

# VICAL INC

## FORM 10-K (Annual Report)

Filed 03/30/99 for the Period Ending 12/31/98

|             |   |
|-------------|---|
| Address     | 10390 PACIFIC CENTER COURT<br>.<br>SAN DIEGO, CA 92121-4340 |
| Telephone   | 858-646-1100  |
| CIK         | 0000819050  |
| Symbol      | VICL  |
| SIC Code    | 2836 - Biological Products, Except Diagnostic Substances    |
| Industry    | Biotechnology & Drugs                                       |
| Sector      | Healthcare  |
| Fiscal Year | 12/31   |

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

## FORM 10-K

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

For the fiscal year ended December 31, 1998, 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  
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## 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  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.

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 March 15, 1999, was \$166,432,000.

The number of shares of Common Stock outstanding as of March 15, 1999, was 16,190,313.



## **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 1999 Annual Meeting of Stockholders to be held on May 27, 1999, is incorporated by reference in Part III, Items 10 (as to directors), 11, 12 and 13 of this Form 10-K.

## PART I

### ITEM 1. BUSINESS

#### OVERVIEW

Vical is developing gene-based pharmaceutical products for human therapy. Our patented naked DNA gene delivery technology and proprietary lipids are designed to deliver selected genes into some cells in the body. These genes have been shown in clinical trials to cause the cells to produce desired proteins which may prevent or treat infectious and malignant diseases and other disorders. Vical is developing cancer product candidates internally while developing vaccines for infectious diseases and gene-based delivery of therapeutic proteins for other disorders primarily in collaboration with corporate partners.

The key discovery leading to Vical's proprietary direct gene transfer technology was that some muscle tissues can absorb genetic material directly and subsequently express a desired protein for periods ranging from weeks to several months. In addition, we are developing other technologies to deliver DNA directly into some non-muscle tissues, including the use of lipid molecules 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.

Our gene-based therapy approach may offer safer and more cost-effective treatments for many diseases as well as novel treatment alternatives for diseases that are currently poorly addressed. The broad applicability, ease of manufacturing and potential low cost of our gene-based approach may provide competitive advantages for commercialization.

Some of 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 attainment of patent protection for any of these 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 our judgment as of the date of the filing of this Form 10-K. We disclaim, however, any intent or obligation to update these forward-looking statements.

#### GENE TRANSFER TECHNOLOGY

Gene transfer is an approach to the treatment and prevention of diseases in which genes are introduced into cells to direct the production of specific proteins needed to correct or control diseases. 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 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 improper expression of even a single gene can severely alter a cell's normal function, frequently resulting in a disease.

Gene transfer approaches include the use of (1) cells genetically altered EX VIVO (outside the body) using viruses or other gene transfer methods, (2) viruses that have been genetically disabled so that they cannot reproduce and infect other cells and that are delivered IN VIVO to the patient, and (3) non-viral or synthetic formulations of DNA that are delivered IN VIVO to the patient. EX VIVO cell-based therapies are cumbersome and expensive relative to IN VIVO therapies since individual products must be designed and manufactured for each patient.

Gene transfer product candidates in development rely primarily on IN VIVO delivery. IN VIVO approaches using viruses suffer several drawbacks that may limit their widespread usefulness, including adverse immune responses and inflammation that may inhibit the activity of the virus-based therapy and prevent repeated administration. In addition, viruses can induce permanent changes in the patient's genetic makeup, which may cause malignant transformation of cells leading to cancer. IN VIVO methods using non-viral DNA formulations may offer safer and more effective gene transfer.

Vical has developed core technologies that allow the IN VIVO delivery of non-viral DNA formulations, or naked DNA. The discovery that led to Vical's naked DNA gene transfer approach was that some 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, we have developed proprietary methods to allow the delivery of genes directly into some non-muscle tissues, including the use of lipid molecules that facilitate absorption into cells.

Vical's naked DNA 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 that control the rate and location of protein expression.

The potential benefits of Vical's gene transfer technology may include:

- CONVENIENCE. Vical's gene-based drug therapy is intended to be directly administered like conventional pharmaceuticals.
- SAFETY. Vical's anticipated products will contain no viral components that may cause an unwanted immune response or infection.
- EASE OF MANUFACTURING. Vical's product candidates are manufactured using conventional fermentation techniques and standard purification procedures.
- COST-EFFECTIVENESS. Vical's gene transfer technology may prove more cost-effective than systems requiring EX VIVO manipulation of cells on a patient-by-patient basis. In some situations, administering DNA encoding a particular protein may be more cost-effective than administering 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.

## **CLINICAL TRIALS**

U.S. Food and Drug Administration ("FDA") approval is required prior to marketing a pharmaceutical product in the United States. To obtain this approval the FDA requires clinical trials to demonstrate the safety, efficacy, and potency of the product candidates. Clinical trials are the means by which experimental drugs or treatments are tested in humans. New therapies typically advance from laboratory (research) testing through animal (preclinical) testing and finally through several phases of clinical (human) testing. Upon successful completion of clinical trials, approval to market the therapy for a particular patient population may be requested from the FDA in the United States and/or its counterparts in other countries.

Clinical trials are normally done in three phases. In Phase I, trials are conducted with a small number of patients or healthy volunteers to determine the safety profile, the pattern of drug distribution and metabolism and early evidence on effectiveness. 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, efficacy, and potency required by the FDA and other regulatory authorities. For life-threatening diseases, initial human testing generally is done in patients rather than healthy volunteers. Such studies may provide results traditionally obtained in Phase II trials. Such trials are referred to as "Phase I/II" trials.

## CANCER PRODUCT DEVELOPMENT PROGRAMS

Vical is developing cancer product candidates internally while developing vaccines for infectious diseases and gene-based delivery of therapeutic proteins for other disorders primarily in collaboration with corporate partners.

### CANCER

Cancer is a group of diseases 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, also rapidly divide and 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 approach would be to generate a specific immune response targeting cancer cells without damaging other normal tissues. 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 lymphocyte (CTL), or killer T-cell, response produced by cancer patients 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 systemic administration of natural immune-enhancing proteins such as interleukin 2 (IL-2), either alone or in combination with other agents. These methods have shown encouraging results in some patients with some tumor types but also cause serious side effects.

Vical scientists are developing novel gene-based cancer immunotherapies to address the shortcomings, including adverse side effects of existing therapies. Vical is focusing on some types of cancer including melanoma, head and neck cancer, kidney cancer, prostate cancer and B-cell lymphoma.

Current U.S. market data for these cancers and Vical's product candidates are summarized below.

| TYPE OF PRIMARY<br>CANCER | 1998<br>NEW<br>CASES | 1998<br>CURRENT<br>CASES | 1998<br>ESTIMATED<br>DEATHS | INCREASE IN<br>DEATHS<br>1974-1994 | PRODUCT CANDIDATE    |
|---------------------------|----------------------|--------------------------|-----------------------------|------------------------------------|----------------------|
| Melanoma                  | 41,600               | 476,000                  | 7,300                       | 79%                                | ALLOVECTIN 7 & GP100 |
| Head & Neck               | 41,400               | 342,000                  | 12,300                      | 6%                                 | ALLOVECTIN 7         |
| Kidney                    | 29,900               | 201,000                  | 11,600                      | 62%                                | LEUVECTIN            |
| Prostate                  | 184,500              | 1,000,000                | 39,200                      | 82%                                | LEUVECTIN            |
| B-cell Lymphoma           | 55,400               | 296,000                  | 24,900                      | 105%                               | VAXID                |

Sources: American Cancer Society, SEER Cancer Statistics

**MELANOMA.** This is a skin cancer found predominantly in Caucasians, particularly fair-skinned individuals who have experienced repeated sunburn. If detected when the disease is still limited to one site (stage I and II) it usually can be treated successfully by surgery. If untreated, the disease spreads to the lymph glands, lungs, liver, brain and other organs. Stage III is defined as metastatic (spread) disease limited to one region and is treated with a combination of surgery and chemotherapy. Stage IV disease involves advanced regional or any distant tumors and it is usually treated with some combination of chemotherapy, radiotherapy, and surgery. The five-year survival of patients with stage III and stage IV disease is 60% and 15%, respectively. In patients whose disease continues to progress after they have received all available treatments, the median survival is 6 to 8 months.

**HEAD AND NECK CANCER.** This describes any of several localized tumors affecting the oral cavity, the pharynx or larynx. Head and neck cancers are found more frequently in men than in women, and most often in men over age 40. Risk factors vary with the particular location, but can include use of tobacco and excessive consumption of alcohol.



Most head and neck cancers are treated by surgical removal and/or localized radiation therapy, with widely ranging degrees of success depending on the number of tumors, their size, and their specific location. In advanced disease, standard treatment may be preceded by systemic chemotherapy to improve treatability, or followed by systemic chemotherapy to address remaining cancer cells, most often with a combination of agents. The five-year survival rate for head and neck cancer patients, if treated, varies from more than 90 percent for localized, accessible disease to less than 5 percent for widespread malignancies not curable by surgery.

**KIDNEY CANCER.** The most common type of kidney cancer, renal cell carcinoma, is more prevalent in males than females, predominantly in people over 35. The greatest single risk factor is cigarette smoking. Other risk factors include exposure to asbestos, cadmium, or gasoline, and the use of some pain medications containing phenacetin.

Kidney cancer frequently spreads to adjacent tissues and ultimately to other internal organs, most often the lungs, bone, brain or liver. About 30 percent of patients have metastatic disease when first diagnosed. Treatment of regional metastatic kidney cancer involves surgical removal of the affected kidney and surrounding tissue, frequently combined with radiation therapy to alleviate pain. The five-year survival rate for metastatic disease where surgery cannot be curative is less than 10 percent with very few treatment alternatives.

**PROSTATE CANCER.** The most frequently diagnosed type of cancer, and second leading cause of cancer fatalities among men in the United States, is prostate cancer. African Americans are at significantly greater risk than Caucasians, and men over age 65 account for over 80 percent of all diagnoses.

Early detection has been increasing the number of annual diagnoses and improving overall survival rates. Most patients are diagnosed while the disease is confined to the prostate gland, with a five-year survival rate of 99 percent. If the disease is discovered after it spreads to connective tissue, lymph nodes, or other internal organs, survival rates decline. Treatment options include "watchful waiting" for older patients with no symptoms or with other more serious illnesses, radiation therapy, and surgical removal of the prostate gland and/or affected lymph nodes. Symptoms may also be relieved by hormone therapy or surgery.

**B-CELL LYMPHOMA.** Non-Hodgkin's B-cell lymphoma is a disease in which cells in the lymph nodes or other lymphatic tissue grow abnormally. They divide too rapidly and grow without any order or control. Too much tissue is formed and tumors, usually cancerous, begin to grow. Low-grade non-Hodgkin's B-cell lymphoma is a less aggressive form of the disease. This disease is characterized by a slow growth rate and excellent initial response to current treatments; however, a regular pattern of relapse to a widespread, aggressive lymphoma occurs for which no curative therapy has been identified.

## **CANCER PRODUCT CANDIDATES**

**ALLOVECTIN-7 (MELANOMA AND HEAD AND NECK CANCER).** We are developing a product candidate, ALLOVECTIN-7, for treatment of various solid tumors. ALLOVECTIN-7 is a DNA/lipid complex containing the gene encoding the HLA-B7 antigen. ALLOVECTIN-7 is designed to be injected directly into a tumor, where malignant cells take it in and display the HLA-B7 antigen on their surface. This antigen alerts the immune system to the presence of foreign tissue, inducing the type of powerful immune response seen in organ transplant rejection.

**LEUVECTIN (KIDNEY AND PROSTATE CANCERS).** Our second oncology product candidate, LEUVECTIN, is another DNA/lipid complex designed for direct injection into a tumor. LEUVECTIN contains the gene encoding IL-2. Systemic IL-2 protein therapy is approved as a treatment for kidney cancer and melanoma, but can cause severe side effects. We expect that LEUVECTIN, when injected into tumors, will cause the malignant cells to produce IL-2. Local expression of IL-2 may stimulate the patient's immune system to attack and destroy the tumor cells. Because LEUVECTIN delivers IL-2 locally, it may provide efficacy comparable to the protein treatment with fewer side effects.

**GP100 (MELANOMA).** In collaboration with the National Cancer Institute, we are using an experimental DNA vaccine containing a gene which may cause cells at the injection site to produce a modified gp100 melanoma antigen (melanoma-related protein). The antigen is expected to trigger an immune response against melanoma tumor cells. In earlier studies, the National Cancer Institute tested a vaccine using peptides (portions of the modified antigen) in combination with IL-2 protein therapy. A DNA vaccine may be more generally applicable and may provide advantages in manufacturing and administration.

VAXID (B-CELL LYMPHOMA). In collaboration with Stanford University Medical Center, we are developing a naked DNA vaccine, VAXID, against low-grade non-Hodgkin's B-cell lymphoma. VAXID contains a gene that encodes the patient-specific idiotype (characteristic feature) of cancerous B-cells. Preclinical studies showed that the injection into mice of a B-cell lymphoma idiotype DNA vaccine resulted in strong anti-idiotypic immune responses and significant protection against tumor challenge. We believe that immunization of post-chemotherapy patients with VAXID could result in the elimination of residual disease and the prevention of the relapse of disease.

### **CANCER CLINICAL TRIALS**

ALLOVECTIN-7 (MELANOMA). Ninety patients with advanced melanoma have received treatment with ALLOVECTIN-7 during two phase II clinical trials. Four (17%) of 23 evaluable patients with disease limited to the skin, lymph nodes, or lung achieved clinical responses. There were one complete response and three partial responses. Of the 73 evaluable patients in the two trials, 19 patients (26%) appeared to derive clinical benefit from treatment. Current treatments for melanoma frequently result in grade 3 adverse events which require hospitalization and grade 4 events which are considered life-threatening. There were no grade 3 or 4 adverse events caused by ALLOVECTIN-7. We believe ALLOVECTIN-7's minimal side effects will provide a much safer and better tolerated treatment than available treatments. As a result of these promising data, additional studies are underway. Two studies are recruiting in 50 centers across the United States, one involving end-stage patients in a single-agent trial and one comparing dacarbazine (the only FDA approved chemotherapeutic agent for metastatic melanoma) to a combination of dacarbazine plus ALLOVECTIN-7. Positive results from either or both of these trials could allow us to apply to the FDA for approval to market the drug candidate.

ALLOVECTIN-7 (HEAD AND NECK CANCER). In a phase I/II and an early phase II study in advanced or recurrent squamous cell cancer of the head and neck, 39 patients were treated. Of 32 evaluable patients, five (16%) responded, two of whom were complete responders and three of whom were partial responders. A multi-center phase II study is now ongoing.

LEUVECTIN (KIDNEY CANCER). IL-2 is the only FDA approved drug for the treatment of metastatic kidney disease but its administration is associated with serious toxicity in the majority of patients. The goal of the LEUVECTIN kidney cancer program is to match IL-2's efficacy without major adverse events.

Initial results from the phase I/II trial in kidney cancer suggested that LEUVECTIN had a favorable risk-benefit profile in these patients. To date there has been only one grade 3 adverse event and no grade 4 adverse events caused by LEUVECTIN out of over 130 patients treated. A multi-center study is ongoing.

LEUVECTIN (PROSTATE CANCER). We released initial data in 1998 from a Phase I/II pilot trial in patients with prostate cancer. The data indicated that the treatment was safe and well-tolerated, that it may stimulate an immune response against the disease, and that it may result in an increased time to disease progression. On the basis of these data, we intend to pursue further clinical development.

GP100 (MELANOMA). The National Cancer Institute published data from a previous clinical trial indicating a 42% response rate in end-stage melanoma patients after treatment with systemic IL-2 and the gp100 protein. This study is being repeated (Phase I/II) with a gp100 naked DNA vaccine from Vical.

VAXID (B-CELL LYMPHOMA). An initial phase I/II study is now ongoing in collaboration with Stanford University Medical Center.

### **INFECTIOUS DISEASE VACCINE DEVELOPMENT PROGRAMS**

According to the World Health Organization, of a global total of 52.2 million deaths in 1997, 17.3 million were due to infectious and parasitic diseases making it the leading category. Most deaths from infectious diseases were caused by acute lower respiratory infections, tuberculosis, diarrhea, human immunodeficiency virus (HIV) and malaria.

### **NAKED DNA VACCINE TECHNOLOGY**

Vical's naked DNA technology may address two deficiencies of traditional preventive vaccine approaches: (1) the inability to predict the random changes in the strains of various infectious agents and (2) the need for safe formulations (adjuvants) that boost an antibody response or that cause sufficient killer T-cell responses. We believe our potential vaccine products should be simpler to manufacture than vaccines that are made using cumbersome and labor-intensive techniques involving difficult tissue culture procedures and live viruses.

Vical 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 antibody and killer T-cell 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, treated animals demonstrated higher survival rates than untreated control animals when challenged with various strains of inhaled influenza virus. This observed cross-strain protection, if reproducible in humans, will offer a key advantage compared with conventional vaccines. Thus, Vical's direct gene transfer technology may be universal, not requiring frequent re-design or product modification for each new viral strain.

Only a few years ago, DNA vaccines were an unproven novelty with limited acceptance in the scientific community. Today, more than 700 scientific publications have documented the efficacy of DNA vaccines in providing protective immunity against viruses, bacteria and parasites in dozens of species from fish to primates. Additional studies have extended these findings to other models of infectious diseases for which there are no approved vaccines, such as HIV, herpes and malaria.

### **NAKED DNA VACCINE LICENSES**

Vical has licensed its naked DNA gene delivery technology to Merck for a total of seven preventive vaccines: influenza, HIV, herpes, hepatitis B virus (HBV), hepatitis C virus (HCV), human papilloma virus (HPV) and tuberculosis and three therapeutic vaccines: HPV, HIV and HBV. We also have a license and option agreement with Pasteur Merieux Connaught (PMC) for a total of six preventive vaccines: cytomegalovirus (CMV), respiratory syncytial virus (RSV), Lyme disease, helicobacter pylori, malaria and herpes zoster. Vical also has an option agreement with Merial, the joint venture between Merck's animal health business and Rhone Merieux, for veterinary vaccines. Because of the large-scale development programs, manufacturing capacity and distribution channels required to successfully market a vaccine, we believe collaborations with major pharmaceutical companies are the most effective way to apply our patented technology in the emerging DNA vaccine field. See "-- Collaboration and Licensing Agreements--Corporate Partners--Merck & Co., Inc.," "--Pasteur Merieux Connaught," "--Merial" and "-- Collaboration and Licensing Agreements--Research Institutions--Office of Naval Research."

**MALARIA.** We are collaborating with PMC and the U.S. Naval Medical Research Center (NMRC) to develop a DNA vaccine against malaria. There is no effective vaccine against malaria. This is a severe infectious disease characterized by fever, headache and joint pain, which if untreated can lead to death. Infection normally occurs when the parasite enters a victim's bloodstream during a mosquito bite. An estimated 300 million people are affected by malaria worldwide, with more than one million deaths each year.

In July 1997, Vical and PMC began a Phase I trial of an experimental vaccine against the parasite that causes malaria. NMRC conducted the clinical trial with approximately twenty volunteers. Trial results, reported in an October 1998 issue of *SCIENCE*, indicated that subjects immunized with a potential malaria DNA vaccine developed dose-related killer T-cell immune responses. As a result of these encouraging data, further clinical development is planned.

### **GENE-BASED THERAPEUTIC PROTEIN DELIVERY**

Vical's direct gene transfer technology may permit the development of alternatives to therapeutic protein administration for other diseases. Major shortcomings of some therapeutic proteins include their short duration of action and the potential side effects associated with high levels of circulating protein after intravenous administration. We believe that direct injection into muscles of genes that encode for the protein of interest may enable the muscle to act as a protein factory causing a sustained release of low levels of the therapeutic proteins and reducing side effects and the need for repeated dosing. Vical's technology may be most suitable for the delivery of proteins that are required in small amounts over prolonged periods of time.

Much attention is being focused on the emerging field of angiogenesis, which involves inducing the growth of new blood vessels to replace those blocked by disease. Gene-based delivery of growth factors has been successfully demonstrated in human trials. Other potential applications, still being tested in animal models, could involve the delivery of proteins that maintain nerve cell function for treating certain neurodegenerative diseases, or the delivery of biologically active compounds such as insulin to treat diabetes or erythropoietin to treat certain forms of anemia.

In 1997, Vical licensed its patented naked DNA technology to Merck for the delivery of certain angiogenic growth factors that may be useful in cardiovascular applications such as coronary artery disease and peripheral vascular disease. Coronary artery disease, a narrowing of the blood vessels supplying the heart, can lead to severe chest pain and heart attack. Coronary artery disease is the single largest cause of death in the United States. Peripheral vascular disease affects the blood vessels in the limbs, most commonly narrowing of the blood vessels of the lower extremities for which therapy is very limited. In September 1998, we licensed our catheter-based intravascular gene delivery technology to Boston Scientific Corporation.

We licensed our gene delivery technology to Rhone-Poulenc Rorer (RPR) in 1997 for the delivery of neurologically active proteins that may be applicable in treating neurodegenerative diseases such as Alzheimer's, Parkinson's and Lou Gehrig's diseases. In early 1999, Vical licensed its gene delivery technologies to Pfizer Inc. for potential use in delivering therapeutic proteins for animal health applications. See "--Collaboration and Licensing Agreements--Corporate Partners--Merck & Co., Inc.," "--Rhone-Poulenc Rorer," "--Boston Scientific Corporation" and "--Pfizer Inc."

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

| Project                    | Target Indication(s)                                    | Development Status(1)  | Development Rights(2)     |
|----------------------------|---|------------------------|---------------------------|
| <b>CANCER</b>              |   |                        |                           |
| ALLOVECTIN-7               | Melanoma,<br>Head and neck cancer                       | Phase III<br>Phase II  | Vical<br>Vical            |
| LEUVECTIN                  | Renal cell carcinoma<br>Prostate cancer                 | Phase II<br>Phase I/II | Vical<br>Vical            |
| VAXID                      | B-cell lymphoma   | Phase I/II             | Vical                     |
| gp100                      | Melanoma  | Phase I/II             | Vical (3)                 |
| Therapeutic DNA vaccines   | Various cancers   | Preclinical/Phase I    | Centocor                  |
| <b>INFECTIOUS DISEASES</b> |   |                        |                           |
| Preventive DNA vaccines    | Influenza   | Phase I                | Merck                     |
|                            | Malaria   | Phase I                | Pasteur Merieux Connaught |
|                            | HIV, herpes, hepatitis B and C, tuberculosis, papilloma | Research/preclinical   | Merck                     |
|                            | CMV, RSV, Lyme, H.pylori, herpes zoster                 | Research/preclinical   | Pasteur Merieux Connaught |
|                            | Chlamydia   | Research/preclinical   | Vical                     |
| Therapeutic DNA vaccines   | Hepatitis B, HIV, papilloma                             | Research/preclinical   | Merck                     |
| Veterinary DNA vaccines    | Various   | Research               | Merck                     |
| <b>OTHER DISEASES</b>      |   |                        |                           |
| Therapeutic protein DNA    | Cardiovascular diseases                                 | Research/preclinical   | Merck                     |
| Therapeutic protein DNA    | Neurodegenerative Diseases                              | Research/preclinical   | Rhone-Poulenc Rorer       |
| Catheter-based DNA therapy | Cardiovascular diseases                                 | Research/preclinical   | Boston Scientific         |
| Therapeutic protein DNA    | Animal Health   | Research               | Pfizer                    |

(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 application for an investigational new drug (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 "--Clinical Trials."

(2) See "--Collaboration and Licensing Agreements--Corporate Partners."

(3) Vical owns the rights to any inventions developed solely by Vical employees under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) and has the option to obtain a license for inventions developed jointly with NCI or solely by NCI under the CRADA.

## **COLLABORATION AND LICENSING AGREEMENTS**

Vical has entered into various arrangements with corporate, academic and government collaborators, licensors, licensees and others. Our success is partially dependent upon the subsequent success of these outside parties in performing their responsibilities. We believe these parties have an economic incentive to perform their contractual responsibilities. However, the progress of these activities is not controlled by us. The parties may not perform their obligations and we may not derive any revenue from such arrangements. In addition, the collaborators may pursue alternative technologies.

We have entered into, and expect to enter into, research collaborations, licensing agreements and corporate collaborations. In addition to the agreements summarized below, we conduct ongoing negotiations with potential corporate partners. However, we may not be able to negotiate additional acceptable collaborative agreements.

### **CORPORATE PARTNERS**

**MERCK & CO., INC.** In May 1991, we entered into a research collaboration and license agreement with Merck to develop vaccines utilizing Vical's intramuscular delivery technology to prevent infection and/or disease in humans. In connection with the 1991 agreement, we granted Merck a worldwide exclusive license to preventive vaccines using our technology against seven human infectious diseases: influenza, HIV, herpes simplex, HBV, HCV, HPV and tuberculosis.

In addition, Merck has rights to therapeutic uses of preventive vaccines developed under the 1991 agreement. In December 1995 and November 1997, Merck acquired additional rights to develop and market therapeutic vaccines against HPV, HIV and HBV. Under the November 1997 amendment, Merck made an investment of \$5.0 million for approximately 262,000 shares of Vical's common stock.

In September 1997, we also entered into an option and license agreement granting Merck the rights to use Vical's naked DNA technology to deliver certain growth factors as potential treatments for cardiovascular applications. The agreement resulted in an initial payment to Vical of \$2.0 million.

In connection with these agreements, Merck has paid Vical \$19.1 million as of December 31, 1998. Merck is obligated to pay additional fees if research milestones are achieved with respect to the products developed under the various Merck agreements and royalties on net sales by Merck of products, if any products are developed and marketed. For some indications Vical has an opportunity to co-promote product sales.

**PASTEUR MERIEUX CONNAUGHT.** In September 1994, Vical entered into a collaborative agreement with the vaccine manufacturer PMC covering the use of Vical's proprietary gene delivery and technologies for developing vaccines against CMV, RSV, Lyme disease, helicobacter pylori and malaria. In April 1996, herpes zoster was added. PMC is obligated to make milestone and royalty payments to Vical if any products are developed and marketed. In July 1997, PMC paid us \$1.0 million as a milestone payment upon initiation of a Phase I trial of an experimental vaccine against the parasite that causes malaria. Through December 31, 1998, Vical had received \$7.8 million under this agreement.

**RHONE-POULENC RORER PHARMACEUTICALS, INC.** In October 1997, Vical and Rhone-Poulenc Rorer Pharmaceuticals, Inc. ("RPR") entered into an agreement granting RPR an exclusive worldwide license to use our naked DNA gene delivery technology to deliver certain neurologically active proteins for potential treatment of neurodegenerative diseases. Under the terms of the agreement, we received \$1.0 million in 1997. This agreement provides for us to receive additional payments based upon achievement of milestones and royalty payments on product sales.

**CENTOCOR, INC.** In February 1998, Vical entered into a license agreement allowing Centocor, Inc. to use our naked DNA technology to develop and market certain gene-based vaccines for the potential treatment of some types of cancer. We received an initial payment of \$2.0 million plus reimbursement of \$200,000 of patent costs. We may receive additional payments based upon achievement of milestones and royalty payments on product sales.

**MERIAL.** Vical entered into a corporate alliance in March 1995 relating to DNA vaccines in the animal health area with Merial (a joint venture between Merck and Rhone Merieux). Merial has options to take exclusive licenses to Vical's gene delivery technologies to develop and commercialize gene-based vaccines to prevent infectious diseases in domesticated animals. Through December 31, 1998, Vical had received \$2.1 million under this agreement. If Merial exercises its license options and markets these vaccines, cash payments and royalties on sales would be due to Vical.

**PFIZER INC.** In January 1999, Vical and Pfizer entered into a collaborative license and option agreement to develop and market gene-based delivery of therapeutic proteins for animal health applications. Under the agreement, Pfizer made an investment of \$6.0 million for approximately 318,000 shares of Vical common stock. Pfizer also paid Vical a \$1.0 million upfront license fee, and is obligated to pay Vical \$1.5 million for research and development over the first three years of the agreement.

**BOSTON SCIENTIFIC CORPORATION.** In September 1998, Vical and Boston Scientific Corporation entered into a license and option agreement for the development of catheter-based intravascular gene delivery technology. We received \$1.1 million in October 1998 under this agreement. The agreement provides for us to receive royalty payments on any related product sales.

**GENZYME CORPORATION.** In October 1993, Vical entered into a collaborative research and option agreement with Genzyme to evaluate the use of our proprietary lipids to deliver genes for the treatment of cystic fibrosis. In 1996, Genzyme exercised its option to use Vical's lipid technology in cystic fibrosis. Through December 31, 1998, Vical had received \$2.3 million from Genzyme under this agreement. The license agreement includes provisions for research, milestone and royalty payments to Vical.

Under the Merck, PMC, Merial, RPR, Centocor and Pfizer agreements, if Vical were to receive milestone or royalty payments, Vical would be required to pay 10 percent of some of these payments to Wisconsin Alumni Research Foundation. See "--Research Institutions--Wisconsin Alumni Research Foundation."

## **RESEARCH INSTITUTIONS**

**OFFICE OF NAVAL RESEARCH.** Vical entered into an agreement in September 1998 with the Office of Naval Research for the development work on a potential multi-gene DNA vaccine to prevent malaria. The agreement may provide funding up to \$2.7 million through 2000.

**THE UNIVERSITY OF MICHIGAN.** In October 1992, Vical entered into a license agreement with the University of Michigan and obtained the exclusive license to products using technology for delivering gene-based products into cancer cells and blood vessels by catheters. Michigan retained the right to grant non-exclusive, non-royalty bearing licenses to the United States government and the Howard Hughes Medical Institute. In April 1997, Vical entered into a sublicense agreement with Cardiogene Therapeutics, Inc. with respect to certain cardiovascular applications of this technology. Cardiogene subsequently was acquired by Boston Scientific Corporation which then entered into an agreement with Vical in September 1998 for the development of intravascular gene delivery technology.

**WISCONSIN ALUMNI RESEARCH FOUNDATION (WARF).** Under a 1989 research agreement, scientists at the University of Wisconsin, Madison, and at Vical co-invented a core technology related to intramuscular naked DNA administration. In 1991, Vical licensed WARF's interest in that technology, except as to the U.S. government which may hold non-exclusive licenses to technology developed with government funds. Vical paid WARF an initial license fee and agreed to pay WARF a royalty on sales of any products incorporating the licensed technology and a percentage of up-front license payments from third parties.

## **ACCESS TO PROPRIETARY GENES AND PROTEINS**

A number of the genetic sequences or proteins encoded by those sequences that Vical is currently using or may use in its gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct certain research, to manufacture or to market products that contain proprietary genetic sequences. Licenses may not be available on commercially reasonable terms, or at all.

## **PATENTS AND PROPRIETARY RIGHTS**

Patents and other proprietary rights are important to our business. We file patent applications to protect our technology, inventions, and improvements to our inventions that are considered important to the development of our business.

Vical also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain its competitive position. We have filed or participated as licensee in the filing of more than 300 patent applications in the United States and in foreign countries relating to our technology. We have filed a series of patent applications seeking to cover naked DNA gene transfer for immunization and for delivering therapeutic proteins to patients, specific gene sequences and formulations of gene-based product candidates, methods for producing pharmaceutical-grade DNA and the composition of matter of several families of lipid molecules and their uses in gene delivery. Some of these patents have been issued by the U.S. Patent and Trademark Office ("PTO"). Several other applications are still pending in the United States, and corresponding foreign applications have been filed. The claims may not issue in their present form, if at all, and patents, if issued, may be challenged, invalidated or circumvented and the rights granted may not provide proprietary protection or commercial advantage to Vical. See "--Risk Factors--Uncertainty Regarding Our Intellectual Property Rights."

As of December 31, 1998, Vical or its exclusive licensors had received fifteen U.S. patents covering various aspects of its proprietary technology. These patents are described below:

### **TECHNOLOGY COVERED**

Direct administration of lipid-complexed DNA for immunization

Method to deliver a protein by injecting DNA into cardiac muscle

Plasmids expressing IL-2

Direct administration of naked DNA for immunization

Direct administration of naked DNA for protein expression

Process to reduce RNA during DNA production

Process to manufacture pharmaceutical-grade DNA

Use of cationic lipids to deliver genes IN VIVO

Catheter to facilitate intravascular gene transfer

Cationic lipid compositions to facilitate gene transfer IN VIVO

Improved purification of DNA using polyethylene glycol (PEG)

Method to transfect cells surrounding a blood vessel by catheter

Direct administration of naked DNA to transfect vascular wall

Compositions and methods for Lyme Disease DNA vaccine

Lipids to facilitate gene delivery

In addition to these issued U.S. patents, Vical's core DNA delivery technology is covered by a patent issued in Europe. According to European patent procedures, issued patents may be opposed by parties interested in challenging the scope or validity of the issued claims. Vical's European patent is currently being opposed by several companies pursuant to these procedures. We intend to overcome the oppositions and defend our patent position in these proceedings. An unfavorable result in these opposition proceedings could adversely affect us.

The patent positions of pharmaceutical and biotechnology firms, including Vical, are uncertain and involve complex legal and factual questions which are largely unresolved. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued. Consequently, we do 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, we cannot be certain that Vical or any licensor was the first creator of inventions covered by pending patent applications or was the first to file patent applications for such inventions. Moreover, we might have to participate in



interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to us, even if we were to prevail. Our patents, if issued, may not be held to be valid or enforceable by a court or a competitor's technology or product may be found to not 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 our business. Some of these technologies, applications or patents may conflict with our technologies or patent applications. Such conflict could limit the scope of the patents, if any, that we may be able to obtain or result in the denial of our patent applications. In addition, if patents that cover Vical's activities are issued to other companies, we might not be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technologies.

In addition to patent protection, we also rely upon trade secret protection for our confidential and proprietary information. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology. We may not be able to meaningfully protect our trade secrets.

We require our employees, consultants, and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment, consulting relationships, or a collaboration with us. These agreements provide that all confidential information developed or made known during the course of the relationship with Vical 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 Vical, utilizing property of Vical or relating to Vical's business and conceived or completed by the individual during employment, shall be the exclusive property of Vical to the extent permitted by applicable law. These agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. See "--Risk Factors--Uncertainty Regarding Our Intellectual Property Rights May Harm Us."

## **COMMERCIALIZATION AND MANUFACTURING**

Because of the broad potential applications of our technology, we intend to develop and commercialize products both on our own and through corporate partners. We intend to develop and market products to well-defined specialty markets, such as oncology, infectious diseases and metabolic disorders. Where appropriate, we will rely on strategic marketing and distribution partners for manufacturing and marketing products addressing diseases treated by primary care physicians. We may not be able to reach satisfactory arrangements with such distribution partners or such arrangements may not be successful.

We believe our 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, our lipid formulations consist of components that are synthesized chemically using traditional, readily scaleable, organic synthesis procedures.

We produce supplies of product for all of our clinical trials and intend to produce sufficient supplies for additional clinical investigations. We may also choose to have outside organizations manufacture our product candidates for expanded clinical trials under close supervision utilizing our proprietary processes. We may not 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 Vical's potential products or technologies becoming obsolete before we recover a significant portion of our related research, development and capital expenditures. We may experience competition both from other companies in the field and from companies which have other forms of treatment for the diseases we are targeting. We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, which are exploring gene-based drugs or are actively engaged in gene transfer research and development. We may also experience competition from companies that have acquired or may acquire technology from companies, universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may materially and adversely affect Vical. See "--Risk Factors--Uncertainty Regarding Our Intellectual Property Rights May Harm Us."

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

Our competitive position will be affected by the disease indications addressed by our potential products and those of our competitors, the timing of market introduction for these potential products and the stage of development of other technologies to address these disease indications. For Vical and its competitors, proprietary positions, the ability to complete clinical trials on a timely basis and the ability to obtain timely regulatory approvals to market these potential products are likely to be significant competitive factors. Other important competitive factors will include the efficacy, safety, reliability, availability and price of potential products and the ability to secure sufficient capital resources for the often-substantial period between technological conception and commercial sales. See "--Risk Factors--The Effect of Competition and Technological Change May Hurt Us."

## **GOVERNMENT REGULATION**

Any products we develop 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 we will have to comply are uncertain at this time due to the novelty of the human gene products and therapies currently under development. We believe that our potential products will be regulated either as biological products or as drugs. Drugs are subject to regulation under the Federal Food, Drug and Cosmetic Act, 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 related regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and other promotional practices. FDA approval or other clearances must be obtained before clinical testing, and before manufacturing and marketing of biologics or drugs.

Obtaining FDA approval historically has been a costly and time-consuming process. Generally, in order to gain FDA premarket approval, preclinical studies must be conducted 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 can start. The IND includes a detailed description of the clinical investigations.

A company must sponsor and file an IND for each proposed product and must conduct clinical studies to demonstrate the safety, efficacy and potency that are necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing, and it may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients. Human gene therapy products are a new category of therapeutics, and the clinical trial period may be lengthy or the number of patients may be numerous in order to establish safety, efficacy and potency.

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

Applications submitted to the FDA can take typically two to five years to receive approval after filing. If questions arise during the FDA review process, approval can take more than five years. The FDA may ultimately decide that the application does not satisfy its criteria for approval or 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 civil or criminal sanctions. Before marketing clearance is secured, the manufacturing facility will be inspected for current Good Manufacturing Practices (GMP) compliance by FDA inspectors. The manufacturing facility must satisfy current GMP requirements prior to marketing clearance. In addition, after marketing clearance is secured, the manufacturing facility will be inspected periodically for GMP compliance by FDA inspectors, and, if the facility is located in California, by inspectors from the Food and Drug Branch of the California Department of Health Services.

In addition to the FDA requirements, the National Institutes of Health ("NIH") has established guidelines for research involving recombinant DNA molecules. These guidelines apply to all recombinant DNA research which is conducted at or supported by the NIH, including proposals to conduct clinical research involving gene therapy. The NIH review of clinical trial proposals is a public process and usually involves review and approval by the Recombinant DNA Advisory Committee of the NIH.

In both domestic and foreign markets, sales of any approved products will depend on reimbursement 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 we succeed in bringing one or more products to market, these products may not be considered cost-effective, reimbursement may not be available, or reimbursement policies may adversely affect our ability to sell our products on a profitable basis.

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

## **HUMAN RESOURCES**

As of March 15, 1999, Vical had 101 full-time employees, 20 of whom hold degrees at the doctorate level. Of these employees, 78 are engaged in, or directly support, research and development activities, and 23 are in administrative and business development positions. A significant number of our management and professional employees have prior experience with pharmaceutical and biotechnology companies. None of our 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 we produce could expose us to product liability claims. We currently carry insurance against such claims for clinical trials only. We may not have sufficient coverage, or sufficient coverage may not be available 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 Vical. A product liability claim or recall could have a material adverse effect on our business or financial condition.

## **RISK FACTORS**

You should carefully consider the following risk factors when evaluating Vical and its prospects as presented in this report or elsewhere by management.

### **UNCERTAINTY CONCERNING OUR POTENTIAL PRODUCTS AND TECHNOLOGY MAY ADVERSELY AFFECT US**

Very little data exists regarding the safety and efficacy of gene therapy. Moreover, existing studies do not necessarily predict that some therapy will be safe or effective in humans. This is significant because all of our potential products are either in research or development. A failure to successfully develop and commercialize products will materially adversely affect us. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our products. This research and development may indicate that our potential products are unsafe or ineffective, in which case, regulatory authorities may not approve them. Even if approved, our products may not be commercially successful.

### **OUR LOSSES**

We have not sold any products and do not expect to sell any products for the next several years. We have incurred cumulative losses totaling approximately \$37.7 million through December 31, 1998. Moreover, we expect that our negative cash flow and losses from operations will continue and increase for the foreseeable future. Indeed, we may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, some of which could be significant.

### **OUR ADDITIONAL FINANCING REQUIREMENTS AND LACK OF ACCESS TO CAPITAL COULD ADVERSELY AFFECT US**

We will need to raise more money to continue the research and development necessary to bring products to market and to establish manufacturing and marketing capabilities. If we cannot obtain more money we will be materially and adversely affected. The amount of money we will need will depend on many factors, including:

- the progress of our research and development programs
- the scope and results of our preclinical studies and clinical trials
- the time and costs involved in:
  - obtaining necessary regulatory approvals
  - filing, prosecuting and enforcing patent claims
  - scaling up our manufacturing capabilities
  - competing technological and market developments
- the commercial arrangements we may establish
- other factors not within our control

We intend to seek additional funds through public and private stock offerings, arrangements with corporate collaborators or other sources. However, we may be unable to obtain the money we need on acceptable terms. If this happens, we may have to eliminate or scale back some or all of our research and development programs or license others to develop products and/or technologies that we otherwise would seek to develop ourselves.

### **THE REGULATORY APPROVAL PROCESS IS EXPENSIVE, TIME CONSUMING AND UNCERTAIN WHICH MAY ADVERSELY AFFECT US**

The regulations governing gene therapy products are evolving and uncertain; seeking to comply with them is expensive and time consuming. Failure to obtain FDA approval of our products will materially and adversely affect us. For example, the FDA has not established guidelines concerning the length of the clinical trial period required for gene therapy products. Nor has that agency indicated how many patients it will require to be enrolled in clinical trials to establish the safety, efficacy and potency of gene therapy products. Furthermore, existing regulations are subject to substantial review by various governmental agencies. Therefore, future U.S. or foreign regulations could prevent or delay regulatory approval of our products or affect adversely our ability to develop, test, manufacture and market our products.

We believe that the FDA and comparable foreign regulatory bodies will regulate the commercial use of any of our products as either biologics or drugs. These agencies are likely to regulate each product containing a particular gene

as a separate biologic or drug depending on its intended use and evolving policy. Presently, to commercialize any product we must sponsor and file a regulatory application for each proposed product. We then must conduct clinical studies to demonstrate the safety, efficacy and potency of the product necessary to obtain FDA approval.

The NIH also has established guidelines for research involving recombinant DNA molecules which is conducted at or supported by the NIH. We must comply with these guidelines because we and certain of our collaborators use recombinant DNA molecules in our research and we have received grants from the NIH. Under current guidelines, we must submit for review to the NIH and the Recombinant DNA Advisory Committee each of our proposals to conduct clinical research.

We may be unable to obtain the necessary approvals for clinical trials or for the manufacturing or marketing of our products. Even if we do obtain regulatory clearance, marketed products remain subject to continual review by U.S. regulators. If regulators discover a previously unknown problem with one of our products, or if we fail to comply with applicable regulations, regulators may:

- restrict marketing of the product
- withdraw the product from the market
- impose civil or criminal sanctions

In addition, many other companies and academic institutions are conducting research in the gene therapy field using a variety of approaches and technologies. If any of these researchers were to obtain adverse results in preclinical or clinical studies this could adversely affect the regulatory environment for gene therapy products in general, possibly leading to delays in the approval process for our potential products.

#### **UNCERTAINTY REGARDING OUR INTELLECTUAL PROPERTY RIGHTS MAY HARM US**

Patents may not issue from any of our applications. Moreover, if patents do issue, governmental authorities may not allow claims in such patents sufficient to protect our technology. Finally, others may challenge or seek to circumvent or invalidate patents that are issued to us or to licensors of our technology. In that event, the rights granted under patents may be inadequate to protect our proprietary technology or to provide any commercial advantage.

Our success will depend in part on our ability to obtain patent protection for our products and processes both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields. We also seek to protect our proprietary technology through confidentiality agreements with corporate collaborators, employees, consultants and contractors. Others may breach these agreements and we may not have a remedy that is adequate to protect our rights.

Protecting intellectual property rights can also be very expensive. Litigation may be necessary to enforce a patent or to determine the scope and validity of third-party proprietary rights. Moreover, if a competitor were to file a patent application claiming technology also invented by us, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office or in a foreign counterpart to determine the priority of the invention.

Our success also will depend in part on our ability to keep from infringing upon patents issued to competitors and breaching the technology licenses that might cover technology used in our products. We do not know whether any patents held by others will require us to alter our products or processes, obtain licenses, or stop activities. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we may have to obtain licenses to test, use or market these products. Our business may suffer if we cannot obtain licenses, or if we can obtain them only on terms that are commercially unfavorable.

#### **OUR DEPENDENCE ON OTHERS MAY ADVERSELY AFFECT US**

Our strategy for the research, development and commercialization of our products requires us to enter into contractual arrangements with corporate collaborators, licensors, licensees and others. Our success depends upon the performance by these persons of their responsibilities under these arrangements. We cannot control the timing of their

performance or the amount of resources they will devote to these activities. Some persons may not perform their obligations as we expect or we may not derive any revenue from these arrangements.

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

### **THE EFFECT OF COMPETITION AND TECHNOLOGICAL CHANGE MAY HURT US**

Gene therapy is a new and rapidly evolving field. We expect that the field will continue to undergo significant and rapid technological change. Such change could render our products or technologies obsolete.

We compete with companies in the field of gene therapy and with companies pursuing other forms of treatment or prevention for the diseases we have targeted. Several development stage and established entities, including major pharmaceutical and biotechnology firms, are exploring the field of human gene therapy or are actively engaged in research and development in areas related to gene therapy. We also may experience competition from companies that have acquired or may acquire technology from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions in aspects of gene therapy which may materially and adversely affect our business.

Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Other companies may succeed in developing products earlier than we do, obtaining FDA approval for products more rapidly than we do, or developing products that are more effective than those we propose to develop. While we will seek to expand our technological capabilities to remain competitive, research and development by others might render our technology or products obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. Additionally, consumers may not prefer therapies developed by us over existing or newly developed therapies.

### **WE CANNOT MANUFACTURE OR MARKET PRODUCTS ON A COMMERCIAL SCALE WHICH MAY HURT US**

We have neither the resources nor the capability to manufacture or market our proposed products on a commercial scale. We may be dependent initially on corporate partners, licensees or others to manufacture and market our products commercially. If we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and personnel. We also will be required to comply with extensive regulations applicable to a manufacturing facility. We may be unable to enter into any arrangement for the manufacture or marketing of our products. We also may be unable to obtain additional capital to perform these activities ourselves.

### **THERE IS UNCERTAINTY CONCERNING INSURANCE COVERAGE AND REIMBURSEMENT FOR OUR POTENTIAL PRODUCTS WHICH MAY ADVERSELY AFFECT US**

As with many health care products and services, the commercial viability of our gene therapy products and related treatments may depend in part on whether their costs are covered by health insurers. These insurers include:

- government health administration authorities
- private health coverage insurers
- managed care organizations
- other similar organizations

Whenever a new health care product is approved by the regulatory authorities it is always uncertain whether insurers will cover the product. We do not know whether or to what extent insurers will cover our potential products. If purchasers or users of our potential products are not entitled to adequate reimbursement for the cost of using our potential products, they may decide not to use them or to limit their use. This could harm our business.



## **OUR USE OF HAZARDOUS MATERIALS COULD ADVERSELY AFFECT US**

Although we do not manufacture commercial quantities of our potential products we do produce limited quantities of our potential products for clinical trials. Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. There is a risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed our resources. We could be required to incur significant costs to comply with current or future environmental laws and regulations. This could materially or adversely affect our operations, business or assets.

## **VOLATILITY OF STOCK PRICE AND ABSENCE OF DIVIDENDS**

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

- the results of our preclinical studies and clinical trials or those of one of our collaborators or competitors
- other evidence of the safety or efficacy of our potential products or the products of our competitors
- the announcement by us or one of our competitors of technological innovations or new products
- governmental regulatory actions
- developments with our collaborators
- developments concerning our patent or other proprietary rights or those of one of our competitors (including litigation)
- concern as to the safety of our potential products
- period to period fluctuations in our operating results
- market conditions for life science stocks in general
- other factors not within our control

We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

## **YEAR 2000 ISSUES**

We are unable to control whether our current and future strategic partners' computer systems are Year 2000 compliant. Any of the following events could affect our operations:

- if a strategic partner were unable to purchase our clinical materials or services
- if a strategic partner were unable to manage its clinical trials or research and development activities
- if a strategic partner were unable to pay its invoices owed to us
- if a supplier were unable to manufacture and ship materials to us or provide requested contract services

Failure of systems maintained by our strategic partners or suppliers could cause us to incur significant expenses to remedy any problems, or otherwise seriously damage our business.

## EXECUTIVE OFFICERS

The executive officers of Vical are as follows:

| NAME                       | AGE | POSITION   |
|----------------------------|-----|--|
| -----                      | --- | -----  |
| Alain B. Schreiber, M.D.   | 43  | President, Chief Executive Officer and Director                  |
| Deirdre Y. Gillespie, M.D. | 42  | Executive Vice President and Chief Business Officer              |
| Martha J. Demski           | 46  | Vice President, Chief Financial Officer, Treasurer and Secretary |
| George J. Gray             | 52  | Vice President, Operations                                       |
| Jon A. Norman, Ph.D.       | 50  | Vice President, Research   |
| Robert H. Zaugg, Ph.D.     | 49  | Vice President, Business Development                             |

ALAIN B. SCHREIBER, M.D., has been President, Chief Executive Officer and a director of Vical since May 1992. Prior to joining Vical, Dr. Schreiber held various executive level positions at Rhone-Poulenc Rorer Inc. from July 1985 to April 1992, most recently as Senior Vice President of Discovery Research. From October 1982 to June 1985, Dr. Schreiber served as Biochemistry Department Head at Syntex Corp. 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. Dr. Schreiber serves on the Board of Spiros Development Corporation and is an appointed Advisor for Foreign Trade for Belgium.

DEIRDRE Y. GILLESPIE, M.D., joined Vical as Executive Vice President and Chief Business Officer in March 1998. Dr. Gillespie served as Vice President of Business Development for 3-Dimensional Pharmaceuticals, Inc. in Pennsylvania from 1997 until joining Vical. From 1991 to 1996, she held various management positions with DuPont Merck Pharmaceutical Co. in England and Delaware. From 1986 to 1990, Dr. Gillespie directed clinical research activities for Sandoz Pharma AG in Switzerland and England. Dr. Gillespie received a B.Sc. in Pharmacology and Therapeutics and an M.D. from London University. She has MRCP certification (equivalent to internal medicine boards in the U.S.). Dr. Gillespie received her M.B.A. from the London Business School with a specialization in marketing and international management.

MARTHA J. DEMSKI joined Vical as Chief Financial Officer in December 1988 and 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 Vical in January 1993 as Vice President, Research. From 1986 until joining Vical, Dr. Norman was the Group Leader/Section Head for the Departments of Pharmacology and Biochemistry at Bristol-Myers Squibb Corporation. He was a Senior Research Scientist at Ciba-Geigy Corporation, 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 Friedrich Miescher Institute in Basel, Switzerland.

GEORGE J. GRAY joined Vical 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, U.S./U.K. 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 Vical 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 Vical, 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.

## ITEM 2. PROPERTIES

Vical 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 \$95,000.

## ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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

Not applicable.

## PART II

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

Vical'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, 1997.

| 1997           | HIGH    | LOW     |
|----------------|---------|---------|
| ----           | ----    | ---     |
| First Quarter  | \$18.25 | \$14.00 |
| Second Quarter | 15.75   | 9.25    |
| Third Quarter  | 15.00   | 10.625  |
| Fourth Quarter | 17.25   | 11.00   |
| 1998           |         |         |
| ----           |         |         |
| First Quarter  | \$18.00 | \$12.00 |
| Second Quarter | 19.00   | 14.00   |
| Third Quarter  | 17.875  | 7.188   |
| Fourth Quarter | 18.00   | 8.00    |

As of March 15, 1999, there were approximately 553 stockholders of record of Vical common stock with 16,190,313 shares outstanding. We have never declared or paid any dividends and do not expect to pay any dividends in the foreseeable future.

In January 1999, Vical and Pfizer Inc. ("Pfizer") entered into a license and option agreement, and a stock purchase agreement under which Pfizer made an investment of \$6.0 million for approximately 318,000 shares of Vical common stock. For this sale of stock, we relied on the exemption from registration under Section 4(2) of the Securities Act of 1933.

**ITEM 6. SELECTED FINANCIAL DATA**

|   | YEAR ENDED DECEMBER 31,                            |            |            |            |            |
|---|--|------------|------------|------------|------------|
|   | 1998   | 1997       | 1996       | 1995       | 1994       |
|   | (in thousands, except per share and share amounts) |            |            |            |            |
| <b>STATEMENT OF OPERATIONS DATA:</b>                  |  |            |            |            |            |
| Revenues:   |  |            |            |            |            |
| Contract revenue.....                                 | \$ 876   | \$ 1,326   | \$ 1,061   | \$ 900     | \$ 1,005   |
| License/royalty revenue.....                          | 5,044  | 6,477      | 5,679      | 5,402      | 4,509      |
|   | 5,920  | 7,803      | 6,740      | 6,302      | 5,514      |
| Expenses:   |  |            |            |            |            |
| Research and development...                           | 12,054   | 11,936     | 11,318     | 8,997      | 8,336      |
| General and administrative...                         | 3,650  | 3,733      | 3,168      | 2,902      | 2,615      |
| Loss from operations.....                             | (9,784)  | (7,866)    | (7,746)    | (5,597)    | (5,437)    |
| Interest income.....                                  | 2,465  | 2,447      | 2,773      | 1,687      | 1,159      |
| Interest expense.....                                 | 162  | 192        | 108        | 73         | 80         |
| Net loss.....   | \$ (7,481)   | \$ (5,611) | \$ (5,081) | \$ (3,983) | \$ (4,358) |
| Net loss per share (basic and diluted) .....          | \$ (.47)   | \$ (.36)   | \$ (.33)   | \$ (.29)   | \$ (.34)   |
| Shares used in per share calculation.....             | 15,797,585   | 15,484,952 | 15,382,848 | 13,504,790 | 12,831,585 |
|   | AS OF DECEMBER 31,                                 |            |            |            |            |
|   | 1998   | 1997       | 1996       | 1995       | 1994       |
|   | (in thousands)                                     |            |            |            |            |
| <b>BALANCE SHEET DATA:</b>                            |  |            |            |            |            |
| Cash, cash equivalents and marketable securities..... | \$ 40,184  | \$ 45,555  | \$ 46,846  | \$ 52,528  | \$ 27,339  |
| Working capital.....                                  | 38,398   | 44,856     | 46,315     | 51,541     | 25,956     |
| Total assets.....                                     | 44,844   | 50,691     | 52,440     | 55,118     | 30,324     |
| Long-term obligations.....                            | 801  | 1,232      | 1,617      | 339        | 527        |
| Stockholders' equity.....                             | 40,824   | 47,194     | 48,365     | 53,264     | 27,852     |

**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. We are focusing our resources on the development of our direct gene transfer and related technologies. To date, we have not received revenues from the sale of products. We cannot assure that we will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. As of December 31, 1998, our accumulated deficit was approximately \$37.7 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 our product candidates, increased patent and regulatory costs, and associated increases in personnel, laboratory supplies, contract services and facilities. 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. These statements are subject to 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 of this report. We undertake 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 of this report to reflect the occurrence of unanticipated events.

## RESULTS OF OPERATIONS

Vical had revenues of \$5.9 million for the year ended December 31, 1998, compared with \$7.8 million in 1997 and \$6.7 million in 1996. License revenues in 1998 consisted of \$2.2 million from Centocor, Inc. for an agreement covering technology for the potential treatment of some types of cancer, \$1.1 million from an agreement with Boston Scientific Corporation for the development of catheter-based vascular gene therapy, recognition of \$0.9 million of deferred license fees from a further extension of the license and option agreement with Merial, royalty revenues of \$0.7 million and \$0.2 million of other license revenue. Contract revenues in 1998 consisted principally of \$0.7 million from an agreement with the Office of Naval Research for the development work on a potential DNA vaccine to prevent malaria. This agreement is a multi-year agreement which could provide up to an additional \$2.0 million in revenues through 2000. Contract revenue in 1998 also included \$0.2 million of reimbursements from PMC and other sources.

Vical had revenues of \$7.8 million for the year ended December 31, 1997, compared with \$6.7 million in 1996. Revenues in 1997 were composed of research and license revenue from a 1997 Merck agreement covering certain growth factors (\$2.0 million); the equity premium on the investment Merck made in 1997 in Vical common stock under an amendment to the 1991 collaborative agreement (\$1.0 million); the PMC collaboration (\$2.4 million); a 1997 collaborative agreement with RPR for neurodegenerative disease targets (\$1.0 million); and other agreements which totaled \$1.4 million. In November 1997, Vical and Merck amended the 1991 agreement and granted Merck rights to develop and market therapeutic vaccines against HIV and HBV. Under the November 1997 amendment, Merck made an investment of \$5.0 million for approximately 262,000 shares of Vical common stock. The price per share reflected a twenty-five percent premium over the trading price of the common stock. The premium on the investment was reflected in revenue in 1997. The PMC revenue represented contract revenue of \$1.1 million as payment for clinical and preclinical work and license revenue of \$1.3 million, of which \$1.0 million was for a milestone payment for the start of the malaria clinical trial and the balance was the recognition of deferred license fees. Revenues in 1996 resulted from research and license revenue from: the PMC collaboration in the amount of \$2.7 million, the 1991 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 Vical's performance of clinical and preclinical work. The Merck revenue resulted from milestone payments due under the 1991 Merck agreement. The Genzyme collaboration income was the result of Genzyme exercising its option to license our technology for the treatment of cystic fibrosis as well as payments for our performance of research and preclinical work.

Research and development expense increased to \$12.1 million in 1998 from \$11.9 million in 1997 and \$11.3 million in 1996. The increases in research and development expense were generally due to expansion of our research and development activities. The increase in 1998 principally was due to increased clinical trial costs and additional royalty expense for license agreements. The increase in expenses in 1997 compared to 1996 included increased clinical and preclinical efforts which resulted in increases to staffing, increased facilities related costs and increased expenditures on laboratory supplies. Clinical trials expense increased to \$1.9 million during 1998 from \$1.6 million in 1997. This increase was due to the commencement of the Phase II and Phase III clinical trials of ALLOVECTIN 7 for melanoma. Clinical trials expense increased to \$1.6 million during 1997 from \$1.2 million in 1996 primarily due to the commencement of the malaria clinical trial and increased clinical trials activity on LEUVECTIN. During 1996, we 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. Research and development expense is expected to increase in 1999 and thereafter as our preclinical and clinical trial activities increase.

General and administrative expense decreased to \$3.6 million in 1998 from \$3.7 million in 1997 due to lower insurance and facilities expenses. The increase to \$3.7 million in 1997 from \$3.2 million during 1996 was due primarily to additional staffing and related expenses. General and administrative expenses are expected to continue to increase as research and development activities expand.

Interest income increased to \$2.5 million in 1998 from \$2.4 million in 1997 due to higher rates of return on investments. Interest income of \$2.4 million during 1997 declined from the \$2.8 million in 1996, due to lower investment balances as we redeemed investments to fund operating expenses. Interest expense decreased during 1998 due to lower capital lease obligations, lower balance of bank note payable and lower interest rates on the newer capital lease obligations. Interest expense increased in 1997 compared to the previous year due to increased capital lease obligations to finance equipment needs and the addition of a debt instrument in 1996.

## **YEAR 2000 ISSUES**

The Year 2000 problem is due to many computer systems using only two digits rather than four to designate a specific year. As a result, many of these systems may fail to function properly if a date beyond 1999 is entered. We have completed our assessment of any potential Year 2000 issues for our internal computer applications, including embedded control systems in equipment, to determine whether they will function for the year 2000 and beyond and what modifications, if any, would be required to ensure their continuing functionality. We plan to upgrade our existing business applications software to the latest Year 2000 compliant release of the software by June 1, 1999. We also plan to implement a new financial and accounting system and related hardware to meet our growing needs into the near future. This new system will be Year 2000 compliant and implemented prior to yearend. Given the relatively small size of our systems and the predominantly new hardware, software and operating systems, we do not anticipate any significant delays in becoming Year 2000 compliant. To date our costs for Year 2000 compliance have been immaterial and we expect our costs to finish becoming Year 2000 compliant to be immaterial.

We are unable to control whether our current and future strategic partners' systems are Year 2000 compliant. The failure of systems maintained by our strategic partners or suppliers could cause us to incur significant expenses to remedy any problems, or otherwise seriously damage our business. We are communicating with strategic partners to assess the risk of Year 2000 issues. We have not completed the inquiries of the strategic partners. However, we are not aware, at this time, of any material Year 2000 issues regarding our dealings with our strategic partners. We anticipate that our assessment will be completed by July 31, 1999.

At this time, we have no reason to believe that Year 2000 changes will have a material impact on Vical's business, financial condition or results of operations. Since no significant issues have been identified, we do not have a comprehensive contingency plan to address any material Year 2000 issues. A contingency plan, if required, will be developed for all applications and systems that affect core business functions upon completion of our assessment of Year 2000 issues. We do plan to perform backups of the existing and upgraded versions of the computer system so that in the event our planned new financial and accounting system and related hardware do not function properly we can continue to operate under the old system. Vical has not identified what it believes would be a reasonably likely worst case scenario with respect to Year 2000 failures.

## **LIQUIDITY AND CAPITAL RESOURCES**

Since its inception, Vical has financed its operations primarily through private placements of common stock and preferred stock, three public offerings of common stock, and revenues from collaborative agreements. As of December 31, 1998, we had working capital of approximately \$38.4 million compared with \$44.9 million at December 31, 1997. Cash and marketable securities totaled approximately \$40.2 million at December 31, 1998, compared with \$45.6 million at December 31, 1997.

We expect to incur substantial additional research and development expense and general and administrative expense. Our future capital requirements will depend on many factors, including the rate of scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the cost of manufacturing scale-up, commercialization activities and arrangements and other factors not within our control. We intend to seek additional funding through research and development relationships with suitable potential corporate collaborators and/or through public or private financings. We cannot assure that additional financing will be available on favorable terms, if at all.

If additional financing is not available, Vical anticipates that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2000.

## **ITEM 7.a QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Vical's investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. No investments in equity securities are made. At December 31, 1998, 96 percent of the investments would mature within two years, none would mature beyond three years, and the average maturity was nine months. Our investments are all classified as available-for-sale securities. We are subject to interest rate risk. We projected an ending fair value of our cash equivalents and marketable securities using a twelve-month time horizon, a nine-month average maturity and assuming a 150-basis-point increase in interest rates. The decrease in fair value assuming a 150-basis-point increase in interest rates compared with fair value with no change in interest rates was not material.

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

The consolidated financial statements and supplementary data of Vical 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.

### **PART III**

## **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS**

### **DIRECTORS**

The directors of Vical are as follows:

| <u>NAME</u>              | <u>AFFILIATION</u>                  |
|--------------------------|-------------------------------------|
| 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 Ventures                 |
| Dale A. Smith            | Baxter International Inc. (retired) |
| Philip M. Young          | U.S. Venture Partners               |
| Gary A. Lyons            | Neurocrine Biosciences, Inc.        |

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 Vical's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for Vical's 1999 Annual Meeting of Stockholders to be held on May 27, 1999 ("Proxy Statement").

The required information concerning Executive Officers of Vical 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.

## 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, 1998 and 1997                                   | F-2 |
| Statements of Operations for the three years ended December 31, 1998           | F-3 |
| Statements of Stockholders' Equity for the three years ended December 31, 1998 | F-4 |
| Statements of Cash Flows for the three years ended December 31, 1998           | 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, 1998.



(c) EXHIBITS

| EXHIBIT<br>NUMBER | DESCRIPTION OF DOCUMENT   |
|-------------------|---|
| 3.1(i)(10)        | Restated Certificate of Incorporation.  |
| 3.1(ii)(10)       | Amended and Restated Bylaws of the Company.   |
| 3.2(i)(2)         | Certificate of Designation, Rights and Preferences of Series A Participating Preferred Stock of Vical Incorporated.                             |
| 4.1(10)           | Specimen Common Stock Certificate.  |
| 4.2(2)            | Rights Agreement dated as of March 20, 1995, between the Company and First Interstate Bank of California.                                       |
| 4.3(11)           | Stock Purchase Agreement dated November 3, 1997, between the Company and Merck & Co., Inc.  |
| 10.1(4)#          | Stock Incentive 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.   |
| 10.5(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.                                      |
| 10.12(1)*         | License Agreement dated January 1, 1991, between the Company and Wisconsin Alumni Research Foundation.  |
| 10.14(1)*         | License Agreement dated October 23, 1992, between the Company and the Regents of University of Michigan.  |
| 10.16(7)          | Research, Option and License Agreement dated September 29, 1994, between the Company and Pasteur Merieux Serums & Vaccins.                      |
| 10.17(8)          | Amendment dated April 27, 1994, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.   |
| 10.18(9)*         | Agreement between Merck & Co., Inc. and the Company dated September 12, 1997.   |
| 10.19(11)*        | Amendment dated November 3, 1997, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc. |
| 23.1              | Consent of Arthur Andersen LLP.   |
| 24                | Power of Attorney (see page 30).  |
| 27                | Financial Data Schedule   |

(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 A filed with the Company's Schedule 14A Definitive Proxy Statement on Form DEF 14A filed on April 14, 1998.

(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 A of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1994.

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

(9) Incorporated by reference to the exhibit of the same number to the Company's Quarterly Report on the Form 10-Q for the quarter ended September 30, 1997, as amended by Form 10-Q/A filed January 30, 1998.

(10) 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.

(11) Incorporated by reference to the exhibit of the same number to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, filed on March 30, 1998.

\* The Company has received confidential treatment of certain portions of these agreements. # Indicates management contract or compensatory plan or arrangement.

#### (d) FINANCIAL STATEMENT SCHEDULES

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

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 30, 1999.

### VICAL INCORPORATED

By:           /s/ ALAIN B. SCHREIBER, M.D.

*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.

|  |   |                |
|--|---|----------------|
| <u>          /s/ ALAIN B. SCHREIBER, M.D.</u><br>-----<br>Alain B. Schreiber, M.D. | President,<br>Chief Executive Officer<br>and Director                         | March 30, 1999 |
| <u>          /s/ MARTHA J. DEMSKI</u><br>-----<br>Martha J. Demski                 | Vice President, Finance<br>Chief Financial Officer<br>Secretary and Treasurer | March 30, 1999 |
| <u>          /s/ ROBERT C. BELLAS, Jr.</u><br>-----<br>Robert C. Bellas, Jr.       | Director  | March 30, 1999 |
| <u>          /s/ FRED A. MIDDLETON</u><br>-----<br>Fred A. Middleton               | Director  | March 30, 1999 |
| <u>          /s/ PHILIP M. YOUNG</u><br>-----<br>Philip M. Young                   | Director  | March 30, 1999 |
| <u>          /s/ PATRICK F. LATTERELL</u><br>-----<br>Patrick F. Latterell         | Director  | March 30, 1999 |
| <u>          /s/ DALE A. SMITH</u><br>-----<br>Dale A. Smith                       | Director  | March 30, 1999 |
| <u>          /s/ M. BLAKE INGLE</u><br>-----<br>M. Blake Ingle                     | Director  | March 30, 1999 |
| <u>          /s/ GARY A. LYONS</u><br>-----<br>Gary A. Lyons                       | Director  | March 30, 1999 |

## 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, 1998 and 1997, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 1998. 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, 1998 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1998, in conformity with generally accepted accounting principles.

**ARTHUR ANDERSEN LLP**

San Diego, California  
February 8, 1999

**VICAL INCORPORATED**  
**BALANCE SHEETS**

|   | December 31,  |               |
|---|---------------|---------------|
|   | 1998          | 1997          |
| <b>ASSETS</b>   |               |               |
| Current Assets:   |               |               |
| Cash and cash equivalents (Note 2)  | \$ 13,567,817 | \$ 12,157,149 |
| Marketable securities - available-for-sale (Note 2)   | 26,615,939    | 33,397,482    |
| Receivables and other   | 1,432,711     | 1,566,532     |
| Total current assets  | 41,616,467    | 47,121,163    |
| Property and Equipment (Note 5):  |               |               |
| Equipment   | 5,139,944     | 4,966,955     |
| Leasehold improvements  | 1,558,554     | 1,587,554     |
|   | 6,698,498     | 6,554,509     |
| Less--accumulated depreciation and amortization   | (4,992,121)   | (4,334,224)   |
|   | 1,706,377     | 2,220,285     |
| Patent costs, net of accumulated amortization of \$126,638 and \$74,063 (Note 1)  | 1,387,936     | 1,247,059     |
| Other assets  | 133,385       | 102,500       |
|   | \$ 44,844,165 | \$ 50,691,007 |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |               |               |
| Current Liabilities:  |               |               |
| Accounts payable and accrued expenses (Note 4)  | \$ 2,281,252  | \$ 1,424,603  |
| Current portion of capital lease obligations (Note 5)   | 473,466       | 448,261       |
| Current portion of notes payable (Note 5)   | 213,773       | 213,773       |
| Deferred revenue (Note 3)   | 250,000       | 178,261       |
| Total current liabilities   | 3,218,491     | 2,264,898     |
| Long-Term Obligations:  |               |               |
| Long-term obligations under capital leases (Note 5)   | 747,807       | 911,794       |
| Notes payable (Note 5)  | 53,443        | 320,660       |
| Total long-term obligations   | 801,250       | 1,232,454     |
| Commitments (Note 5)  |               |               |
| Stockholders' Equity (Note 6):  |               |               |
| Preferred stock, \$.01 par value--5,000,000 shares authorized--none outstanding   | -             | -             |
| Common stock, \$.01 par value--40,000,000 shares authorized--15,866,544 and 15,731,316 shares issued and outstanding in 1998 and 1997, respectively | 158,665       | 157,313       |
| Additional paid-in capital  | 78,332,483    | 77,267,971    |
| Accumulated other comprehensive income (Note 2)   | 69,440        | 24,028        |
| Accumulated deficit   | (37,736,164)  | (30,255,657)  |
| Total stockholders' equity  | 40,824,424    | 47,193,655    |
|   | \$ 44,844,165 | \$ 50,691,007 |

See accompanying notes.

**VICAL INCORPORATED**  
**STATEMENTS OF OPERATIONS**

|  | Year ended December 31, |                |                |
|--|-------------------------|----------------|----------------|
|  | 1998                    | 1997           | 1996           |
| Revenues (Note 3):   |                         |                |                |
| Contract revenue   | \$ 875,773              | \$ 1,325,925   | \$ 1,060,557   |
| License/Royalty revenue                                      | 5,044,607               | 6,477,244      | 5,679,542      |
|  | 5,920,380               | 7,803,169      | 6,740,099      |
| Expenses:  |                         |                |                |
| Research and development                                     | 12,054,367              | 11,936,068     | 11,317,908     |
| General and administrative                                   | 3,649,841               | 3,733,290      | 3,168,331      |
|  | 15,704,208              | 15,669,358     | 14,486,239     |
| Loss from operations   | (9,783,828)             | (7,866,189)    | (7,746,140)    |
| Other income (expense):                                      |                         |                |                |
| Interest income  | 2,465,545               | 2,447,139      | 2,772,845      |
| Interest expense   | (162,224)               | (192,181)      | (107,296)      |
| Net loss   | \$ (7,480,507)          | \$ (5,611,231) | \$ (5,080,591) |
| Net loss per share (basic and diluted--Note 1)               | \$ (0.47)               | \$ (0.36)      | \$ (0.33)      |
| Weighted average shares used in computing net loss per share | 15,797,585              | 15,484,952     | 15,382,848     |

See accompanying notes.

**VICAL INCORPORATED**  
**STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE THREE YEARS ENDED DECEMBER 31, 1998**

|  | Common<br>Shares | Stock<br>Amount | Additional<br>Paid-in<br>Capital | Deferred<br>Compensation | Accumulated<br>Other<br>Comprehensive<br>Income | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity | Total<br>Comprehensive<br>Loss |
|--|------------------|-----------------|----------------------------------|--------------------------|---|------------------------|----------------------------------|--------------------------------|
| 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 loss on marketable securities arising during holding period |                  |                 |                                  |                          |   |                        |                                  | \$ (136,199)                   |
| Reclassification of realized gain included in net loss                 |                  |                 |                                  |                          |   |                        |                                  | (16,762)                       |
| Unrealized gain (loss) on marketable securities                        | -                | -               | -                                | -                        | (152,961)                                       | -                      | (152,961)                        | (152,961)                      |
| Net loss   | -                | -               | -                                | -                        | -   | (5,080,591)            | (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                       | (5,233,552)                    |
| Issuance of common stock at \$15.28 per share (Note 3)                 | 261,812          | 2,618           | 3,992,143                        | -                        | -   | -                      | 3,994,761                        |                                |
| Stock option exercises   | 72,922           | 729             | 371,356                          | -                        | -   | -                      | 372,085                          |                                |
| Unrealized gain on marketable securities arising during holding period |                  |                 |                                  |                          |   |                        |                                  | 87,763                         |
| Reclassification of realized loss included in net loss                 |                  |                 |                                  |                          |   |                        |                                  | (14,950)                       |
| Unrealized gain (loss) on marketable securities                        | -                | -               | -                                | -                        | 72,813  | -                      | 72,813                           | 72,813                         |
| Net loss   | -                | -               | -                                | -                        | -   | (5,611,231)            | (5,611,231)                      | (5,611,231)                    |
| BALANCE, December 31, 1997   | 15,731,316       | 157,313         | 77,267,971                       | -                        | 24,028  | (30,255,657)           | 47,193,655                       | (5,538,418)                    |
| Stock option exercises   | 135,228          | 1,352           | 1,064,512                        | -                        | -   | -                      | 1,065,864                        |                                |
| Unrealized gain on marketable securities arising during holding period |                  |                 |                                  |                          |   |                        |                                  | 57,041                         |
| Reclassification of realized gain included in net loss                 |                  |                 |                                  |                          |   |                        |                                  | (11,629)                       |
| Unrealized gain (loss) on marketable securities                        | -                | -               | -                                | -                        | 45,412  | -                      | 45,412                           | 45,412                         |
| Net loss   | -                | -               | -                                | -                        | -   | (7,480,507)            | (7,480,507)                      | (7,480,507)                    |
| BALANCE, December 31, 1998   | 15,866,544       | \$ 158,665      | \$ 78,332,483                    | \$ -                     | \$ 69,440                                       | \$ (37,736,164)        | \$ 40,824,424                    | \$ (7,435,095)                 |

See accompanying notes.

**VICAL INCORPORATED**  
**STATEMENTS OF CASH FLOWS**

|   | Year ended December 31, |                |                |
|---|-------------------------|----------------|----------------|
|   | 1998                    | 1997           | 1996           |
| <b>OPERATING ACTIVITIES:</b>  |                         |                |                |
| Net loss  | \$ (7,480,507)          | \$ (5,611,231) | \$ (5,080,591) |
| Adjustments to reconcile net loss to net cash provided from (used in) operating activities: |                         |                |                |
| Depreciation and amortization   | 920,695                 | 939,956        | 620,033        |
| Compensation expense related to stock purchases   | -                       | -              | 158,427        |
| Write-off of abandoned patent application costs   | 94,800                  | 80,994         | 3,247          |
| Changes in operating assets and liabilities:  |                         |                |                |
| Receivables and other   | 133,821                 | 359,463        | (1,397,906)    |
| Accounts payable and accrued expenses   | 856,649                 | 614,219        | 282,087        |
| Deferred revenue  | 71,739                  | (1,013,043)    | 512,137        |
| Net cash used in operating activities   | (5,402,803)             | (4,629,642)    | (4,902,566)    |
| <b>INVESTING ACTIVITIES:</b>  |                         |                |                |
| Marketable securities   | 6,826,955               | 912,645        | 10,963,363     |
| Capital expenditures  | (34,292)                | (418,507)      | (980,709)      |
| Other assets  | (1,885)                 | 210,400        | 221,288        |
| Patent expenditures   | (288,252)               | (280,778)      | (269,682)      |
| Net cash provided from (used in) investing activities                                       | 6,502,526               | 423,760        | 9,934,260      |
| <b>FINANCING ACTIVITIES:</b>  |                         |                |                |
| Principal payments under capital lease obligations  | (487,702)               | (506,205)      | (414,176)      |
| Proceeds from (payments on) notes payable   | (267,217)               | (106,887)      | 641,320        |
| Issuance of common stock, net   | 1,065,864               | 4,366,846      | 176,311        |
| Net cash provided from financing activities   | 310,945                 | 3,753,754      | 403,455        |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS  | 1,410,668               | (452,128)      | 5,435,149      |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD  | 12,157,149              | 12,609,277     | 7,174,128      |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD  | \$ 13,567,817           | \$ 12,157,149  | \$ 12,609,277  |
| <b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>                                   |                         |                |                |
| Interest Paid   | \$ 167,622              | \$ 184,191     | \$ 107,296     |
| <b>NONCASH INVESTING AND FINANCING ACTIVITIES:</b>  |                         |                |                |
| Equipment acquired under capital leases   | \$ 348,920              | \$ 434,416     | \$ 1,200,022   |

See accompanying notes.



**VICAL INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS**  
December 31, 1998

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**ORGANIZATION AND BUSINESS ACTIVITY**

Vical Incorporated (the "Company"), a Delaware corporation, was incorporated in 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company is focusing its resources on the development of its direct gene transfer and related technologies.

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 and not generate positive cash flow from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flow from operations at all or on a sustained basis.

**USE OF ESTIMATES**

The preparation of financial statements in conformity with 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**

Basic and diluted net loss per share for each of the three years in the period ended December 31, 1998, has been computed using the weighted average number of shares of common stock outstanding during the periods pursuant to Statement of Financial Accounting Standards No. 128, "Earnings Per Share." Diluted loss per share does not include any stock options as the effect would be antidilutive. See Note 6 for information on the number of options outstanding and the weighted average exercise price at December 31, 1998, 1997 and 1996.

**INCOME TAXES**

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



## FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of financial instruments such as accounts receivable, accounts payable and accrued expenses reasonably approximate fair value because of the short maturity of these items. The Company believes the carrying amounts of the Company's notes payable and obligations under capital leases approximate fair value because the interest rates on these instruments change with, or approximate, market interest rates.

## COMPREHENSIVE INCOME

The Company has implemented Statement of Financial Accounting Standards No. 130 ("SFAS 130"), "Reporting Comprehensive Income." This statement requires that all items that are required to be recognized under accounting standards as components of comprehensive income be reported in a financial statement that is displayed with the same prominence as other financial statements. Accordingly, in addition to reporting net income (loss) under the current rules, the Company was required to display the impact of any unrealized gain or loss on marketable securities as a component of comprehensive income and to display an amount representing total comprehensive income for each period presented. The Company has presented the required information in the Statements of Stockholders' Equity.

## RECENT ACCOUNTING PRONOUNCEMENTS

In March 1998, the Accounting Standards Executive Committee issued AICPA Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use" ("SOP 98-1"). This statement provides guidance on accounting for the costs of computer software developed or obtained for internal use. The statement identifies characteristics of internal use software and assists in determining when computer software is for internal use. SOP 98-1 is effective for fiscal years beginning after December 15, 1998, with earlier application permitted. The Company has not determined the impact of the adoption of SOP 98-1 as this is highly dependent upon the nature, timing and extent of future internal use software development.

The Company has adopted Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" and, has determined that it operates in one business segment dedicated to research in gene delivery technology.

## 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, 1998 and 1997, consist primarily of \$11,671,743 and \$12,080,473, respectively, in commercial paper, federal agency discount notes and money market funds.

The Company has adopted Statement of Financial Accounting Standards No. 115 ("SFAS 115"), "Accounting for Certain Investments in Debt and Equity Securities," which requires 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, calculated based on the specific identification method, were not material for the years ended December 31, 1998, 1997 and 1996.

At December 31, 1998, marketable securities consisted of the following:

|                             | Amortized Cost | Market Value | Unrealized Gain |
|-----------------------------|----------------|--------------|-----------------|
|                             | -----          | -----        | -----           |
| U.S. Government Obligations | \$ 5,508,897   | \$ 5,529,915 | \$21,018        |
| Commercial Paper            | 21,037,602     | 21,086,024   | 48,422          |
|                             | -----          | -----        | -----           |
| Total Marketable Securities | \$26,546,499   | \$26,615,939 | \$69,440        |
|                             | =====          | =====        | =====           |

Approximately 60%, 36% and 4% of these securities mature within one, two and three years, respectively, of December 31, 1998.

At December 31, 1997, marketable securities consisted of the following:

|                             | Amortized Cost | Market Value | Unrealized Gain |
|-----------------------------|----------------|--------------|-----------------|
| U.S. Government Obligations | \$12,978,062   | \$12,982,090 | \$ 4,028        |
| Commercial Paper            | 20,395,392     | 20,415,392   | 20,000          |
| Total Marketable Securities | \$33,373,454   | \$33,397,482 | \$24,028        |

### 3. SIGNIFICANT CONTRACTS AND LICENSE AGREEMENTS

#### **MERCK & CO., INC.**

The Company has entered into three separate agreements with Merck & Co., Inc. ("Merck") which provide Merck with certain exclusive rights to develop and commercialize vaccines using the Company's "naked" DNA technology for certain disease targets. The 1991 and 1997 agreements are for human vaccine targets and the 1992 agreement is for animal vaccine targets. Prior to 1996, Merck exercised its options to seven preventive human infectious disease vaccines using the Company's naked DNA technology pursuant to the 1991 agreement. 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. In November 1997, the Company and Merck amended the 1991 agreement and granted Merck certain rights to develop and market therapeutic vaccines against the human immunodeficiency virus (HIV) and hepatitis B virus (HBV). Under the amended agreement, Merck made an investment of \$5,000,000 for approximately 262,000 shares of the Company's common stock including a twenty-five percent premium over the average per share closing price for the twenty trading days prior to the date of the agreement. The premium of \$1,000,000 on the investment was reflected in revenue in 1997 and the balance of the investment, net of costs to issue the shares of stock, was reflected in common stock and additional paid-in capital.

The September 1997 agreement between the Company and Merck granted Merck the rights to use the Company's naked DNA technology to deliver certain growth factors as potential treatments for a range of applications including revascularization. The agreement resulted in an initial payment to the Company of \$2,000,000. Through December 31, 1998, the Company had received a total of \$19,130,000 (including the payment for the investment for common stock) under these agreements of which \$0, \$3,000,000, and \$1,500,000 was recognized as revenue in 1998, 1997, and 1996, respectively. All three agreements provide for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

#### **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 was paid an annual research fee through September 1997 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. In 1997, PMC paid the Company \$1,000,000 as a milestone payment under the agreement because the Company and PMC began a Phase I clinical trial of an experimental vaccine against the parasite that causes malaria. The Company and PMC are sponsoring the trial which is being conducted by the U.S. Naval Medical Research Institute and the U.S. Army Medical Research Institute of Infectious Diseases. Through December 31, 1998, Vical has received \$7,816,000 of which \$239,000, \$2,399,000, and \$2,746,000, was recognized as revenue in 1998, 1997, and 1996, 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.

#### **RHONE-POULENC RORER PHARMACEUTICALS, INC.**

In October 1997, the Company and Rhone-Poulenc Rorer Pharmaceuticals, Inc. ("RPR") entered into an agreement granting RPR an exclusive worldwide license to use the Company's naked DNA gene delivery technology to develop certain gene therapy products for potential treatment of neurodegenerative diseases. Under the terms of the agreement, the Company received \$1,000,000 which was recognized as revenue in 1997. This agreement provides for the Company to receive additional payments based upon achievement of certain defined milestones and royalty payments based on net product sales.

#### **CENTOCOR, INC.**

In February 1998, the Company signed an agreement allowing Centocor, Inc. ("Centocor") to use Vical's naked DNA technology to develop and market gene-based vaccines for the potential treatment of certain types of cancer. The agreement

resulted in a payment to Vical of \$2,200,000, which was recognized as revenue in 1998. The payment represented an initial payment of \$2,000,000 under the license agreement and reimbursement of \$200,000 of patent costs. The Company may receive further payments plus royalties if Centocor successfully develops products using the Vical technology. The agreement grants to Centocor exclusive worldwide licenses and options to license Vical's naked DNA technology to deliver certain antigens to induce immune responses against the associated cancer cells.

#### **BOSTON SCIENTIFIC CORPORATION**

In September 1998, the Company and Boston Scientific Corporation entered into a license and option agreement for the development of catheter-based intravascular gene delivery technology. The Company received \$1,100,000 which was recognized as revenue in 1998. The agreement also provides for the Company to receive royalty payments on net product sales.

#### **NAVAL MEDICAL RESEARCH INSTITUTE**

In September 1998, the Company signed a cooperative agreement with the Office of Naval Research for funding of up to \$2,700,000 to develop a multi-gene malaria DNA vaccine and test its ability to protect humans against malaria. The Company recognized \$697,000 of contract revenue under this agreement in 1998.

#### **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 \$1,585,000, \$1,404,000, and \$2,494,000, was recognized as revenue during the years ended December 31, 1998, 1997, and 1996, respectively. Included in these amounts is revenue recognized for a corporate alliance entered into in March 1995 relating to DNA vaccines in the animal health area with Merial (a joint venture between Merck and Rhone Merieux), a leading manufacturer and marketer of animal health products worldwide. The agreement includes options for Merial 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. In 1997, a patent milestone payment was made to the Company pursuant to the agreement. In 1998 a payment was made to the Company and the agreement was extended to March 1999. If Merial exercises its license options, cash payments and royalties on net sales would be due to the Company.

In 1996, the Company received \$1,100,000 and recognized revenue of \$1,300,000, under a 1993 agreement with Genzyme Corporation. This agreement was for the exercise of an option to obtain exclusive worldwide license rights related to the use of the Company's lipid technology in the treatment of cystic fibrosis. No cash was received and no revenue was recognized under this agreement in 1998 or 1997. Under a U.S. government agreement that commenced in the first quarter of 1996 and ended June 30, 1997, the Company and the Naval Medical Research Institute were awarded a grant that provided \$1,000,000 to support further development of a malaria vaccine based on Vical's naked DNA vaccine technology. In December 1996, the Company also recognized \$92,000 of revenue under an agreement which expired in December 1996 with Baxter International, Inc.

Under separate agreements, the Company is obligated to pay third parties 10 percent of certain payments received by the Company under the Merck, PMC, RPR, Merial, Centocor, Boston Scientific Corporation and Pfizer, Inc. (see "Note 10-Subsequent Event") agreements.

#### **4. OTHER FINANCIAL DATA**

Accounts payable and accrued expenses consisted of the following at December 31, 1998 and 1997:

|                               | 1998        | 1997        |
|-------------------------------|-------------|-------------|
|                               | ----        | ----        |
| Employee compensation         | \$692,716   | \$678,588   |
| Accounts payable              | 768,796     | 327,617     |
| Accrued clinical trials costs | 492,914     | 310,891     |
| Other accrued liabilities     | 326,826     | 107,507     |
|                               | -----       | -----       |
|                               | \$2,281,252 | \$1,424,603 |
|                               | -----       | -----       |
|                               | -----       | -----       |

## 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 subject to certain minimum and maximum annual increases. The Company is also required to pay taxes, insurance and operating costs under the facilities leases. The equipment capital leases are secured by substantially all equipment of the Company.

|  | Operating Leases | Capital Leases |
|--|------------------|----------------|
|  | -----            | -----          |
| Years ended December 31,                   |                  |                |
| 1999                                       | \$1,076,700      | \$566,014      |
| 2000                                       | 460,788          | 538,482        |
| 2001                                       | 116,241          | 186,781        |
| 2002                                       | -                | 84,896         |
| 2003                                       | -                | -              |
|  | -----            | -----          |
| Total minimum lease payments               | \$1,653,729      | 1,376,173      |
|  | -----            | -----          |
| Less amount representing interest          |                  | (154,900)      |
|  |                  | -----          |
| Present value of capital lease payments    |                  | 1,221,273      |
| Less current portion                       |                  | (473,466)      |
|  |                  | -----          |
| Long-term obligations under capital leases |                  | \$747,807      |
|  |                  | -----          |

Rent expense for the years ended December 31, 1998, 1997, and 1996, was \$998,195, \$969,899, and \$807,713, respectively.

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

|                   | Cost        | Accumulated<br>Depreciation | Net         |
|-------------------|-------------|-----------------------------|-------------|
|                   | ----        | -----                       | ---         |
| December 31, 1998 | \$2,163,877 | \$1,109,781                 | \$1,054,096 |
| December 31, 1997 | 2,312,876   | 1,066,488                   | 1,246,388   |

### NOTES PAYABLE

The Company has a term loan which bears interest at the bank's prime rate (8.25% at December 31, 1998) plus .5%, or the Company may alternatively choose to have its borrowings bear interest at the LIBOR rate plus 3.25%. The term loan is secured by any Company deposits at the bank, however, the Company is not required to, and does not, maintain any deposits at the bank. The term loan has a fifteen-month remaining amortization period. At December 31, 1998, the loan balance was \$267,216, including \$213,773 reflected in current liabilities.

### RESEARCH AND LICENSE AGREEMENTS

In 1998 and 1997, 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, 1998 or 1997.

### **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 15,866,544, and 15,731,316 were outstanding at December 31, 1998 and 1997, respectively.

### **STOCK PLAN AND DIRECTORS OPTION PLAN**

The Company has a stock plan ("Stock Incentive Plan of Vical Incorporated") under which 2,450,000 shares of common stock are reserved for issuance to employees, non-employee directors and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares. The exercise price of stock options must equal at least the fair market value on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to directors which vest at the next annual meeting, options generally vest 25% on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. The plan has also limited the number of options that may be granted to any plan participant in a single calendar year to 300,000 shares.

The Company also has a directors stock option plan ("Directors Plan") that provides for the issuance to non-employee directors of up to 210,000 shares of the Company's common stock, of which options for 202,500 shares have been granted. The initial grant to a director of options under this plan generally vests 25% on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. In 1997, the stockholders approved an amendment to the Stock Incentive Plan of Vical Incorporated allowing non-employee directors to receive grants under that plan and, accordingly, it is not anticipated that there will be any future grants under the Directors Plan.

The following table summarizes stock option transactions for the Company's stock option plans for the years ended December 31, 1998, 1997 and 1996:

|                                   | Shares<br>----- | Weighted Ave.<br>Exercise Price<br>----- | Weighted Ave.<br>Fair Value of Grants<br>----- |
|-----------------------------------|-----------------|--|--|
| Outstanding,<br>December 31, 1995 | 749,912         | \$7.60                                   |  |
| Granted                           | 456,350         | \$15.99                                  | \$11.95  |
| Exercised                         | (32,317)        | \$5.48                                   |  |
| Forfeited                         | (14,264)        | \$10.97                                  |  |
|                                   | -----           |  |  |
| Outstanding,<br>December 31, 1996 | 1,159,681       | \$10.92                                  |  |
| Granted                           | 403,845         | \$14.14                                  | \$10.17  |
| Exercised                         | (72,922)        | \$ 5.10                                  |  |
| Forfeited                         | (48,106)        | \$13.25                                  |  |
|                                   | -----           |  |  |
| Outstanding,<br>December 31, 1997 | 1,442,498       | \$12.04                                  |  |
| Granted                           | 580,875         | \$15.56                                  | \$11.12  |
| Exercised                         | (135,228)       | 7.88                                     |  |
| Forfeited                         | (73,100)        | 13.99                                    |  |
|                                   | -----           |  |  |
| Outstanding,<br>December 31, 1998 | 1,815,045       | \$13.39                                  |  |
|                                   | -----           | -----                                    |  |

The following table summarizes information about stock options outstanding under the Company's stock option plans at December 31, 1998:

| Options Outstanding         |   |  |  | Options Exercisable                     |                                       |
|-----------------------------|---|--|--|---|---------------------------------------|
| Range of<br>Exercise Prices | Number<br>Outstanding<br>As of 12/31/98 | Weighted<br>Average<br>Remaining<br>Contractual Life | Weighted<br>Average<br>Exercise<br>Price | Number<br>Exercisable<br>As of 12/31/98 | Weighted<br>Average<br>Exercise Price |
| \$0.1600 - \$13.2500        | 457,284                                 | 6.1  | \$7.50                                   | 376,850                                 | \$6.75                                |
| \$13.3750 - \$15.0000       | 455,050                                 | 7.8  | \$14.00                                  | 241,363                                 | \$13.82                               |
| \$15.1875 - \$15.5000       | 582,238                                 | 9.1  | \$15.36                                  | 96,838                                  | \$15.20                               |
| \$15.6250 - \$20.5000       | 320,473                                 | 8.5  | \$17.40                                  | 129,778                                 | \$18.39                               |
|                             | -----                                   |  |  | -----                                   |                                       |
| \$0.1600 - \$20.5000        | 1,815,045                               | 7.9  | \$13.39                                  | 844,829                                 | \$11.53                               |

The number of shares and weighted average price of options exercisable at December 31, 1998, 1997 and 1996 were 844,829 shares at \$11.53, 688,126 shares at \$9.90, and 487,750 shares at \$6.82, respectively.



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:

|                                  | 1998         | 1997        | 1996        |
|----------------------------------|--------------|-------------|-------------|
|                                  | ----         | ----        | ----        |
| Net loss - as reported           | \$7,480,507  | \$5,611,231 | \$5,080,591 |
| Net loss - pro forma             | \$11,645,607 | \$8,878,712 | \$6,497,447 |
| Net loss per share - as reported | \$.47        | \$.36       | \$.33       |
| Net loss per share - pro forma   | \$.74        | \$.57       | \$.42       |

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants: risk free interest rates of 5.09% (1998), 5.99% (1997) and 6.57% (1996) and, expected volatility of 71% (1998), 70% (1997) and 74% (1996). An expected option life of 5 years and a dividend rate of zero is assumed for all years presented.

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, 1998 and 1997, 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 is \$60,000 and \$25,000 at December 31, 1998 and 1997, respectively. The current portion, included in receivables and other, is \$55,000 and \$25,000 at December 31, 1998 and 1997, respectively.

## 8. INCOME TAXES

As of December 31, 1998, the Company has available net operating loss carryforwards of approximately \$36,700,000 and research and development credit carryforwards of approximately \$1,700,000 to reduce future federal income taxes, if any. These carryforwards expire through 2018 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 \$17,400,000 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 employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$95,000, \$94,000, and \$78,000, in 1998, 1997, and 1996, respectively.

## 10. SUBSEQUENT EVENT

In January 1999, Pfizer Inc. entered into a license and option agreement and a stock purchase agreement with the Company. Under the terms of the agreements Pfizer Inc. paid the Company \$1,000,000 in license fees and \$6,000,000 for the purchase of approximately 318,000 shares of common stock at \$18.87 per share, reflecting a 25% premium. The license fee and the \$1,200,000 premium on the purchase of stock will be recognized as revenue in 1999, and the balance of the common stock investment, net of any cost to issue the shares of stock, will be reflected in common stock and additional paid-in capital in 1999.

## 11. SUMMARY OF UNAUDITED QUARTERLY FINANCIAL INFORMATION

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 1998 and 1997 (in thousands, except per share amounts):

|   | March 31 | Quarter Ended |              | December 31 |
|---|----------|---------------|--------------|-------------|
|   | -----    | June 30       | September 30 | -----       |
|   | -----    | -----         | -----        | -----       |
| 1998  |          |               |              |             |
| Revenues                                      | \$ 2,732 | \$ 560        | \$ 1,696     | \$ 932      |
| Research and development costs                | 3,095    | 3,058         | 3,158        | 2,743       |
| Total operating costs and expenses            | 4,062    | 4,072         | 4,012        | 3,558       |
| Net loss                                      | (721)    | (2,935)       | (1,750)      | (2,075)     |
| Net loss per common share (basic and diluted) | (.05)    | (.19)         | (.11)        | (.13)       |
| Shares used in per share calculation          | 15,753   | 15,789        | 15,817       | 15,892      |
|   | March 31 | June 30       | September 30 | December 31 |
|   | -----    | -----         | -----        | -----       |
| 1997  |          |               |              |             |
| Revenues                                      | \$ 1,126 | \$ 867        | \$ 3,480     | \$ 2,330    |
| Research and development costs                | 2,794    | 2,797         | 3,319        | 3,026       |
| Total operating costs and expenses            | 3,691    | 3,678         | 4,247        | 4,054       |
| Net loss                                      | (2,002)  | (2,267)       | (225)        | (1,117)     |
| Net loss per common share (basic and diluted) | (.13)    | (.15)         | (.01)        | (.07)       |
| Shares used in per share calculation          | 15,423   | 15,448        | 15,458       | 15,609      |

**EXHIBIT 23.1**

**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, No. 33-87972 and 333-30181.

**ARTHUR ANDERSEN LLP**

San Diego, California

February 8, 1999

## ARTICLE 5

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE BALANCE SHEETS AND STATEMENTS OF OPERATIONS OF THE COMPANY'S FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 1998, AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

MULTIPLIER: 1,000

| PERIOD TYPE                | YEAR        |
|----------------------------|-------------|
| FISCAL YEAR END            | DEC 31 1998 |
| PERIOD START               | JAN 01 1998 |
| PERIOD END                 | DEC 31 1998 |
| CASH                       | 13,568      |
| SECURITIES                 | 26,616      |
| RECEIVABLES                | 477         |
| ALLOWANCES                 | 0           |
| INVENTORY                  | 0           |
| CURRENT ASSETS             | 41,616      |
| PP&E                       | 6,698       |
| DEPRECIATION               | 4,992       |
| TOTAL ASSETS               | 44,844      |
| CURRENT LIABILITIES        | 3,218       |
| BONDS                      | 801         |
| PREFERRED MANDATORY        | 0           |
| PREFERRED                  | 0           |
| COMMON                     | 159         |
| OTHER SE                   | 40,665      |
| TOTAL LIABILITY AND EQUITY | 44,844      |
| SALES                      | 0           |
| TOTAL REVENUES             | 5,920       |
| CGS                        | 0           |
| TOTAL COSTS                | 0           |
| OTHER EXPENSES             | 12,054      |
| LOSS PROVISION             | 0           |
| INTEREST EXPENSE           | 162         |
| INCOME PRETAX              | (7,481)     |
| INCOME TAX                 | 0           |
| INCOME CONTINUING          | (7,481)     |
| DISCONTINUED               | 0           |
| EXTRAORDINARY              | 0           |
| CHANGES                    | 0           |
| NET INCOME                 | (7,481)     |
| EPS PRIMARY                | (.47)       |
| EPS DILUTED                | (.47)       |

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