31, 1996, 1995, and 1994, respectively. Included in the 1996 and 1995 amounts is revenue recognized for a corporate alliance entered into in March 1995 relating to DNA vaccines in the animal health area with Rhone Merieux, a leading manufacturer and marketer of animal health products worldwide. The agreement includes options for Rhone Merieux to take exclusive licenses to Vical's naked DNA vaccine technology and the cytofectin technology to develop and commercialize certain gene-based products for use in the prevention of infectious diseases in domesticated animals. In 1996, the agreement was extended to March 1998. If Rhone Merieux exercises its license options, cash payments and royalties on net sales would be due to the Company. Under a U.S. government agreement announced in September 1995, the Company and the Naval Medical Research Institute were awarded a grant that was to provide up to \$1,000,000 per year for up to three years to support further development of a malaria vaccine based on Vical's naked DNA vaccine technology. The agreement commenced in the first quarter of 1996. As a result of subsequent federal budget cuts, funding for the grant has been capped at \$1,000,000 total and the agreement now is expected to end June 30, 1997.

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#### 4. Other Financial Data

Accounts payable and accrued expenses consisted of the following at December 31, 1996 and 1995:

<TABLE>  
<CAPTION>

	1996	1995
<S>	<C>	<C>
Employee compensation	\$ 556,224	\$ 321,233
Accounts payable	148,062	130,242
Other accrued liabilities	106,098	76,822
	-----	-----
	\$ 810,384	\$ 528,297
	=====	=====

</TABLE>

#### 5. Commitments

##### Leases

The Company leases its office and research facilities and certain equipment under operating and capital leases. The minimum annual rents on the office and research facilities are subject to increases based on changes in the Consumer Price Index, taxes, insurance and operating costs, subject to certain minimum and maximum annual increases.

Annual future minimum obligations for capital and operating leases as of December 31, 1996, are as follows:

<TABLE>  
<CAPTION>

	Operating Leases -----	Capital Leases -----
Years ended December 31, <S>	<C>	<C>
1997	\$ 1,072,946	\$ 574,290
1998	1,110,388	438,638
1999	1,089,336	353,050
2000	453,204	325,518
2001	114,404	-
	-----	-----
Total minimum lease payments	\$3,840,278	1,691,496
	=====	
Less amount representing interest		(259,651)
		-----
Present value of capital lease payments		1,431,845
Less current portion		(455,681)
		-----
Long-term obligations under capital leases		\$ 976,164
		=====

</TABLE>

Rent expense for the years ended December 31, 1996, 1995, and 1994, was \$807,713, \$517,446, and \$549,490, respectively.

Cost and accumulated depreciation of equipment under capital leases were as follows:

<TABLE>  
<CAPTION>

	Cost	Accumulated Depreciation
Net	----	-----
---		
<C>	<S>	<C>
1,378,751	December 31, 1996	\$2,186,648
602,556	December 31, 1995	807,897
		812,646

</TABLE>

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#### Notes Payable

In June 1996, the Company entered into a loan and security agreement with a bank which provides for borrowings of up to \$2,500,000. Borrowings currently bear interest at the bank's prime rate (8.25% at December 31, 1996) plus .5%, or the Company may alternatively choose to have its borrowings bear interest at the LIBOR rate plus 3.25%. Borrowings under the line of credit are secured by substantially all assets of the Company, and the Company is required to comply with certain financial covenants. The Company was in compliance with such covenants at December 31, 1996. In April 1997, any outstanding borrowings convert to a term loan with amortization over a three year period. The term loan will bear interest at the same rate options. At December 31, 1996, borrowings under the line of credit totaled \$641,000.

#### Research and License Agreements

In 1996 and 1995, the Company continued research and exclusive license agreements with various universities for continuing research and license rights to technology related to gene therapy. The agreements generally grant the Company the right to commercialize any product derived from specified technology. Fees paid and future obligations on these agreements are not significant.

6. Stockholders' Equity

Preferred Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 5,000,000 preferred shares. No shares of preferred stock were outstanding at December 31, 1996 or 1995.

Common Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 40,000,000 common shares. Common stock shares totaling 15,396,582 and 15,364,265 were outstanding at December 31, 1996 and 1995, respectively.

Deferred Compensation

Prior to its initial public offering the Company recorded approximately \$1,018,000 of deferred compensation for the difference between the price of stock sold and options granted and the deemed fair value of the Company's common stock. Such deferred compensation was amortized to expense over the various vesting periods and is fully amortized at December 31, 1996. Amortization expense amounted to \$158,427 and \$248,331 for the years ended December 31, 1996 and 1995, respectively.

Stock Plan and Directors Option Plan

The Company has a stock plan ("1992 Stock Plan") under which 1,000,000 shares of common stock are reserved for issuance to employees and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares. The exercise price of incentive stock options must equal at least the fair market value on the date of grant. The exercise price of nonstatutory stock options and direct awards or sales of shares may be no less than 85 percent of the fair market value on the date of grant. The maximum term of options granted under the plan is ten 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 December 1996, the Company's Board of Directors adopted an amendment to increase the number of shares of common stock reserved for issuance under this plan by 700,000 shares and to allow non-employee director participation in the plan. The amendment is subject to the approval of the stockholders at the 1997 annual meeting.

The Company also has a directors stock option plan ("Directors Plan") that provides for the issuance of up to 210,000 shares of the Company's common stock to non-employee directors.

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The following table summarizes stock option transactions for the years ended December 31, 1996 and 1995:

<TABLE>  
<CAPTION>

	1992 Stock Plan and Directors Plan	
	Shares	Weighted Ave.
<S>	<C>	<C>
Outstanding, December 31, 1994	655,850	\$ 7.2307
Granted	174,650	\$ 9.0631
Exercised	(19,000)	\$ 1.0752
Forfeited	(61,588)	\$ 9.8354
	-----	
Outstanding, December 31, 1995	749,912	\$ 7.5994
Granted	456,350	\$ 15.9872
Exercised	(32,317)	\$ 5.4839
Forfeited	(14,264)	\$ 10.9745
	-----	
Outstanding, December 31, 1996	1,159,681	\$ 10.9176
	=====	=====

Exercisable, December 31, 1996	487,625 =====	\$ 6.8222 =====
-----------------------------------	------------------	--------------------

</TABLE>

The Company has adopted the disclosure-only provisions of SFAS 123. Accordingly, no compensation cost has been recognized for the stock option plans. Had compensation cost for the Company's stock option plans been determined consistent with the provisions of SFAS 123, the Company's net loss and loss per share would have increased to the pro forma amounts indicated below:

<TABLE>  
<CAPTION>

	1996 -----	1995 -----
<S>	<C>	<C>
Net loss - as reported	\$5,080,591	\$3,983,451
Net loss - pro forma	\$6,497,447	\$4,143,062
Net loss per share - as reported	\$.33	\$.29
Net loss per share - pro forma	\$.42	\$.31

</TABLE>

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants in 1996 and 1995: risk free interest rate of 6.57%, expected option life of 5 years, expected volatility of 73.65% and a dividend rate of zero.

Because SFAS 123 has not been applied to options granted prior to January 1, 1995, the resulting pro forma compensation cost may not be representative of that to be expected in future years.

#### 7. Related Parties

Included in other assets at December 31, 1996 and 1995, is the long-term portion of notes receivable, representing amounts due from certain officers and employees of the Company. Imputed interest is applied at the applicable federal rate. The loan agreements allow for the notes to be forgiven under certain circumstances over the next three years. The long-term portion at December 31, 1996, is \$50,000. There were no long-term amounts outstanding at December 31, 1995. The current portion, included in receivables and other, is \$25,000 and \$50,000, at December 31, 1996 and 1995, respectively.

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#### 8. Income Taxes

As of December 31, 1996, the Company has available net operating loss carryforwards of approximately \$22,400,000 and research and development credit carryforwards of approximately \$1,100,000 to reduce future federal income taxes, if any. These carryforwards expire through 2011 and are subject to review and possible adjustment by the Internal Revenue Service.

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

The Company has a deferred tax asset of approximately \$11,600,000 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 realization of such asset is uncertain.

#### 9. Employee Benefit Plans

The Company has a defined contribution savings plan under section 401(k) of the Internal Revenue Code. The plan covers substantially all full-time employees. In 1994, the Company implemented a matching program in which the Company matches employee contributions according to a specified formula. The Company's matching contributions totaled approximately \$78,000, \$71,000, and \$61,000 in

1996, 1995, and 1994, respectively.

10. Summary of Unaudited Quarterly Financial Information

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 1996 and 1995 (in thousands, except per share amounts):

<TABLE>  
<CAPTION>

	Quarter Ended			
	March 31	June 30	September 30	December 31
	-----	-----	-----	-----
1996				
----				
<S>	<C>	<C>	<C>	<C>
Revenues	\$ 520	\$ 3,555	\$ 541	\$ 2,124
Research and development costs	2,380	3,133	2,628	3,177
Total operating costs and expenses	3,110	3,872	3,378	4,126
Net income (loss)	(1,905)	350	(2,190)	(1,336)
Net income (loss) per common share	(.12)	.02	(.14)	(.09)
Shares used in per share calculation	15,373	15,791	15,385	15,392

</TABLE>

<TABLE>  
<CAPTION>

	Quarter Ended			
	March 31	June 30	September 30	December 31
	-----	-----	-----	-----
1995				
----				
<S>	<C>	<C>	<C>	<C>
Revenues	\$ 977	\$ 3,488	\$ 1,161	\$ 676
Research and development costs	2,088	2,819	2,016	2,074
Total operating costs and expenses	2,771	3,849	2,525	2,754
Net loss	(1,517)	(46)	(1,057)	(1,363)
Net loss per common share	(.12)	(.00)	(.08)	(.09)
Shares used in per share calculation	12,846	12,846	12,955	15,351

</TABLE>

Exhibit 11

COMPUTATION OF NET LOSS PER SHARE

<TABLE>  
<CAPTION>

	YEARS ENDED DECEMBER 31,		
	1991	1992	1993
<S>	<C>	<C>	<C>
Net loss	\$ (2,263,138)	\$ (1,989,895)	\$ (1,364,689)
Weighted average common shares outstanding	2,143,892	2,144,740	4,586,361
Weighted average convertible preferred stock outstanding	6,197,882	6,197,882	6,478,996
Common stock equivalents (relating to options)	402,832	402,832	--
Common shares subject to SAB 83	1,491,887	1,491,887	--
Convertible preferred shares subject to SAB 83	6,760,143	6,760,143	--
Total shares outstanding	16,996,636	16,997,484	11,065,357
2-1 REVERSE STOCK SPLIT	8,498,318	8,498,742	n/a
Net loss per share	\$ (.27)	\$ (.23)	\$ (.12)

</TABLE>

<TABLE>  
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	1994	1995	1996
	<S>	<C>	
Net loss	\$ (4,357,868)	\$ (3,983,451)	\$ (5,080,591)
Weighted average common shares outstanding	12,831,585	13,504,790	15,382,848
Common stock equivalents (relating to options)	--	--	--
Common shares subject to SAB 83	--	--	--
Convertible preferred shares subject to SAB 83	--	--	--
Total shares outstanding	12,831,585	13,504,790	15,382,848
Net loss per share	\$ (.34)	\$ (.29)	\$ (.33)

</TABLE>



CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report included in this Form 10-K into Vical Incorporated's previously filed Registration Statements Files No. 33-60826, No. 33-60824, No. 33-81602, No. 33-81600, and No. 33-87972.

ARTHUR ANDERSEN LLP

San Diego, California  
March 24, 1997

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