

ARL



04028271



INC

Annual Report 2003

REI
12/31/03

MAY 6 2004

PROCESSED

MAY 10 2004

THOMSON
FINANCIAL



April 2004

To Our Shareholders:

During 2003 we completed our transition from a research-focused enterprise to a development-driven operation. Going forward, we are focusing the majority of our resources on demonstrating the safety and efficacy of our epitope vaccine technology in humans.

The success of this transition is reflected in the clinical milestones we announced during 2003 and early 2004:

2003 Clinical Milestones

- January • We received FDA clearance to initiate Phase I/II lung and colorectal cancer vaccine trials
- April • Our HIV vaccine candidate was advanced into Phase I prophylactic trials by the NIH and the HIV Vaccine Trials Network
- July • We were awarded a NCI grant to support our development of cancer vaccines using analog epitopes
- September • We restructured to focus on clinical programs
- September • Our NIH contract for high-throughput development of epitope vaccines was amended to include smallpox
- September • We were awarded a \$16.7 million NIH contract for prophylactic HIV vaccine development

2004 Clinical Milestones

- January • We completed patient enrollment in our therapeutic HIV vaccine trial
- February • The NIH and HIV Vaccine Trials Network, using our vaccine candidate, completed patient enrollment in their prophylactic HIV vaccine trial
- March • We were awarded a NCI grant for development and preclinical testing of a multi-epitope vaccine for ovarian and breast cancer

In addition to our clinical programs, we continued to expand our portfolio of commercial collaborations aimed at demonstrating the value of our epitope technology:

2003 Collaboration Milestones

- January • Beckman Coulter took an option on our epitopes
- May • Merck agreed to evaluate our epitopes for certain of their vaccines
- July • Immuno-Designed Molecules exercised their option to license our epitopes
- September • Amgen took a non-exclusive license to our PADRE technology
- September • Anosys made a milestone payment for their license of our cancer epitopes

2004 Collaboration Milestones

- February • Genencor's IND for a therapeutic vaccine for HBV was allowed and they made a milestone payment to us
- March • Innogenetics took over the HBV, HCV, and HPV programs from Genencor and we extended the collaboration term through September 2005

Looking forward in 2004, we plan to announce our Phase I/II clinical trial results for HIV and for the lung and colorectal cancer indications. Assuming the HIV results are satisfactory, we plan to initiate a Phase II clinical trial for our HIV vaccine candidate before the end of 2004.

While clinical trials will represent our most important expenses, we are aiming to offset much of our burn rate with licensing and milestone payments from our commercial collaborators and with government sponsorship.

As always, we are grateful to our dedicated employees who have worked so hard to make these clinical programs a reality and the major focus of your Company. We wish to express special thanks to Bob Chesnut for his 15 years of service, and we wish him well in his pursuit of personal endeavors outside the biotech arena.

Finally, to our shareholders, on behalf of our Board of Directors and our employees, we thank you for your continuing support of Epimmune.

We look forward to sharing our first multi-epitope results in humans with you later this year.

Sincerely,



Howard E. (Ted) Greene, Jr.
Chairman of the Board



Emile Loria
President and Chief Executive Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2003

or

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

For the transition period from to

Commission File No. 0-19591

Epimmune Inc.

(Exact name of registrant as specified in its charter)

Delaware

*(State or other jurisdiction of
incorporation or organization)*

33-0245076

*(I.R.S. Employer
Identification No.)*

**5820 Nancy Ridge Drive,
San Diego, California 92121**

(Address of Principal executive offices)

Registrant's telephone number, including area code:

(858) 860-2500

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.01 par value

(Title of class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is an accelerated filer as defined in Rule 12b-2 of the Securities Exchange Act of 1934. Yes No

The aggregate market value of the Registrant's Common Stock held by non-affiliates of the Registrant as of June 30, 2003 was approximately \$8.7 million, based on the closing price on that date of Common Stock on the Nasdaq National Stock Market.*

The number of shares outstanding of the Registrant's Common Stock, \$.01 par value, was 13,525,622 as of March 15, 2004.

* Excludes 6,042,889 shares of Common Stock held by directors and officers and stockholders whose ownership exceeds 10% of the Common Stock outstanding on June 30, 2003. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, or that such person is controlled by or under common control with the Registrant.

(This page intentionally left blank)

PART I

Item 1. *Business*

Except for the historical information contained herein, the following discussion contains forward-looking statements that involve risks and uncertainties. These statements reflect management's current views with respect to future events and financial performance and actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, without limitation, those discussed in the description of our business below and the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other SEC filings.

Epimmune® and PADRE® are our trademarks and EIS and ImmunoSense are our service marks.

Overview

We are developing therapeutic vaccines that use multiple epitopes, or protein fragments, to specifically activate the body's immune system for the more effective management of infectious diseases and cancer. In September 2002, we commenced a Phase I/II clinical trial of our therapeutic, multi-epitope vaccine candidate EP HIV-1090 in patients infected with HIV 1, which is the predominant strain of HIV in North America and Western Europe. Patients enrolled in the trial are immunized while receiving multiple antiretroviral drugs. In January 2004, we announced that we had completed patient enrollment in the trial and that all of the patients in the final dose group had received their initial vaccinations. The primary objective of this trial is to determine the safety and the effect on the immune system, or immunogenicity, of the EP HIV-1090 vaccine. The vaccine candidate is designed to induce a sufficiently potent immune response so that the patient's immune system can control the virus, allowing the patient to suspend or stop taking antiretroviral drugs that have serious side effects and can induce drug resistance when taken over time. In February 2003, we also commenced two Phase I/II clinical trials of our therapeutic, multi-epitope vaccine candidate EP-2101, one in patients with lung cancer and one in patients with colorectal cancer. The primary objective of these trials is to determine the safety and immunogenicity of the EP-2101 vaccine. In addition, we are conducting research and preclinical development of vaccines to treat breast, prostate and other cancers and vaccines for the prevention of HIV and malaria under contracts from the National Institutes of Health, or NIH.

In July 2001, we entered into a collaboration with Genencor International, Inc. for vaccines to treat or prevent hepatitis B virus, hepatitis C virus and human papilloma virus. In February 2004, we announced that we had earned a milestone payment from Genencor as a result of Genencor filing an Investigational New Drug Application, or IND, for a vaccine to treat hepatitis B, the lead program in the collaboration. In March 2004, Genencor assigned its rights under our collaboration to Innogenetics NV. In connection with the assignment by Genencor, we extended the collaboration term with Innogenetics through September 2005. Innogenetics will have the right to terminate the collaboration early, upon three months written notice.

Eliciting a strong cellular, or T cell, immune response is crucial for treating and preventing many infectious diseases and tumors. Clinical experience has shown that the cellular immune response is directly related to viral clearance and tumor regression in those patients who are able to clear chronic viral infection without treatment and in cancer patients who respond to immunotherapy, or treatment that stimulates an immune response. This successful cellular immune response includes activity of cytotoxic T cells, or CTLs, and helper T cells, or HTLs, which are directed toward specific antigen fragments, known as epitopes.

Our vaccines are composed of proprietary epitopes that can stimulate specific T cell immune responses. We can rapidly identify such epitopes from any protein or gene sequence using EIS, our Epitope Identification System, which enables the rapid identification of novel epitopes that can stimulate specific CTL and HTL immune responses. These epitopes can be identified from any protein or gene sequence. In an attempt to establish a broad patent position, we have identified, evaluated and disclosed in our patent applications more than 72,000 epitopes. We also make analogs of the epitopes we discover by selectively altering their

composition to increase vaccine potency, and we apply for patent protection for these analogs. We select a small subset of these epitopes and analogs, typically 10 to 50, to develop each of our vaccine candidates.

In September 2003, we announced and completed a reduction of our work force aimed at focusing our efforts on our most advanced clinical programs and our sponsored and partnered programs. We reduced our research and administrative staff by 11 individuals or 23%, which resulted in a one-time restructuring charge of approximately \$336,000 in the third quarter ending September 30, 2003.

In September 2003, Dr. Loria, our chief executive officer, surrendered an aggregate of 963,740 shares of our common stock at the fair market value of \$3.17 per share, in exchange for the prepayment of the outstanding principal and interest under the promissory note dated January 16, 2001 issued by Dr. Loria to us. This event resulted in a non cash, stock-based compensation charge of approximately \$645,000 in the third quarter ended September 30, 2003.

Market Opportunities

HIV

It is estimated that approximately 940,000 people in North America and nearly 560,000 people in Western Europe are currently infected with HIV. According to estimates, in the United States alone, an additional 40,000 people are newly infected with HIV each year. The standard approach to treating HIV infection has been to lower viral loads by using drugs that inhibit two of the viral enzymes that are necessary for the virus to reproduce: reverse transcriptase inhibitors, or RTIs, protease inhibitors, or PIs, or a combination of these drugs. Current therapies based on combinations of RTIs or PIs, reduce HIV viral loads in many patients. In 2000, deaths attributable to HIV infection were reduced to approximately 15,000 from 38,000 in 1996, largely due to improvements in treatment regimens. Total sales in 2001 of approved RTIs and PIs exceeded \$3.1 billion in the United States and \$5.0 billion worldwide.

While significant progress has been made in combating HIV, current treatments continue to have significant limitations, such as viral resistance, toxicity and non-adherence to the complicated treatment regimens. HIV is prone to genetic changes that can produce strains of HIV that are resistant to currently approved RTIs and PIs. Generally, HIV that is resistant to one drug within a class is likely to become resistant to the entire class, a phenomenon known as cross-resistance. As a result of cross-resistance, attempts to re-establish suppression of HIV viral load by substituting different RTI and PI combinations often fail. It is estimated that, in the United States, over 70% of patients currently taking medications have failed at least one regimen. Studies suggest that 10% to 15% of newly-infected HIV patients in the United States have become resistant to at least one member of each of the classes of currently approved anti-HIV drugs, and that number is believed to be growing.

Over time, in addition to generating resistance to drugs, many patients develop intolerance to different medications. Data suggest that some HIV infected patients refuse to commence or continue taking RTIs and PIs, either alone or in combination, because of side effects and difficult dosing regimens. Several side effects commonly associated with currently approved anti-HIV drugs include neurological disorders, gastrointestinal disorders, diabetes-like symptoms, elevated cholesterol levels, other abnormal lipid metabolism and bone disorders. Dosing regimens can require taking as many as 30 pills per day. The emergence of drug-resistant strains of HIV, as well as toxic side effects associated with existing therapies, have heightened demand for new HIV therapies that work by different mechanisms of action, and have unique resistance profiles, fewer side effects and a simpler dosing regimen.

Lung and Colorectal Cancer

The World Health Organization (WHO) predicts that by 2020 there will be 15 million cases of cancer every year. In the United States approximately 1.25 million new cases of cancer are diagnosed annually and cancer is, by 2020, expected to surpass heart disease as the primary cause of death in adults. Of the various cancers, the four most common types include lung, breast, prostate and colorectal cancer. These four cancers have the greatest incidence of new cases and are responsible for the highest combined mortality, approxi-

mately 58.1% of all cancer deaths worldwide. In the United States alone, there were an estimated 147,500 new cases of colorectal cancer diagnosed in 2003 and colorectal cancer represents the third highest incidence of any cancer for American men. In 2003, an estimated 57,000 deaths in the United States were attributed to colorectal cancer. Cancer of the lungs continues to be a major health problem with a very high mortality rate and represents the leading cause of cancer death in the United States. Approximately 171,900 new lung cancer cases were diagnosed in the United States in 2003, and an estimated 157,200 patients died from lung cancer. In addition nearly 75% of cancers are expected to occur in individuals over the age of 55 and demographic trends clearly show an aging population.

The current course of treatment for lung cancer includes surgery, if possible, followed by various regimens of radiation and chemotherapy to try to destroy cancer cells that have spread. Chemotherapy causes well-known adverse side effects such as hair loss, decreased function of various organs, and a substantial suppression of the immune system, leading to susceptibility to other diseases. The side effects of these treatments, combined with relatively low success rates for most cancers, have led to the need for development of different methods of treatment. The unmet needs for more effective cancer treatments provide a significant market potential for emerging therapeutics. Current pharmaceutical therapies for lung cancer include taxanes, platinum-based drugs and nucleoside analogs, with combined sales exceeding \$2.3 billion in 2001. Drug therapies for colorectal cancer had combined sales in excess of \$700 million in 2001. According to a *PhRMA* 2003 report on pharmaceutical drug development, there were 395 new product candidates in clinical development for the treatment of cancer and at least 30 companies were developing more than 50 vaccines against various cancers.

The Immune Response

The immune system is the body's natural defense mechanism to prevent and combat disease. The immune system differentiates between normal tissue, or self, and diseased tissue, or non-self. When a competent immune system recognizes diseased cells, a series of steps ensues resulting in the elimination of these cells. There are two types of immune response: antibody-based and cellular or T cell-based.

The antibody immune response is involved primarily in the prevention of diseases. Antibodies are proteins produced by the body in response to disease causing agents known as pathogens. Antibodies bind to pathogens, including viruses and bacteria, and block their ability to infect cells. Preventative vaccines that trigger an antibody-based immune response have been very successful in reducing the incidence of several deadly diseases, including polio and measles. These vaccines generally consist of weakened or attenuated pathogens that stimulate the production of antibodies. However, these types of vaccines have not been effective in the prevention or treatment of many serious diseases, including cancers and infectious diseases.

The cellular, or T cell-based, immune response is involved primarily in combating cancers and infectious diseases. T cells are specialized white blood cells that are normally produced by the body to kill cancer cells and infected cells. The cellular immune response begins when specialized immune cells, called antigen-presenting cells, capture antigens, the structural components that distinguish cancers and pathogens from normal tissues. Once inside antigen-presenting cells, these protein antigens are broken down into small peptide fragments, called epitopes that are subsequently displayed on the surface of the antigen-presenting cell. T cells continually scan the surface of antigen-presenting cells for epitopes bound to a cell surface receptor referred to as the major histocompatibility complex, or MHC. If T cells recognize displayed epitopes as foreign or non-self, the T cells replicate rapidly and then search for and kill other diseased cells displaying those same epitopes.

Significant scientific evidence suggests that cancers and infections trigger a T cell-based immune response during the initial course of disease progression. For diseases such as the ones we are targeting, this immune response alone is usually insufficient to eradicate the disease. Studies have analyzed the effective cellular response in individuals who clear chronic viral infection without treatment, and in cancer patients who respond to immunotherapy. This effective cellular response is comprised of CTL and HTL directed toward multiple, discrete, specific, antigen-specific epitopes. Therapeutic vaccines attempt to recreate this successful multi-specific CTL and HTL response.

To date, efforts to develop vaccines that stimulate multi-specific T cell responses sufficient to selectively and accurately target and kill diseased cells have failed. We believe this failure is due to one or both of the following:

- the inability of drug developers to identify the antigens appropriate to induce the desired immune response; and
- the inability to present or display these relevant antigens in a manner that induces T cell responses sufficiently potent and broad enough to actually destroy diseased cells.

Although we have not yet completed any of our Phase I/II clinical trials, based on our animal study data thus far, we believe our technology and vaccine candidates specifically address these issues.

Our Approach

Our approach to T cell vaccine development is to rationally create a multi-specific cellular response, causing the immune system to be stimulated specifically against multiple, select epitopes, which meet stringent criteria. We have developed our proprietary technology, known as EIS, to rapidly identify these antigen-specific epitopes from the genetic information of tumor-associated antigens or infectious agents (such as viruses, bacteria and parasites).

Our approach of using epitopes in vaccine development offers several distinct advantages over traditional vaccine approaches.

- *Enhanced Potency:* For some diseases, such as cancer, whole antigens or even naturally occurring epitopes may not be sufficient to generate an effective immune response. In contrast, we are selectively altering the composition of specific epitopes in vaccines to enhance the desired immune response.
- *Sustained Efficacy:* We select multiple epitopes from conserved regions of multiple viral or tumor-associated antigens, increasing the likelihood that the vaccine will continue to elicit an effective immune response as the virus or tumor changes.
- *Improved Safety:* The use of selected, well defined epitopes is designed to elicit a specifically targeted immune response with fewer undesired side effects than can be caused by whole antigen vaccines.
- *Better Quality Control:* Our approach allows us to develop well-characterized, fully synthetic vaccines with a high degree of consistency, simplifying manufacturing and product characterization.
- *Broader Disease and Population Coverage:* We are designing vaccines using multiple epitopes so that our vaccines can address different strains of a disease or be used to treat the world's diverse population, regardless of varying genetic profiles.

Our Vaccine Product Candidates

We have a number of vaccine product opportunities as described in the following table:

<u>Indication</u>	<u>Product Development Stage(1)</u>	<u>Commercialization Rights</u>
Infectious Diseases		
<i>Therapeutic Vaccines</i>		
HIV	Phase I/II Clinical Trial	Epimmune
Hepatitis B	Phase I Clinical Trial	Innogenetics
Hepatitis C	Preclinical	Innogenetics
Papilloma virus	Preclinical	Innogenetics
<i>Prophylactic Vaccines</i>		
HIV	Preclinical/Phase I Clinical Trial(2)	Epimmune
Malaria	Preclinical	Epimmune
Hepatitis C	Preclinical	Innogenetics
Cancer		
<i>Therapeutic Vaccines</i>		
Colorectal	Phase I/II Clinical Trial	Epimmune
Lung	Phase I/II Clinical Trial	Epimmune
Breast	Preclinical	Epimmune
Prostate	Epitope/Antigen Identification	Epimmune
<i>Ex Vivo Immunotherapy</i>		
Various Solid Tumors	Preclinical	Anosys
Various Solid Tumors	Preclinical	IDM

- (1) By using the term Epitope/Antigen Identification, we mean that we are discovering, evaluating and selecting epitopes for inclusion in candidate vaccines that would be advanced to preclinical development. By using the term Preclinical, we mean that we have identified and selected specific epitope compositions for inclusion in a vaccine and are conducting preclinical testing aimed at optimizing the construction, formulation and manufacture of the vaccine and toxicology studies with the objective of filing an investigational new drug application or IND with regulatory authorities.
- (2) Phase I clinical trial being conducted by the NIH and HIV Vaccine Trials Network, or HVTN.

Therapeutic Vaccine for HIV

We commenced our Phase I/II clinical trial of our EP HIV-1090 therapeutic, multi-epitope vaccine in HIV-1-infected patients in September 2002. The initial Phase I/II trial is a double blind, placebo-controlled, dose escalation study and includes approximately 40 patients. In January 2004, we announced that we had completed patient enrollment in the trial and that all of the patients in the final dose group had received their initial vaccinations. The primary objective of this study is to determine the safety and the immunogenicity of the vaccine as measured by the quantity and breadth of CTLs generated. We expect to present interim safety and immunogenicity results of this trial in July 2004.

Our EP HIV-1090 vaccine is composed of 21 CTL epitopes, which were selected from conserved regions of multiple HIV proteins using our EIS proprietary technology. The use of conserved epitopes is expected to make it much less likely that the virus will develop genetic changes or mutations that can escape the vaccine-induced immune response. The vaccine candidate is delivered as DNA combined with PVP, a polymer shown to increase the potency of DNA vaccines in animal studies. In addition, the vaccine includes our PADRE universal helper T cell epitope, which is designed to enhance the magnitude and duration of CTL response. We have filed several patent applications in the United States and abroad that disclose the epitopes comprising the EP HIV-1090 vaccine construct, both as individual epitopes and as our EP HIV-1090 epigene construct itself. An epigene is a string of DNA coding for select epitopes from several antigens. The applications are at various stages of prosecution.

Patients enrolled in the trial are immunized while receiving multiple antiretroviral drugs, a regimen termed highly active antiretroviral therapy, to reduce the suppressive effects that HIV has on the immune

system. The goal of our vaccine is to induce a sufficiently potent immune response so that the patient's immune system can control the virus, allowing the patient to suspend or stop taking the antiretroviral drugs that can have serious side effects and induce drug resistance when taken over time.

Therapeutic Vaccine for Lung and Colorectal Cancer

We commenced our Phase I/II clinical trial of our EP-2101 therapeutic, multi-epitope vaccine in lung and colorectal cancer patients in February 2003. The primary objectives of this initial Phase I/II trial will be to determine the safety and immunogenicity of the EP-2101 vaccine. Completion of the Phase I/II trial and final data are now expected in the third quarter of 2004. This initial clinical trial will involve approximately 20-25 cancer patients who have had surgery to remove the majority of the cancer cells. Patients who have had surgery to remove the majority of the cancer cells generally have normal immune system function.

Our initial cancer vaccine candidate is composed of multiple tumor-specific CTL epitopes that were selected from tumor-associated antigens using our proprietary processes. Some of the epitopes have been modified to create analogs in order to enhance the potency of the T cell response induced by the vaccine. The vaccine candidate is delivered as an injection of peptide epitopes in combination with conventional therapies. In addition, the vaccine candidate includes our PADRE universal helper T cell epitope. We have filed several patent applications in the United States and abroad that disclose the individual peptides that comprise our initial cancer vaccine candidate. These applications are also in various stages of prosecution. In addition, we have filed applications directed to the specific epitopes comprising the vaccine to be delivered in the form of peptides and an adjuvant.

Clinical trial results and studies conducted by others correlating T cell infiltration into tumors with a more favorable prognosis indicate that T cells can play an important role in the control and elimination of cancer cells. However, because cancer cells are inefficient at inducing anti-cancer T cell responses, tumors grow and metastasize without attracting the attention of the immune response. Also, once tumors become large, they suppress the immune system by liberating factors that inhibit T cell activation. Following standard therapy to remove the majority of the cancer cells, our vaccine will be administered to patients in order to induce a strong T cell response that we believe will eliminate any remaining cancer cells and prevent disease recurrence.

Other Vaccines

In February 2004, we announced that we had earned a milestone payment from Genencor as a result of Genencor filing an IND for a vaccine to treat hepatitis B, the lead program in the collaboration. In April 2003, we announced that the NIH held an active IND to test our EP HIV-1090 vaccine for the prevention of HIV infection. The HVTN is conducting the Phase I trial.

In addition, through a combination of strategic collaborations as well as funding from the NIH, we are conducting research and preclinical development of vaccines to treat breast, prostate and other cancers, hepatitis C and human papilloma virus and vaccines for the prevention of hepatitis C, HIV and malaria. We believe our technology has broad applicability and will allow us to develop vaccines to pursue these cancer and infectious disease indications.

Our Technology

Epitope Identification System (EIS)

We developed and optimized our EIS based on extensive work over the past eleven years in the field of T cell recognition and stimulation. Our intellectual property portfolio includes one issued patent and several pending patent applications having claims directed to methods of using sequence motifs to identify and make peptide epitopes. With the genetic sequence of a tumor-associated antigen, virus, bacteria or parasite as input,

we use EIS to rapidly identify antigen-specific epitopes that meet pre-determined criteria for broad conservation, binding, population coverage and immunogenicity.

- We use computer algorithms to analyze the sequence of all known antigens associated with the target disease for the presence of peptides that contain specified types of epitopes from conserved regions of the antigens.
- We synthesize peptides that meet these requirements and perform *in vitro* assays to assess binding to human MHC molecules referred to as human leukocyte antigens, or HLA.
- We evaluate peptides to assess their ability to bind broadly to a spectrum of MHC molecules referred to as HLA. We identify epitopes from these peptides that enable broad population coverage for the vaccine being developed.
- We then test peptides for immunogenicity, both *in vivo* in transgenic mice, which express HLA, and *in vitro* against infected or transfected cells.

Using EIS, we have already identified T cell epitopes for a number of diseases, including breast, colon, lung and prostate cancers, as well as hepatitis C virus, hepatitis B virus, human papilloma virus, HIV and malaria.

Multi-Epitope Vaccines

Our candidate vaccines for each infectious disease and cancer indication are comprised of the particular epitopes that can stimulate the specific T cells needed to combat the relevant indication. We select epitopes for a target indication using EIS and then combine them to form a multi-epitope vaccine. In the case of our initial HIV vaccine candidate, EP HIV-1090, we used proprietary processes to combine the selected epitopes in a specific, optimized sequence and formed an epigene. In animal models, epigene vaccines have elicited strong multi-specific T cell responses that are both stronger and broader than the responses generated by whole antigen DNA vaccines.

The first of our candidate vaccines to enter human clinical trials was our EP HIV-1090 therapeutic vaccine targeting HIV. The vaccine incorporates multiple CTL epitopes from six HIV associated antigens and our PADRE universal helper T cell epitope. We began a Phase I/II clinical trial of our EP HIV-1090 therapeutic, multi-epitope vaccine in HIV-1 infected patients in September 2002. In January 2004, we announced that we had completed patient enrollment in the trial and that all of the patients in the final dose group had received their initial vaccinations. Also, in April 2003, the NIH and HVTN began a Phase I clinical trial of our EP HIV-1090 vaccine for the prevention of HIV infection.

In addition to the Phase I/II clinical trial for our HIV vaccine, we are conducting a Phase I/II clinical trial of our EP 2101 vaccine in lung cancer and colorectal cancer patients. We have also assisted in advancing a partnered program in hepatitis B into a Phase I clinical trial and are advancing other epigene candidate vaccines for HIV, hepatitis C virus and human papilloma virus in preclinical development. To be effective in treating or preventing HIV, hepatitis B virus, hepatitis C virus and human papilloma virus, vaccines should target multiple strains of the virus and induce T cells directed at conserved regions of the virus. Our candidate vaccines incorporate epitopes, which are selected from multiple viral proteins and from highly conserved regions of the virus.

PADRE

Our PADRE universal helper T cell epitope consists of a family of small (13 amino acid), synthetic proprietary molecules that are potent immunostimulants, meaning that they stimulate the immune response. When combined with disease-specific antigens, PADRE induces important signals that enhance the antigen-specific immune response, enabling the production of more effective antibody responses. We believe that

PADRE offers several advantages over the immunogenic carrier proteins traditionally used to enhance antibody vaccines:

- PADRE can be easily synthesized and its linkage to an antigen readily characterized, whereas the carrier proteins traditionally used to enhance immune response can complicate manufacturing;
- The antibody responses generated by PADRE are primarily specific to the vaccine antigen, rather than to PADRE, whereas carrier proteins generate high antibody responses specific primarily to the carrier protein itself rather than to the vaccine antigen, which can render the vaccine ineffective; and
- Because it simplifies vaccine manufacture and induces antibodies primarily specific to the vaccine antigens with which it is used, PADRE could simplify the development of combination vaccines, whereas the use of carrier proteins is generally limited to vaccines containing single protein antigens.

We use our PADRE technology in all of our T cell vaccines and have licensed this technology to several of our corporate collaborators.

ImmunoStealth Technology

Although an enhanced immune response is critical in combating many diseases, in some cases, immunogenicity is a barrier to further development of potential therapeutic products. This barrier is often discovered only late in the development process. Helper T cells play a central role in the body's immune response, including stimulating B cells to produce antibodies. Using our ImmunoStealth technology, we can identify helper T cell epitopes in a product candidate and modify them to potentially reduce or eliminate recognition by helper T cells, thereby enhancing the safety and efficacy of the product. We have the opportunity of using our ImmunoStealth technology at both an early stage and at later stages in the discovery process to identify and potentially eliminate undesirable antibody responses to proteins used as therapeutic drugs or in consumer products.

Collaborations and Licenses

We intend to continue to seek research and development collaborations with multiple pharmaceutical and biotechnology companies to develop and commercialize therapeutic and prophylactic vaccines for select infectious disease and tumor types. Our unique capabilities include expertise in identifying those epitopes from viral and tumor-associated antigens that elicit the desired immune response as well as expertise in creating and evaluating product candidates that elicit a potent immune response.

Collaboration and Technology In-License Agreements

Genencor International, Inc. In July 2001, we entered into a collaboration with Genencor International, Inc. pursuant to which we exclusively licensed to Genencor our PADRE and epitope technologies for vaccines to treat or prevent hepatitis B, hepatitis C and human papilloma virus. In connection with this collaboration, we received an upfront license fee. In addition, Genencor made an initial ten percent equity investment in our common stock at a premium to the market price. Under our agreement with Genencor, we may receive a total of approximately \$60 million in payments, including the initial equity investment but excluding royalties. In January 2002, we received a payment from Genencor for achievement of our first milestone, identification of a product candidate to treat chronic hepatitis B infection. In February 2004, we announced that we had earned a milestone payment from Genencor as a result of Genencor filing an IND for a vaccine to treat hepatitis B. In addition, Genencor fully funds our research in these specific indications and is obligated to pay us royalties on sales of any products that may be developed under the collaboration. The initial collaboration had a term through September 2003, and in October 2002, was extended to September 2004. In March 2004, Genencor assigned its rights under our collaboration to Innogenetics NV. In connection with the assignment by Genencor, we extended the collaboration term with Innogenetics through September 2005. In addition, Genencor agreed not to sell or otherwise dispose of any of our common stock they held, without our prior approval, for a minimum of twelve months. Innogenetics has the right to terminate the

agreement early, upon three months written notice, if we breach our obligations under the collaboration agreement or upon certain force majeure events.

Valentis, Inc. In December 2000, as amended in October 2002, we licensed gene delivery technology on a nonexclusive basis from Valentis, Inc. for preventive and therapeutic DNA vaccines against HIV and hepatitis C virus. In October 2002, we licensed the same gene delivery technology on a nonexclusive basis from Valentis for preventive and therapeutic DNA vaccines against cancer. In connection with both licenses, we paid an upfront license fee and will make payments to Valentis upon achievement of certain clinical milestones and pay royalties on sales of any products incorporating the Valentis technology.

Bavarian Nordic A/S. In November 2001, we entered into a collaboration agreement with Bavarian Nordic A/S to combine our technology and expertise in the fields of T cell epitope identification and vaccine design with Bavarian Nordic's vaccine delivery technology and manufacturing expertise to develop vaccines for the treatment or prevention of HIV infection. We will share equally with Bavarian Nordic in all research related expenses during the five-year term of this collaboration.

License Option Agreements

Beckman Coulter, Inc. In January 2003, we entered into an option and license agreement with Beckman Coulter, Inc. under which Beckman Coulter may acquire a non-exclusive, worldwide license to certain Epimmune epitopes on an epitope-by-epitope basis for certain infectious diseases and cancer indications. Beckman Coulter may use these epitopes for research and diagnostic applications in connection with their MHC Tetramer and other immune response monitoring technologies. Under the terms of the agreement, we are entitled to annual option fees. In the event that Beckman Coulter exercises its option to acquire a license to any specific epitope, we will be entitled to additional license fees for each epitope and royalties on product sales in the event any products are commercialized using our technology.

Merck & Co. In April 2003, we entered into an agreement with Merck & Co., Inc. under which Merck will evaluate select Epimmune epitopes in connection with technology controlled by Merck for the development of certain vaccines. Under the terms of the agreement, we will provide Merck a limited number of our proprietary analog, or modified, epitopes, which will then be evaluated in connection with delivery technologies owned or controlled by Merck to determine the activity of the Epimmune epitopes. We received an evaluation license fee in connection with the agreement. Merck has an option to enter into licensing discussions with us for the development of the Epimmune epitopes for use in vaccines for the treatment of certain diseases.

License Agreements for Technology Outside our Areas of Focus

Pharmexa A/S. In June 2001, we entered into a license agreement with Pharmexa A/S granting Pharmexa a non-exclusive license to our PADRE technology for use in connection with Pharmexa's AutoVac™ technology for controlling autoimmune diseases. In connection with the agreement, we received an upfront license fee and are also entitled to receive milestone and royalty payments on product sales, if any products are developed.

Biosite Incorporated. In August 2001, we entered into a license agreement with Biosite Incorporated granting Biosite a non-exclusive, irrevocable license to our PADRE technology for use in connection with Biosite's antibody technology which can be used to discover any target and its utility as a target for diagnostic or therapeutic products. In connection with the agreement, we received an upfront license fee.

Anosys Inc. In August 2001, we entered into a license agreement with Anosys Inc., formerly AP Cells, granting Anosys a non-exclusive license to certain cancer antigens and associated technology for use in *ex vivo* cell therapy. In connection with the agreement, we received an upfront license fee and are also entitled to receive milestone and royalty payments on product sales, if any products are developed. In September 2003, we received a milestone payment under the agreement as a result of Anosys' filing of an IND for a product incorporating the technology we licensed them.

Immuno-Designed Molecules, S.A. In February 2003, we entered into a license agreement with Immuno-Designed Molecules, S.A., or IDM, whereby we granted IDM a non-exclusive license to certain patented and non-patented rights to our universal cancer epitope packages for use in connection with IDM's Dendritophage™ *ex vivo* technology. In connection with the agreement, we received an upfront license fee and are also entitled to receive commercialization milestone payments and royalties on product sales if IDM develops products using our technology.

Amgen. In September 2003, we entered into an agreement with Amgen Inc. under which Amgen acquired a non-exclusive license to our PADRE technology for research use. In connection with the agreement, we received a license fee.

Government Research Funding

In September 2003, we were awarded a \$16.7 million, five-year contract from the National Institute of Allergy and Infectious Diseases, or NIAID, an institute of the National Institutes of Health, or NIH, for the design and development of prophylactic HIV vaccines for clinical evaluation by the NIAID-sponsored HIV Vaccine Trials Network, or HVTN. The award was made under the NIAID's HIV Vaccine Design and Development Teams, or HVDDT, program whose goal is to fund development of promising vaccine concepts with plans for targeted testing in humans. Epimmune will lead a consortium that includes Bavarian Nordic A/S in Denmark and SRI International and Althea Technologies, both in the U.S. Epimmune will use its proprietary epitope technology to identify epitopes, or protein fragments, from conserved regions of multiple HIV virus proteins for use in candidate vaccines.

In July 2003, we received a grant from the National Cancer Institute, or NCI, an institute of the NIH, to support continued epitope analog identification and preclinical development of multi-epitope, analog based cancer vaccines. The grant has a total potential value of approximately \$0.6 million over two years. The activities funded by this grant complement current studies and Phase I/II clinical trials we are conducting by providing analog epitopes that extend vaccine coverage to larger segments of the population. The grant was made under the NCI's Flexible System to Advance Innovative Research for Cancer Drug Discovery by Small Business, or FLAIR program.

In October 2002, we were awarded a contract from NIAID to conduct research and development aimed at developing a malaria vaccine. The award is part of the NIAID's Millennium Vaccine Initiative that solicits vaccine technology from the private sector to accelerate the development of effective vaccines for malaria and tuberculosis. The program is composed of a Phase A feasibility study and an option for a Phase B development program for a total potential value of \$3.5 million over five years. We are working with investigators at the Naval Medical Research Center on the program.

In August 2000, we were awarded a \$3.8 million grant from the Integrated Preclinical/Clinical Program of the NIH, Division of AIDS, for the development of our vaccine to treat people infected with HIV. Pursuant to the terms of the grant, the government agreed to fund a four-year program designed to evaluate Epimmune's epitope-based vaccines as a therapeutic strategy for the treatment of HIV-1-infected individuals on highly active antiretroviral therapy. The current Phase I/II clinical trial for the treatment of HIV, as well as preclinical activities, is being sponsored in part by this grant.

Patents, Proprietary Rights and Licenses

Our success will depend in part on our ability to obtain patents having claims directed to our products and processes, both in the United States and other countries. The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal and factual questions. We file patent applications, as we believe appropriate, that cover our proprietary technology.

We have developed our patent portfolio over approximately the past eleven years. The patents and patent applications in our patent portfolio include claims directed to epitope identification, epitope analogs, methods for identifying epitopes and epitope analogs, vaccine design, specific vaccines, our PADRE universal HTL epitope and ImmunoStealth epitope modification technologies. As of March 15, 2004, our intellectual

property portfolio, including licenses to intellectual property relevant to epitope discovery and gene delivery, included 19 issued United States patents, 103 granted foreign patents, 59 applications pending in the United States and 153 foreign applications pending.

These patent applications and patents in the portfolio are owned by or are under license to us. We cannot be certain that patents will issue from the patent applications we have filed or licensed, or that if patents do issue, that issued claims in those patents will be sufficiently broad to exclude others from making or using our products and processes. In addition, we cannot be certain that third parties will not challenge, invalidate or circumvent any patents issued to us, or that the rights granted thereunder are sufficiently broad to exclude others from making or using our products and processes.

As is typical in the biotechnology industry, our commercial success will depend in part on our ability to avoid infringing patents issued to competitors or breaching the technology licenses upon which we might base our products. If we fail to obtain a license to any technology that we require to commercialize our products, or to develop an alternative compound and obtain regulatory approval within an acceptable period of time if required to do so, our business would be harmed. Litigation or the threat of litigation, which could result in substantial costs to us, may also be necessary to enforce the claims in any patents issued to us, to defend ourselves against any patents owned by third parties that are asserted against us, or to determine the scope and validity of others' proprietary rights. In addition, we may have to participate in one or more interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial costs to determine the priority of inventorship.

If we become involved in litigation or interference proceedings, we may incur substantial expense, and the proceedings may divert the attention of our technical and management personnel, even if we ultimately prevail. An adverse determination in proceedings of this type could subject us to significant liabilities, allow our competitors to market competitive products without obtaining a license from us, prohibit us from marketing vaccines or other products or require us to seek licenses from third parties that may not be available on commercially reasonable terms, if at all. If we cannot obtain such licenses, we may be restricted or prevented from developing and commercializing our product candidates.

We also attempt to protect our proprietary products and processes in part by confidentiality agreements with our collaborative partners, employees and consultants. These agreements may be breached, and we may not have adequate remedies for any breach, and our trade secrets may become known or be independently discovered by competitors.

Competition

The biotechnology industry continues to undergo rapid change and competition is intense and is expected to increase. Our competitors may succeed in developing technologies and products that are more effective or affordable than any of the products we are developing or which would render our technology and products obsolete and noncompetitive. We compete with many public and private companies, including pharmaceutical companies, chemical companies, specialized biotechnology companies and academic institutions. There are 27 drugs currently approved in the United States for HIV infection/AIDS, and according to a PhRMA 2003 report on pharmaceutical drug development, there were 83 new product candidates in clinical development for HIV and related conditions, including 15 HIV vaccines. In addition, according to the PhRMA 2003 report, there were 395 new product candidates in clinical development for the treatment of cancer, and at least 30 companies were developing more than 50 vaccines against various cancers. Many of our competitors have substantially greater experience, financial and technical resources and production, marketing and development capabilities than us. In addition, many of our competitors have significantly greater experience conducting preclinical studies and clinical trials of new products, and in obtaining regulatory approvals for such products. Accordingly, some of our competitors may succeed in obtaining, developing and commercializing products more rapidly or effectively than us, or in developing technology and products that would render our technology and products obsolete or noncompetitive. We are aware of companies that are pursuing the development of pharmaceuticals that target the same diseases that we are targeting. These and other efforts by potential competitors may be successful, and other technologies may be developed to compete with our technologies. If

we cannot successfully respond to technological change in a timely manner, our commercialization efforts may be harmed.

In addition, our products under development address a range of markets. Almost all large pharmaceutical companies have programs for infectious diseases and cancer. Our competition will ultimately be determined in part by the potential indications for which our compounds are developed and ultimately approved by regulatory authorities. An important factor in competition may be the timing of market introduction of our products and competitive products. Accordingly, the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. We expect that competition among products approved for sale will be based, among other things, on product effectiveness, safety, reliability, availability, price and patent position.

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often-substantial period between technological conception and commercial sales.

Government Regulation

Our research and development activities and any future manufacturing and marketing of our products are subject to regulation for safety and efficacy by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation by the Food and Drug Administration, or FDA. The process from development to approval typically takes between 7 and 12 years, depending upon the type, complexity and novelty of the pharmaceutical product. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. In addition to FDA regulations, we are also subject to other federal and state regulations such as the Occupational Safety and Health Act and the Environmental Protection Act. Product development and approval within this regulatory framework involves the expenditure of substantial resources. In addition, this regulatory framework may change and additional regulation may arise at any stage of our product development, which may affect approval or delay an application or require additional expenditures.

The steps required before a pharmaceutical agent may be marketed in the United States include:

- preclinical laboratory and animal tests,
- the submission to the FDA of an application for an IND, which must become effective before human clinical trials may commence in the United States,
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug,
- the submission of a new drug application, or NDA, or a biologic license application, or BLA, to the FDA, and
- the FDA approval of the NDA or BLA prior to any commercial sale or shipment of the drug.

In addition to obtaining FDA approval for each product, each domestic drug-manufacturing establishment must be registered with, and approved by, the FDA. Drug product manufacturing establishments located in California also must be licensed by the state of California in compliance with separate regulatory requirements.

Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the safety and efficacy of the product and its formulation. The results of the preclinical tests are submitted to the FDA as part of an IND and subsequently when additional non-clinical work is completed and, unless the FDA objects, the IND will become effective 30 days following its receipt by the FDA. Submission of an IND may never result in the commencement of human clinical trials.

Clinical trials involve the administration of the drug under the supervision of a qualified principal investigator to healthy volunteers or to patients identified as ones with the condition for which the drug is

being tested. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Each clinical study is conducted under the auspices of an independent Institutional Review Board, or IRB, at the institution at which the study will be conducted. Prior to its approval for the study to be conducted, the IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases prior to product approval, but the phases may overlap, be repeated or subdivided. Phase I involves the initial introduction of the drug into healthy human subjects and often into patients as well. In Phase I, the drug is tested for safety (adverse effects), dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase II involves studies in a limited patient population to:

- determine the effectiveness of the drug for specific targeted indications,
- determine dosage tolerance and optimal dosage and regimen, and
- identify possible adverse side effects and safety risks.

When a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate clinical efficacy further and to test further for safety within an expanded patient population at multiple clinical study sites. Even after NDA or BLA approval, the FDA may require additional Phase IV clinical trials. The FDA reviews both the clinical plans and the results of the trials and may discontinue the trials at any time if there are significant safety issues.

The results of the preclinical tests and clinical trials and other data are submitted to the FDA in the form of an NDA or BLA for marketing approval. The testing and approval process is likely to require substantial time and effort and any approval may not be granted on a timely basis, or may not be granted at all. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review period and may delay marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. The FDA mandates that adverse effects be reported to the FDA and may also require post-marketing testing to monitor for adverse effects, which can involve significant expense.

Among the conditions for NDA or BLA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practices prescribed by the FDA. Domestic manufacturing facilities are subject to FDA inspections twice yearly and foreign manufacturing facilities are subject to periodic FDA inspections or inspections by the foreign regulatory authorities with reciprocal inspection agreements with the FDA.

The Prescription Drug User Fee Act of 1992, as amended, requires companies engaged in pharmaceutical development, such as our company, to pay user fees in the amount of at least \$100,000 upon submission of an NDA. We do not believe that this requirement will harm our business.

For marketing outside the United States, we are also subject to foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country.

The time required for completing such testing and obtaining such approvals is uncertain and approval itself may not be obtained. In addition, delays or rejections may be encountered based upon changes in FDA policy during the period of product development and FDA regulatory review of each submitted NDA or BLA. Similar delays may also be encountered in foreign countries. Even after such time and expenditures, regulatory approval may not be obtained for any drugs that we develop. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which the drug may be marketed. Further, even if such regulatory approval is obtained, a marketed drug, its manufacturer and the facilities in which the drug is manufactured are subject to continual review and periodic inspections. Later discovery of

previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including withdrawal of the product from the market.

Manufacturing

To be successful, our products and the products of our partners must be manufactured in commercial quantities in compliance with regulatory requirements and at an acceptable cost. We have not commercialized any products, nor have we demonstrated that we can manufacture commercial quantities of our product candidates or our partners' product candidates in accordance with regulatory requirements. If we cannot manufacture products in suitable quantities in accordance with regulatory standards, either on our own or through contracts with third parties, it may delay clinical trials, regulatory approvals and marketing efforts for such products. Such delays could adversely affect our competitive position and our chances of achieving profitability. We cannot be sure that we can manufacture, either on our own or through contracts with third parties, such products at a cost or in quantities, which are commercially viable. We currently rely and intend to continue to rely on third-party contract manufacturers to produce materials needed for clinical trials and, ultimately, for product commercialization.

Employees

As of March 15, 2004, we employed 36 individuals full-time, of whom 27 were engaged in research and development, and 10 of whom hold Ph.D. or M.D. degrees. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

Available Information

Our website address is www.epimmune.com. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission.

RISK FACTORS

We wish to caution readers that the following important factors, among others, in some cases have affected our results and in the future could cause our actual results and needs to vary materially from forward-looking statements made from time to time by us on the basis of management's then-current expectations. The business in which we are engaged is in rapidly changing and competitive markets and involves a high degree of risk, and accuracy with respect to forward-looking projections is difficult.

Our substantial additional financing requirements and limited access to financing may adversely affect our ability to develop products and fund our operations.

We will continue to spend substantial amounts on research and development, including amounts spent for manufacturing clinical supplies, conducting clinical trials for our product candidates and advancing development of certain sponsored and partnered programs. Therefore, we will need to raise additional funding, in addition to the approximately \$5.5 million we raised in April 2004. We do not have committed external sources of funding and may not be able to obtain any additional funding, especially if volatile market conditions persist for biotechnology companies. If we are unable to obtain additional funding, we will be required to delay, further reduce the scope of or eliminate one or more of our research and development projects, sell the Company or certain of its assets or technologies, or dissolve and liquidate all of its assets. As of December 31, 2003, we had approximately \$6.4 million in cash and cash equivalents, which excludes the net proceeds to us from our April 2004 financing. Our future operational and capital requirements will depend on many factors, including:

- whether we are able to secure additional financing on favorable terms, or at all;
- the costs associated with our clinical trials for our vaccine targeting HIV, which began in September 2002, including the status of our contract with the NIH;
- the costs associated with our clinical trials for our vaccine targeting lung and colorectal cancer, which began in February 2003;
- progress with other preclinical testing and clinical trials in the future;
- our ability to establish and maintain collaboration and license agreements and any government contracts and grants;
- the actual revenue we receive under our collaboration and license agreements;
- the actual costs we incur under our research collaboration with Bavarian Nordic;
- the actual payment of license fees which may become payable at the option of the licensor;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and any other proprietary rights;
- competing technological and market developments;
- changes in our existing research relationships;
- continued scientific progress in our drug discovery programs; and
- the magnitude of our drug discovery and development programs.

We intend to seek additional funding through collaboration and license agreements, government research grants or equity or debt financings. In the event we are able to obtain financing, it may not be on favorable terms. In addition, we may not be able to enter into additional collaborations to reduce our funding requirements. If we acquire funds by issuing securities, dilution to existing stockholders will result, in addition to the dilution that occurred as a result of our September 2003 financing. If we raise funds through additional collaborations and license agreements, we will likely have to relinquish some or all of the rights to product

candidates or technologies that we may have otherwise developed ourselves. If we are unable to obtain funding, we may be required to engage in another restructuring, cease development of some product candidates, further reduce the scope of our operations, sell the Company or certain of its assets or technologies or cease operations.

We may not meet all of The Nasdaq National Market's continued listing requirements and we may be delisted, which could reduce the liquidity of our common stock and adversely affect our ability to raise additional necessary capital.

In order to continue trading on The Nasdaq National Market, we must comply with The Nasdaq National Market's continued listing requirements, which require that we maintain a minimum stockholders' equity of \$10.0 million and a minimum closing bid price of \$1.00 per share. As of December 31, 2003, our stockholders' equity was \$9.7 million, which did not satisfy the \$10.0 million continued listing requirement. We believe that, after receipt of the net proceeds from our April 2004 financing, we satisfy the \$10.0 million continued listing requirement. If we fail to satisfy The Nasdaq National Market's continued listing requirements, our common stock may be delisted from The Nasdaq National Market. The delisting of our common stock may result in the trading of the stock on The Nasdaq SmallCap Market or the OTC Bulletin Board. Consequently, a delisting of our common stock from The Nasdaq National Market may reduce the liquidity of our common stock and adversely affect our ability to raise additional necessary capital.

The process of developing therapeutic products requires significant research and development, preclinical testing and clinical trials, all of which are extremely expensive and time-consuming and may not result in a commercial product.

Except for our HIV and lung and colorectal cancer vaccine candidates, for which we began clinical trials in September 2002 and February 2003 respectively, all of our potential vaccine products are in research or preclinical development, the results of which do not necessarily predict or prove safety or efficacy in humans. We must demonstrate for each vaccine, safety and efficacy in humans through extensive clinical testing, which is very expensive, can take many years, and has an uncertain outcome. We may experience numerous unforeseen events during or as a result of the testing process that could delay or prevent testing or commercialization of our products, including the following:

- the results of preclinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising;
- we, our collaborators or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks;
- we may have to delay clinical trials as a result of scheduling conflicts with participating clinicians and clinical institutions, or difficulties in identifying and enrolling patients who meet trial eligibility criteria;
- safety and efficacy results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials; and
- the effects our vaccine candidates have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if ever approved.

The data collected from clinical trials may not be sufficient to support regulatory approval of any of our products, and the FDA may not ultimately approve any of our therapeutic products for commercial sale, which will adversely affect our revenues and prospects. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our operating income, our stock price and our ability to conduct our business as currently planned could be harmed.

Some of our programs are funded by the government and the government may not allocate funds for these programs in future fiscal years.

We fund certain of our research and development related to our HIV, cancer and malaria programs pursuant to multi-year grants and contracts from the government. The government is under no obligation to and may not fund these programs over their full term which would have a significant impact on our ability to continue development of our HIV, cancer and malaria programs.

Our history of operating losses and our expectations of continuing losses may hurt our ability to reach profitability or continue operations.

We have experienced significant operating losses since our inception in 1987. As of December 31, 2003, we had an accumulated deficit of \$157.9 million. We expect to continue to incur substantial operating expenses and net operating losses for the foreseeable future, which may hurt our ability to continue operations. We have not generated revenues from the commercialization of any product. All of our revenues to date have consisted of contract research and development revenues, license and milestone payments, research grants, certain asset divestitures and interest income. We expect that substantially all of our revenues for the foreseeable future will result from similar sources. To achieve profitable operations, we, alone or with collaborators, must successfully identify, develop, register and market proprietary products. We do not expect to generate revenues from the commercialization of any product for at least six years (and this would assume approval of either our HIV or lung and colorectal product candidates, which may not occur). We may not be able to generate sufficient product revenue to become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability on a quarterly or yearly basis.

The subordination of our common stock to our preferred stock could hurt common stockholders and, upon conversion, our preferred stock will further dilute our holders of common stock.

Our common stock is expressly subordinate to our series S and series S-1 preferred stock in the event of our liquidation, dissolution or winding up. With respect to our series S preferred, any merger or sale of substantially all of our assets shall be considered a deemed liquidation. If we were to cease operations and liquidate our assets, we would first be required to pay \$10 million to our holders of preferred stock and there may not be any remaining value available for distribution to the holders of common stock after providing for the series S and series S-1 preferred stock liquidation preference. In addition, due to adjustments to the conversion price of our series S preferred stock, in the event our series S preferred stock is converted to common stock, it will further dilute our holders of common stock.

We are at an early stage of development, and we may experience delays and other problems in entering clinical trials.

We are an early stage research and development company, and only commenced our first Phase I/II clinical trials for two of our vaccines within the past two years. There are many factors outside of our control that may affect the timing of completion of our current clinical trials, and any future clinical trials may not commence when planned or be completed within any anticipated time frame. We have already experienced unexpected delays in filing an IND for our therapeutic vaccine candidate targeting HIV, due to additional time necessary to complete all of the animal safety studies that were contemplated in our pre-IND discussions with the FDA. We may experience unexpected delays in our research and development efforts that would require us to postpone the commencement or completion of clinical trials of other vaccine candidates. The FDA may comment or raise concerns or questions with respect to any IND that we file and, therefore, clinical trials may not begin when planned, if at all.

Our failure to obtain issued patents and, consequently, to protect our proprietary technology, could hurt our competitive position.

Our success will depend in part on our ability to obtain and enforce claims in our patents directed to our products, technologies and processes, both in the United States and other countries. Although we have filed

various patent applications, our patent position is highly uncertain and involves complex legal and factual questions. Legal standards relating to patentability, validity and scope of patent claims in epitope identification and other aspects of our technology field are still evolving. Patents may not issue from any of the patent applications that we own or license and, if patents do issue, claims issued in the patents may not be sufficiently broad to protect our vaccines, technologies and processes. For example, even though our patent portfolio includes patent applications with claims directed to peptide epitopes and methods of utilizing sequence motifs to identify peptide epitopes, we cannot assure you of the breadth of claims that will be allowed or that may issue in future patents. Other risks and uncertainties that we face with respect to our patents and patent applications include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the allowed claims of any patents that issue may not provide meaningful protection;
- we may be unable to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us may not provide a competitive advantage;
- other companies may challenge patents licensed or issued to us;
- disputes may arise regarding inventions and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us, our licensors, or collaborators; and
- other companies may design around our patented technologies.

Our competitors may develop products that are more effective and that render our potential products obsolete.

The biotechnology industry continues to undergo rapid change, and competition is intense and is expected to increase. Our competitors may succeed in developing technologies, vaccines or other therapeutic products that are more effective than any of the products we are developing, which would render our technology and products obsolete and noncompetitive.

If we are unable to compete effectively in the highly competitive biotechnology industry, our business will fail.

Many companies and institutions compete with us in developing vaccines and other therapies to activate the body's immune system or to otherwise treat or more effectively manage infectious diseases and cancer, including:

- pharmaceutical companies;
- chemical companies;
- specialized biotechnology companies;
- academic institutions; and
- research organizations.

Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical development, obtaining regulatory approvals and marketing than we do, and we may not be able to compete effectively against them.

Our vaccines under development address a range of cancer and infectious disease markets. The competition in these markets is extremely formidable. There are 27 drugs currently approved in the United States for HIV and according to a *PhRMA* 2003 report on pharmaceutical drug development, there were 83 new product candidates in clinical development for HIV and related conditions, including 15 HIV vaccines. In

addition, according to the PhRMA 2003 report, there were 395 new product candidates in clinical development for the treatment of cancer, and at least 30 companies were developing more than 50 vaccines against various cancers. An important factor in competition may be the timing of market introduction of our vaccines and competitive products. Accordingly, the relative speed with which we can develop vaccines, complete the clinical trials and approval processes and supply commercial quantities of the vaccines to the market are expected to be important competitive factors. We expect that competition among products approved for sale will be based, among other things, on product effectiveness, safety, reliability, availability, price and patent position.

Litigation regarding intellectual property rights owned or used by us may be costly and time-consuming.

Litigation may be necessary to enforce the claims in any patents issued to us, to defend ourselves against any patents owned by third parties that are asserted against us, or to determine the scope and validity of others' proprietary rights. In addition, we may have to participate in one or more interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial costs to determine the priority of inventions.

If we become involved in litigation or interference proceedings, we may incur substantial expense, and the proceedings may divert the attention of our technical and management personnel, even if we ultimately prevail. An adverse determination in proceedings of this type could subject us to significant liabilities, allow our competitors to market competitive products without obtaining a license from us, prohibit us from marketing vaccines or other products or require us to seek licenses from third parties that may not be available on commercially reasonable terms, if at all. If we cannot obtain such licenses, we may be restricted or prevented from developing and commercializing our product candidates.

The enforcement, defense and prosecution of intellectual property rights, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and elsewhere involve complex legal and factual questions. As a result, these proceedings are costly and time-consuming, and their outcome is uncertain. Litigation may be necessary to:

- assert against others or defend ourselves against claims of infringement;
- enforce patents in our portfolio owned by us or licensed from another party;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of ours or others.

Unexpected side effects or other characteristics of our technology may delay or otherwise hurt the development of our vaccine candidates.

There may be side effects in our current or future clinical trials that we may discover, including side effects that become apparent only after long-term exposure, even though our safety tests may indicate favorable results. We may also encounter technological challenges relating to these technologies and applications in our research and development programs that we may not be able to resolve. Any such unexpected side effects or technological challenges may delay or otherwise adversely affect the development, regulatory approval or commercialization of our drug candidates.

There are no therapeutic vaccines that have been approved for use by the FDA and our vaccines may not work, which would prevent us from ever becoming profitable.

Because there are not yet any therapeutic vaccines that have undergone the complete clinical development process and FDA review, there is still insufficient evidence that therapeutic vaccines will become products. Our business is dependent upon the concept of a therapeutic vaccine and, therefore, if therapeutic vaccines were found not to be safe or effective, we would never commercialize a product candidate and would never make a profit.

Adverse publicity regarding the safety or side effects of the technology approach or products of others could reduce our revenues and cause our stock price to fall.

Despite any favorable safety tests that may be completed with respect to our product candidates, adverse publicity regarding vaccines or products being developed or marketed by others could negatively affect us. If other researchers' studies raise or substantiate concerns over the safety or side effects of vaccines or our technology approach or product development efforts generally, our reputation and public support for our clinical trials or products could be harmed, which would harm our business and could cause our stock price to fall.

Our research and development programs may not yield effective product candidates, which could prevent us from developing our products.

We cannot guarantee that our research and development programs will be successful in identifying vaccine candidates for clinical trials. Even if we do receive positive data during preclinical testing and during Phase I/II clinical trials for our therapeutic vaccine candidates targeting HIV, and lung and colorectal cancer or any other candidates we may develop, this data cannot be relied upon as evidence that the clinical candidate will be safe and effective in humans, and assuming we initiate any Phase III trials, data from Phase III or other pivotal clinical trials may not be consistent with earlier data or be sufficient to support regulatory approval.

We may not identify the correct epitopes and, therefore, not develop a safe or effective vaccine.

Our strategy involves identifying multiple epitopes in order to create our vaccines. If we are unable to identify the correct epitopes, or if we are unable to combine them in the correct manner, to stimulate desired immune responses we may never develop a vaccine that is safe or effective in any of the indications that we are pursuing.

Our business is based on a novel technology, which has not been used in any commercial drugs, and may not work.

Our vaccine candidates use epitopes to stimulate specific T cell immune responses, but we are not aware of any commercial drugs that are based on this technology. Our technology related to T cell stimulation is unproven and may not produce any commercial vaccines.

If we cannot obtain and maintain strategic collaborations on acceptable terms in the future, we may not be able to develop products in markets where it would be too costly or complex to do so on our own.

We will need to enter into and maintain collaborative arrangements with pharmaceutical and biotechnology companies or other strategic partners both for development and commercialization of potential vaccine products in markets where it would be too costly or complex to do so on our own. Currently, our only collaborations are with Innogenetics and Bavarian Nordic. If we are not able to enter into and maintain additional research and development collaborations or other collaborations in the future on acceptable terms, we may be forced to abandon development and commercialization of some vaccine product candidates.

If our collaboration or license arrangements are unsuccessful, our revenues and product development may be limited.

Our collaborations and license arrangements generally pose the following risks:

- collaborators and licensees may not pursue further development and commercialization of potential products resulting from our collaborations or may elect not to renew research and development programs;
- collaborators and licensees may delay clinical trials, under fund a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require new formulation of a product candidate for clinical testing;

- expected revenue might not be generated because milestones may not be achieved and product candidates may not be developed;
- collaborators and licensees could independently develop, or develop with third parties, products that could compete with our future products;
- the terms of our contracts with our current or future collaborators and licensees may not be favorable to us in the future;
- a collaborator or licensee with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of a product;
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant and costly litigation or arbitration; and
- collaborations and licensee arrangements may be terminated and we will experience increased operating expenses and capital requirements if we elect to pursue further development of the product candidate.

We may not be able to obtain licenses to technology that is necessary for us to develop products.

We may be required to enter into licenses or other collaborations with third parties in order to access technology that is necessary to successfully develop certain of our products. We may not successfully negotiate acceptable licenses or other collaborative arrangements that will allow us to access such technologies. If we cannot obtain and maintain license rights on acceptable terms to access necessary technologies, we may be prevented from developing some product candidates. In addition, any technologies accessed through such licenses or other collaborations may not help us achieve our product development goals.

We may not be able to commercialize our products under development if they infringe claims in existing patents or patents that have not yet issued, and this would materially harm our ability to operate.

As is typical in the biotechnology industry, our commercial success will depend in part on our ability to avoid infringing patents issued to others or breaching the technology licenses upon which we might base our vaccines or other products. We are aware of patents issued to others that contain claims that may cover certain aspects of our or our collaborators' technologies, including cancer vaccine epitopes, HIV vaccine epitopes, and methods for delivering DNA vaccines to patients. We do not believe that any of these known patents are likely to require us to obtain a license in order to pursue the development or commercialization of our vaccine product candidates. However, we may be required to take a license under one or more of these patents to practice certain aspects of our vaccine technologies in the United States, and such a license may not be available on commercially reasonable terms, if at all. If we fail to obtain a license on acceptable terms to any technology that we need in order to develop or commercialize our vaccines or other products, or to develop an alternative vaccine or other product that does not infringe on the patent rights of others, we would be prevented from commercializing our vaccine, and our business would be harmed.

If we or our collaborators cannot cost-effectively manufacture vaccines in commercial quantities and for clinical trials in compliance with regulatory requirements, we or our collaborators may not be able to successfully commercialize the products.

We have not commercialized any products, and we do not have the experience, resources or facilities to manufacture vaccines on a commercial scale. We will not be able to commercialize any vaccines and earn product revenues unless we or our collaborators demonstrate that we can manufacture commercial quantities of vaccines in accordance with regulatory requirements. Among the other requirements for regulatory approval is the requirement that prospective manufacturers conform to the FDA's Good Manufacturing Practices, or GMP, requirements specifically for biological drugs, as well as for other drugs. In complying with the FDA's GMP requirements, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements.

We currently rely and intend to continue to rely on third-party contract manufacturers to produce materials needed for clinical trials and, ultimately, for product commercialization. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we encounter delays or difficulties in our relationships with manufacturers, it may delay clinical trials, regulatory approvals and marketing efforts for our vaccines. Such delays could adversely affect our ability to earn revenues and our chances of achieving profitability. We cannot be sure that we can manufacture, either on our own or through contracts with outside parties, vaccines at a cost or in quantities that are commercially viable.

If we do not successfully develop and commercialize our products, we may never generate significant revenues or become profitable.

We have not completed the development of any product and, accordingly, have not begun to market or generate revenues from the commercialization of any product. We do not expect to market any of our therapeutic or prophylactic vaccines or any other products for at least six years (and this would assume approval of either our HIV or lung and colorectal product candidate, which may not occur). If we do not successfully develop and commercialize products, we will never generate revenues that would allow us to become profitable.

The lengthy approval process and uncertainty of government regulatory requirements may impair our ability to develop, manufacture and sell any vaccines.

We and our collaborators cannot commercialize our vaccines or other products if we do not receive FDA or state regulatory approval to market our products. The regulatory process for new therapeutic drug products, including the required preclinical studies and clinical testing, is lengthy, uncertain and expensive. We and our collaborators may not receive necessary FDA clearances for any of our vaccines or other potential products in a timely manner, or at all. Once approved, we are subject to the continuing requirements of the FDA. Noncompliance with initial or continuing requirements can result in, among other things:

- fines and penalties;
- injunctions;
- seizure of products;
- total or partial suspension of product marketing;
- failure of the government to grant a new drug application;
- withdrawal of marketing approvals; and
- criminal prosecution.

The length of the clinical trial process and the number of patients the FDA will require to be enrolled in clinical trials in order to establish the safety and efficacy of our products is uncertain. In addition, our clinical studies may not provide the FDA with sufficient clinical data to permit approval of a new drug application, or NDA, or a biologic license application, or BLA, even though we or our collaborators believe we are doing the right studies based on the protocol. The FDA or we and our collaborators may decide to discontinue or suspend clinical trials at any time if the subjects or patients who are participating in such trials are being exposed to unacceptable health risks or if the results show no or limited benefit in patients treated with the vaccine compared to patients in the control group.

Regulatory requirements are evolving and uncertain. Future United States or state legislative or administrative acts could also prevent or delay regulatory approval of our products. Even if we obtain commercial regulatory approvals, the approvals may significantly limit the indicated uses for which we may market our products.

The approval process outside the United States is also uncertain and may limit our ability to develop, manufacture and sell our products internationally.

To market any drug products outside of the United States, we and our collaborators are also subject to numerous and varying foreign regulatory requirements, implemented by foreign health authorities, governing the design and conduct of human clinical trials and marketing approval for vaccines or other drug products. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country, nor does the approval by foreign health authorities ensure approval by the FDA.

Even if we obtain regulatory approval, we may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market, which could harm sales of the affected products.

If we or others identify adverse side effects after any of our vaccines or other drug products are on the market, or if manufacturing problems occur:

- regulatory approval may be withdrawn;
- reformulation of our products, additional clinical trials, changes in labeling of our products or changes to or re-approvals of our manufacturing facilities may be required;
- sales of the affected products may drop significantly;
- our reputation in the marketplace may suffer; and
- lawsuits, including costly and lengthy class action suits, may be brought against us.

Any of the above occurrences could halt or reduce sales of the affected vaccines or other products or could increase the costs and expenses of commercializing and marketing these vaccines or other products.

If we are unable to protect our trade secrets, we may be unable to protect from competitors our interests in proprietary know-how that is not patentable or for which we have elected not to seek patent protection.

Our competitive position depends in part on our ability to protect trade secrets that are not patentable or for which we have elected not to seek patent protection. To protect our trade secrets, we rely primarily on confidentiality agreements with our collaborative partners, employees and consultants. Nevertheless, our collaborative partners, employees and consultants may breach these agreements and we may be unable to enforce these agreements. In addition, other companies may develop similar or alternative technologies, methods or products or duplicate our technologies, methods or vaccines that are not protected by our patents or otherwise obtain and use information that we regard as proprietary, and we may not have adequate remedies in such event. Any material leak of our confidential information into the public domain or to third parties could harm our competitive position.

If we lose our key scientific and management personnel or are unable to attract and retain qualified personnel, it could delay or hurt our epitope identification and vaccine development efforts.

We are highly dependent on the principal members of our scientific and management staff. We do not maintain key person life insurance on the life of any employee and, although we have an employment contract with Dr. Emile Loria, he may terminate his employment at any time. Our ability to identify epitopes, develop vaccines and achieve our other business objectives also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional qualified personnel. There is intense competition for qualified personnel in biochemistry, molecular biology, immunology and other areas of our activities, and we may not be able to continue to attract and retain such personnel necessary for the development of our business. Because of the intense competition for qualified personnel among

technology-based businesses, particularly in the San Diego area, we may not be successful in adding technical personnel as needed to meet the staffing requirements of additional collaborative relationships. Our failure to attract and retain key personnel could delay or be significantly detrimental to our product development programs and could cause our stock price to decline.

We out-license technology outside of our core area of focus, and these licensees may not develop any products using our technology, which may limit our revenue.

We have licensed to third parties some of our technology in markets that we are not pursuing ourselves or with our collaborators. If these licensees are not successful in developing and commercializing products using our technology, our revenues would be limited. Our licensees may pursue alternative technologies or develop alternative products either on their own or in collaboration with others in competition with products developed under licenses or collaborations with us.

Some of our programs are funded by the government and, therefore, the government may have rights to certain of our technology and could require us to grant licenses of our technology to third parties.

We fund certain of our research and development related to our HIV, cancer and malaria programs pursuant to grants from the government. As a result of these grants, the government may have rights in the technology, including inventions developed with government funding. In addition, the government may require us to grant to a third party an exclusive license to any inventions resulting from the grant if the government determines that we have not taken adequate steps to commercialize inventions, or for public health or safety needs.

Adverse determinations concerning product pricing, reimbursement and related matters could prevent us from successfully commercializing products and impair our ability to generate revenues.

Our ability to successfully commercialize our vaccines or other products may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Product liability risks may expose us to significant liability that could cause us to incur significant costs or cease developing our products.

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. While we currently have product liability insurance for an early stage clinical trial, we cannot be sure that we can maintain such insurance on acceptable terms or obtain acceptable insurance as we progress through product development and commercialization, or that our insurance will provide adequate coverage against potential liabilities, either in human clinical trials or following commercialization of any vaccines we may develop.

Our use of hazardous materials could expose us to significant costs.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, chemicals and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and some waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed our resources. We cannot be sure that compliance with environmental laws and regulations in the future will not entail significant costs, or that our ability to conduct research and development activities will not be harmed by current or future environmental laws or regulations.

The volatility of the price of our common stock may hurt our stockholders.

The market prices for securities of biotechnology companies, including our common stock, have historically been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are not necessarily related to the operating performance of such companies. From January 1, 2003 through March 31, 2004, our closing stock price has ranged from \$0.760 to \$3.166 and has been and will continue to be influenced by general market and industry conditions. In addition, the following factors may have a significant effect on the market price of our common stock:

- whether we are able to secure additional financing on favorable terms, or at all;
- announcements of technological innovations or new commercial vaccines or other therapeutic products by us or others;
- governmental regulation that affects the biotechnology and pharmaceutical industries;
- developments in patent or other proprietary rights;
- receipt of funding under collaboration and license agreements and government grants;
- developments in, or termination of, our relationships with our collaborators and licensees;
- public concern as to the clinical results and/or the safety of drugs developed by us or others; and
- announcements related to the sale of our stock.

Fluctuations in our financial performance from period to period also may have a significant impact on the market price of our common stock.

Concentration of ownership among our existing officers, directors and principal stockholders may prevent other stockholders from influencing significant corporate decisions and depress our stock price.

As of December 31, 2003, our officers, directors and those stockholders owning at least five percent of our outstanding stock together control approximately 47.4% of our outstanding common stock as converted and Pharmacia, now part of Pfizer, holds 100% of our preferred stock. If some or all of these officers, directors and principal stockholders act together, they will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval or disapproval of any proposed merger or financing or other business combination transaction. The interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. For instance, officers, directors and principal stockholders, acting together, could cause us to enter into transactions or agreements that we would not otherwise consider. Similarly, this concentration of ownership may have the effect of delaying or preventing a change in control of our company otherwise favored by our other stockholders. This concentration of ownership also could depress our stock price.

Item 2. *Properties*

We lease a 24,000 square foot administrative and research laboratory facility in San Diego under an operating lease that expires in March 2009. We believe our existing facilities will be adequate to meet our needs for the foreseeable future.

Item 3. *Legal Proceedings*

We are not a party to any legal proceedings.

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*

Our common stock (Nasdaq symbol "EPMN") is traded publicly through the National Market System. The following table presents quarterly information on the price range of our common stock. This information indicates the high and low sale prices reported by the National Market System. These prices do not include retail markups, markdowns or commissions.

	<u>High</u>	<u>Low</u>
2004		
First Quarter (through March 15)	\$2.99	\$1.76
2003		
First Quarter	\$1.25	\$0.75
Second Quarter	\$2.07	\$0.76
Third Quarter	\$4.29	\$1.01
Fourth Quarter	\$3.21	\$1.50
2002		
First Quarter	\$4.24	\$2.30
Second Quarter	\$2.75	\$1.40
Third Quarter	\$2.10	\$1.17
Fourth Quarter	\$1.50	\$0.85

As of March 15, 2004, there were approximately 260 stockholders of record of our common stock. We have never declared or paid dividends on our common stock and do not anticipate the payment of dividends in the foreseeable future.

For information concerning prior stockholder approval of and other matters relating to our equity incentive plans, see "Equity Compensation Plan Information" under Item 12 in this Annual Report on Form 10-K.

During the period covered by this Annual Report on Form 10-K, we sold and issued the following securities, which were not registered under the Securities Act of 1933, as amended, or the Securities Act:

(1) In September 2003, pursuant to the terms of a unit purchase agreement, we issued 2,168,961 shares of common stock and warrants to purchase 542,238 shares of common stock to a group of nine accredited investors. The purchase price of each unit, which is the combination of one share of common stock and 25% of a warrant, was \$1.86725 for gross proceeds to us for the transaction of \$4.05 million. Our sale of the common stock and warrants was exempt from registration requirements under the Securities Act pursuant to Rule 506 thereof because each of the purchasers of securities was an accredited investor.

Item 6. Selected Financial Data

Please read the following selected financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and related notes included elsewhere in this annual report on Form 10-K.

<u>Statement of Operations Data:</u>	<u>Years Ended December 31,</u>				
	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>
	<i>(In millions, except for net loss per share)</i>				
Operating revenues	\$ 7.2	\$ 7.1	\$ 8.2	\$ 1.6	\$ 4.2
Net loss	(7.1)	(6.5)	(2.6)	(4.7)	(8.3)
Net loss per share — basic and diluted	(0.58)	(0.57)	(0.31)	(0.68)	(1.57)
<u>Balance Sheet Data:</u>	<u>As of December 31,</u>				
	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>
	<i>(In millions)</i>				
Working capital	\$ 4.8	\$ 7.7	\$15.4	\$ 8.2	\$ 6.9
Total assets	12.7	15.5	23.9	14.5	12.7
Long-term obligations	—	—	0.04	0.4	0.4
Stockholders' equity	9.7	12.6	19.4	12.1	10.4

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Except for the historical information contained herein, the following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, without limitation, those discussed below and in the section entitled "Risk Factors."

Since 1997, we have devoted substantially all of our resources to the discovery and development of potential therapeutic and prophylactic products. To date, we have not received any revenues from the sale of products. We have funded our research and development primarily from equity-derived working capital, through strategic alliances and collaborations with other companies and through government research funding, primarily from the National Institutes of Health in the form of grants and contracts. We have not been profitable since our inception and expect to incur substantial operating losses for at least the next several years. As of December 31, 2003, our accumulated deficit was approximately \$157.9 million.

In July 2001, we entered into a collaboration agreement with Genencor. The revenue that we recognize from Genencor includes milestone payments, recognition of upfront license fees over the term of the contract and contract revenue to support our research and development activities over the term of the collaboration. As of December 31, 2003, Genencor owned approximately 10.0% of our common stock and was therefore considered a "related party" for financial reporting purposes. Therefore, all payments that we have received under this agreement are itemized under the category, "Related Party Revenue."

In February 2003, we preliminarily agreed with Anosys, Inc. to merge our operations to create a combined company focused on the field of immunotherapeutics and products for the treatment of cancer and infectious diseases. In August 2003, we announced that the merger agreement between Epimmune and Anosys was terminated. In connection with the termination of the merger agreement, we recorded a charge of \$0.5 million during the second quarter of 2003, which is included in general and administrative costs, to write-off costs we had incurred in connection with the proposed merger.

In September 2003, we announced a reduction of our work force aimed at focusing our efforts on our most advanced clinical programs and our sponsored and partnered programs. We reduced our research and administrative staff by 11 individuals or 23%, which resulted in a one-time restructuring charge of approximately \$336,000 in the third quarter of 2003.

In September 2003, Dr. Loria, our President and CEO surrendered an aggregate of 963,740 shares of our common stock, including 250,139 unvested shares, at the fair market value of \$3.17 per share, in exchange for

the prepayment of the outstanding principal and interest under a promissory note issued by Dr. Loria in January 2001 for the purchase of 1,056,301 shares of our common stock at a purchase price of \$2.50 per share. The aggregate value of the shares surrendered was \$3,055,000. The remaining 92,561 unvested shares will vest in equal daily installments between September 29, 2003 and January 15, 2005. We continue to have the right to purchase any unvested shares at the purchase price paid by Dr. Loria in the event of termination of Dr. Loria's service to us.

In connection with this transaction, we recorded a non-cash, stock-based compensation charge of approximately \$645,000 in the third quarter of 2003 based on the difference between the fair market price on September 29, 2003 and the exercise price of the shares surrendered by Dr. Loria. We will also recognize an additional \$62,000 in non-cash, stock-based compensation charges ratably over the period from September 29, 2003 to January 15, 2005 as the remaining 92,561 unvested shares vest.

Subsequent Events

In March 2004, Genencor assigned its rights under our collaboration to Innogenetics NV. In connection with the assignment by Genencor, we extended the collaboration term with Innogenetics through September 2005. Innogenetics will have the right to terminate the collaboration early, upon three months written notice.

In April 2004, we completed a private placement of 2,466,379 shares of common stock and warrants to purchase up to 1,233,188 shares of common stock to selected institutional and accredited investors, including current shareholders, for a total purchase price of \$5.5 million. We received net proceeds of \$5.1 million. The purchase price of each security, which is the combination of one share of common stock and, for each two shares of common stock purchased, a warrant to purchase one share of common stock, was priced at the market value of \$2.2125, which was equal to or greater than the sum of the closing bid price of our common stock as quoted on the Nasdaq National Market on the date of execution of the purchase agreements, and \$0.0625, the imputed value of a warrant to purchase one share of common stock. In addition, we issued warrants to purchase an aggregate of 250,000 shares of our common stock to a placement agent for services rendered in connection with the private placement. Each warrant, including the warrant issued to the placement agent, has a three-year term and an exercise price equal to 120% of \$2.2125 or \$2.655 per share.

Significant Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, patents and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect the significant judgments and estimates used in the preparation of our consolidated financial statements (see Note 1 to our financial statements).

Revenue Recognition

We recognize revenues pursuant to Staff Accounting Bulletin No. 101, "Revenue Recognition." Collaboration revenues are earned and recognized as research costs are incurred in accordance with the provisions of each agreement. License fees are earned and recognized in accordance with the provisions of each agreement. Upfront license fees for perpetual licenses where we have no performance obligations are recognized when received. License fees with ongoing involvement or performance obligations are recognized over the term of the agreement. For example, in connection with our Genencor collaboration, because we received an upfront license fee, it is being amortized into revenue over the collaboration term. Fees paid to

initiate research projects are deferred and recognized over the project period. Milestone payments are recognized as revenue upon the completion of the milestone as long as the milestone event was substantive, and its achievability was not reasonably assured at inception and our performance obligations after milestone achievement will continue to be funded at a comparable level before the milestone achievement. Revenues from grants are recognized on a percentage-of-completion basis as related costs are incurred. We defer revenue recognition until performance obligations have been completed and collectibility is reasonably assured.

Patents

We capitalize the costs incurred to file patent applications when we believe there is a high likelihood that the patent will issue and there will be future economic benefit associated with the patent. These costs are amortized over a ten-year life from the date of patent filing. We expense all costs related to abandoned patent applications. In addition, we review the carrying value of patents for indicators of impairment on a periodic basis. If we elect to abandon any of our currently issued or unissued patents or we determine that the carrying value is impaired, the related expense could be material to our results of operations for the period of the abandonment.

Investment Policy

The primary objective of our investment activities is to preserve principal while at the same time achieving competitive yields, without significantly increasing risk. To achieve this objective, we primarily invest in cash and money market accounts as well as A1 or P1 or higher rated debt securities with maturities of less than two years, with the weighted average maturity not to exceed eighteen months. We also attempt to minimize our portfolio risk by placing constraints on how much of our portfolio may be held in a specific type of investment such as asset-backed securities or collateralized mortgage obligations as well as limiting our holdings in any one issuer. At December 31, 2003, our investment portfolio included only cash and money market accounts and had no fixed-income securities.

Results of Operations

We had total revenue of \$7.2 million for the year ended December 31, 2003 and \$7.1 million for the year December 31, 2002. A decrease of \$1.2 million in related party revenue from Genencor in 2003 was offset by an increase of \$0.6 million in licensing fees and milestone revenue and a \$0.6 million increase in grant and contract revenue during 2003. The decrease of \$1.2 million in related party revenue in the year ended December 31, 2003, compared to the year ended December 31, 2002, was primarily due to the shift in focus of our collaboration with Genencor from scientific research activities, the part of the collaboration in which we are most involved, to preclinical development on the lead program in support of a late 2003 Investigational New Drug, or IND, filing by Genencor, lower non-recurring milestone payments received in 2003 compared to 2002, and an increase in the time period during which the license fees previously paid by Genencor are being amortized due to the extension of the collaboration term. The change in the estimated life of the license occurred due to the extension of the collaboration term from September 1, 2003 to September 1, 2004. The agreement term was extended in October of 2002. In March 2004, Genencor assigned its rights under our collaboration to Innogenetics NV. In connection with the assignment by Genencor, we extended the collaboration term with Innogenetics through September 2005. Innogenetics will have the right to terminate the collaboration early, upon three months written notice. The increase of \$0.6 million in licensing fees and milestone revenue in the year ended December 31, 2003, compared to the year ended December 31, 2002 was due to the receipt of one-time payments for license fees and milestones during 2003 under the terms of our agreement with Anosys, and an increase in licensing revenue as a result of amortization of evaluation fees and license fees received from Aventis, IDM, Beckman Coulter, Merck and Amgen in 2003, compared to 2002. The increase of \$0.6 million in grant and contract revenue in the year ended December 31, 2003, compared to the year ended December 31, 2002 was due to higher reimbursable expenses on several existing grants and contracts during 2003 than in 2002 and reimbursement of expenses on a new contract we received in September of 2003 from the NIH to develop a preventive HIV vaccine.

Our revenue of \$7.1 million for the year ended December 31, 2002 compares to total revenue of \$8.2 million for the year ended December 31, 2001. The decrease of 13% in 2002 relates primarily to a reduction of \$3.2 million in license fees and milestone payments we received compared to 2001, partially offset by an increase of \$2.1 million in related party revenue we received in 2002 compared to 2001. License fee and milestone revenue for the year ended December 31, 2001 included recognition of non-recurring license fees associated with numerous license agreements we entered into during that period, including agreements with Biosite, Anosys, Nexell and Pharmexa. For the year ended December 31, 2002, we received \$1.9 million in research grants and contract revenue compared to \$1.8 million received in the year ended December 31, 2001. We had related party revenue of \$4.7 million in the year ended December 31, 2002 compared to \$2.6 million of related party revenue in the year ended December 31, 2001. The increase in related party revenue was due to reimbursement for expenditures on our Genencor collaboration and amortization of license fees associated with the Genencor collaboration that was entered into in July 2001.

Research and development expenses decreased to \$10.5 million in the year ended December 31, 2003 from \$11.3 million in the year ended December 31, 2002. The decrease in the year ended December 31, 2003 relates primarily to lower outside costs related to preclinical activities such as formulation and toxicology studies for our HIV and lung and colorectal cancer programs, which are now in clinical trials, lower scientific supplies costs related to completion of preclinical activities, lower patent and intellectual property related expenses, and reduced labor costs related to our work force reduction, partially offset by higher costs associated with outside research support related to our High Throughput Screening contract with the NIH and outside research and development support on a new contract we received in September of 2003 from the NIH to develop a preventive HIV vaccine.

Research and development expenses increased to \$11.3 million in the year ended December 31, 2002 from \$7.9 million in the year ended December 31, 2001. The increase in 2002 relates primarily to an increase of \$1.6 million in outside costs related to preclinical activities such as formulation and toxicology studies for our HIV and lung and colorectal cancer programs, an increase of \$0.6 million in labor and related costs, including recruitment and relocation as a result of an increase in our personnel responsible for research and development activities, an increase of \$0.4 million associated with amortization and other costs related to increased spending to prosecute our patent portfolio and an increase of \$0.3 million on scientific supplies due to increased research and development efforts and our collaboration with Genencor. We expect to continue to incur costs in 2004 for, among other things, outside costs related to clinical trials and development activities for our new NIH contract for a preventive HIV vaccine, product formulation and manufacturing of product for use in clinical trials, medical and clinical consultant costs and product development costs for additional vaccine candidates.

General and administrative costs were approximately \$3.6 million in the year ended December 31, 2003 compared to \$2.9 million in the year ended December 31, 2002. The increase in the year ended December 31, 2003 was due to recognition of non-cash, stock-based compensation charges in connection with the prepayment of a promissory note by our CEO in September 2003, other non-cash, stock-based compensation expenses related to a higher stock price for variable stock equity instruments, and the write off of legal, investment banking, accounting and other expenses related to our proposed merger with Anosys, which was terminated. The increases were partially offset by a reduction in consultant fees and other outside costs, and a reduction in travel expenses.

General and administrative costs were approximately \$2.9 million in the year ended December 31, 2002 and \$3.4 million in the year ended December 31, 2001. The decrease in 2002 was primarily due to \$0.6 million less paid for bonuses in 2002 compared to 2001, a benefit of \$0.3 million of stock compensation related to a lower stock price for variable stock equity instruments, and a decrease of \$0.1 million in legal expenses in 2002 compared to 2001. These decreases were partially offset by a \$0.3 million increase in payroll and related expenses and a \$0.1 million increase in consultant expenses in 2002 compared to 2001.

In September 2003, we announced a reduction of our work force aimed at reducing our cash burn and focusing our efforts on our most advanced clinical programs and our sponsored and partnered programs. We reduced our research and administrative staff by 11 individuals or 23%, which resulted in a one-time

restructuring charge of approximately \$336,000 in the year ended December 31, 2003. We had no restructuring related charges in 2002 or 2001.

Net interest income was approximately \$0.2 million in 2003 compared to \$0.6 million in 2002 and \$0.4 million in 2001. Interest income during 2003 includes approximately \$0.1 million of interest accrued on the note issued for the purchase in January 2001 of our common stock by Dr. Loria, our president and chief executive officer, compared to approximately \$0.3 million of interest accrued on the note in 2002. We had lower average cash balances and rates of return in the year ended December 31, 2003, compared to the year ended December 31, 2002. Higher average cash balances in 2002 were offset by lower average returns than in 2001 due to lower interest rates.

We expect to incur operating losses over at least the next several years due to continuing expenses associated with our research and development programs, including clinical trials, preclinical testing and development activities. Operating losses may fluctuate from quarter to quarter as a result of differences in the timing and amounts of revenues received and expenses incurred, and such fluctuations may be substantial.

Liquidity and Capital Resources

We have financed operations since inception primarily through private placements of our equity securities, two public common stock offerings, license fees, revenues under collaborative research and development agreements, grant revenues, capital and operating lease transactions, certain asset divestitures and interest income. Through December 2003, we have raised approximately \$165.1 million from the sale of equity securities, of which \$30.1 million was raised to fund the business since the formation of our business related to immunotherapy. As of December 31, 2003, we had 15,193,916 shares outstanding on an as-converted to common stock basis, assuming conversion of the series S and S-1 preferred shares.

As of December 31, 2003, our cash and cash equivalents were \$6.4 million compared to \$9.7 million at December 31, 2002. The decrease was primarily due to \$6.1 million of cash used to fund the Company's research and development and clinical activities and \$0.8 million of cash for capitalized patent costs. Our operating expenses were offset by license fees, milestone payments and grant and contract revenues we received. We expect to continue to use our cash and cash equivalents to fund our ongoing and future clinical trials, as well as our drug research and development programs. We expect our net cash burn rate to decrease in 2004 compared to 2003 due to increased reimbursement of research and development costs as a result of a new contract we received in September of 2003 from the NIH to develop a preventive HIV vaccine. We had net working capital of \$4.8 million as of December 31, 2003 compared to \$7.7 million as of December 31, 2002.

Capital expenditures for the year ended December 31, 2003 were \$0.1 million compared to \$0.7 million for the year ended December 31, 2002 and \$0.3 million for the year ended December 31, 2001. The expenditures for 2003 were primarily for small laboratory equipment. The expenditures for 2002 were primarily for laboratory equipment to increase and improve immunological screening throughput, to build out additional laboratory space to accommodate additional employees and for information technology equipment and upgrades to accommodate new employees. Capital expenditures for 2001 were primarily for laboratory equipment. In the past, we have financed our laboratory equipment and research and office facilities primarily through operating lease arrangements and a note payable. During 2003, 2002 and 2001 we made payments under the notes payable of \$0.04 million, \$0.3 million and \$0.4 million, respectively. During 2003, we fully paid off our outstanding note payable. During 2004, we anticipate that payments related to capital expenditures will increase modestly compared to 2003 levels to a range of approximately \$0.3 million to \$0.4 million, primarily for the purchase of equipment to support our clinical trials. We will also pay approximately \$0.6 million in rent on our lease commitments during 2004. The future minimum rental commitment for the lease of our facility will range from approximately \$0.6 million to \$0.7 million each year over six years, based upon pre-established annual rent increases.

Payments related to capitalized patent expenses were approximately \$0.8 million, \$1.2 million and \$0.7 million for 2003, 2002 and 2001, respectively. The decrease in 2003 compared to 2002 is due primarily to consolidation of our patent portfolio with one outside law firm to limit administrative redundancies as well as bringing certain administrative tasks in house to limit outside legal expenses. The increase in 2002 compared

to 2001 was primarily as a result of maturity of our portfolio filings and pursuit of additional claims. We expect payments related to patents to be relatively flat in 2004 compared to 2003 as we anticipate seeing a full year of benefit of our portfolio consolidation with one outside law firm, and as we continue to perform administrative tasks in house whenever possible as we pursue filings and claims in our intellectual property portfolio.

Although we expect our net cash burn to decrease in 2004, we expect to incur higher research and development expenditures in 2004 compared to 2003 levels in connection with our ongoing drug research and development programs, including costs related to clinical trials, research and development activities on sponsored programs and contracts, preclinical testing of product candidates and manufacturing of clinical supplies. We intend to seek collaborative research and development relationships with suitable corporate partners and U.S. government agencies. We have in the past and may in the future also license to third parties some of our technology in markets that we are not pursuing ourselves or through our collaborations. Any agreements that may result from these discussions may not successfully reduce our funding requirements or, if entered into, may be terminated.

We currently anticipate that total revenue for 2004 will be in the range of \$8.5 million to \$10.0 million, which includes anticipated grant and contract revenue, related party revenue and certain license fees. Our estimate assumes that we recognize revenue from milestone or licensing payments under existing agreements with third parties related to the licensing of our technology. We also anticipate that operating expenses for the full year 2004 will rise from \$14.4 million in 2003 to between approximately \$14.5 million and \$15.5 million, representing a 1% to 8% increase over 2003. The anticipated rise in expenses relates to our ongoing Phase I/II clinical trials targeting HIV, lung cancer and colorectal cancer and an increase in expenses under funded grants and contracts from the NIH. We also anticipate using some of our cash in 2004 to fund certain activities in our collaboration with Bavarian Nordic. We will share equally with Bavarian Nordic in all research related expenses not covered under our HIV vaccine contract from the NIH and have included these anticipated expenditures in our operating expense forecast for 2004. We will also become liable in 2004 for payment of license fees of up to \$0.1 million.

With existing cash and interest earned thereon, along with receipts from existing contracts and our recent financing in April 2004, we expect to be able to maintain our current level of operations through 2005, based on anticipated expenditures. We will continue to spend substantial amounts on research and development, including amounts spent for manufacturing clinical supplies, conducting clinical trials for our product candidates and advancing development of certain sponsored and partnered programs. Therefore, we will need to obtain additional funding. We do not have committed external sources of funding and may not be able to obtain any additional funding, especially if volatile market conditions persist for biotechnology companies. If we are unable to obtain additional funding, we will be required to delay, further reduce the scope of or eliminate one or more of our research and development projects, sell the Company or certain of its assets or technologies, or dissolve and liquidate all of its assets. As of December 31, 2003, we had approximately \$6.4 million in cash and cash equivalents. Our future operational and capital requirements will depend on many factors, including:

- whether we are able to secure additional financing on favorable terms, or at all;
- the costs associated with our clinical trials for our vaccine targeting HIV, which began in September 2002, including the status of our contract with the NIH;
- the costs associated with our clinical trials for our vaccine targeting lung and colorectal cancer, which began in February 2003;
- progress with other preclinical testing and clinical trials in the future;
- our ability to establish and maintain collaboration and license agreements and any government contracts and grants;
- the actual revenue we receive under our collaboration and license agreements;
- the actual costs we incur under our research collaboration with Bavarian Nordic;

- the actual payment of license fees which may become payable at the option of the licensor;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and any other proprietary rights;
- competing technological and market developments;
- changes in our existing research relationships;
- continued scientific progress in our drug discovery programs; and
- the magnitude of our drug discovery and development programs.

As is typical in the biotechnology industry, our commercial success will depend in part on not infringing upon the patent or other proprietary rights of others and maintaining the technology licenses upon which our products might be based. Our business is also subject to other significant risks, including the uncertainties associated with our ability to enter into and maintain new collaborations, the lengthy regulatory approval process, and potential competition from other products. Even if our products appear promising at an early stage of development, they may not reach the market for a number of reasons. Such reasons include, but are not limited to, our inability to fund clinical development of such products, or the possibilities that the potential products will be found ineffective during clinical trials, fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale or be uneconomical to market.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2003, and the effect such obligations are expected to have on our liquidity and cash flows in future periods.

	Payments Due by Period				
	Total	Less than 1 Year	Years 2-3	Years 4-5	More than 5 Years
			(unaudited)		
			(in thousands)		
Operating lease obligations(1)	\$3,270	\$585	\$1,222	\$1,297	\$ 166
Licensing and purchase obligations(2)	1,580	94	189	327	970
Deferred compensation	50	48	2	—	—
Total	<u>\$4,900</u>	<u>\$727</u>	<u>\$1,413</u>	<u>\$1,624</u>	<u>\$1,136</u>

- (1) Facilities lease, which expires in March 2009
- (2) Licensing and purchase obligations includes an estimate of \$1,540,000 for future payment obligations under existing license agreements which may become due and payable in the periods specified based on projected achievement of triggering events, although there can be no assurance such events will be achieved in the projected time frames, if at all.

Recently Issued Accounting Standards

In June 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 146 "Accounting for Costs Associated with Exit or Disposal Activities". This statement supercedes Emerging Issues Task Force (EITF) Issue No. 94-3 "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF Issue No. 94-3, a liability is recognized at the date an entity commits to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. The provisions of SFAS No. 146 will be effective for any exit and

disposal activities initiated after December 31, 2002. We adopted these provisions during 2003 and accounted for our work force reduction in September 2003 based on the provisions of SFAS No. 146.

In December 2002, the FASB issued SFAS No. 148 *“Accounting for Stock-Based Compensation — Transition and Disclosure — an amendment of FASB Statement No. 123”*. This statement amends SFAS No. 123 *“Accounting for Stock Based Compensation”* to provide alternative methods of voluntarily transitioning to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123 to require disclosure of the method used to account for stock-based employee compensation and the effect of the method on reported results in both annual and interim financial statements. The disclosure provisions became effective for us beginning with the year ended December 31, 2002. We elected to continue to follow the provisions of the Accounting Principles Board (“APB”) Opinion No. 25, *“Accounting for Stock Issued to Employees”* in accounting for stock based compensation.

In November 2002, EITF reached consensus on EITF Issue No. 00-21, *“Accounting for Revenue Arrangements with Multiple Deliverables,”* which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus of EITF Issue No. 00-21 will be applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. Additionally, companies will be permitted to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, *“Accounting Changes.”*

In May 2003, the FASB issued SFAS No. 150, *“Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity.”* This Statement establishes standards for how we classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires that we classify a financial instrument within its scope as a liability. Some of the provisions of this Statement are consistent with the current definition of liabilities in FASB Concepts Statement No. 6, *“Elements of Financial Statements.”* The remaining provisions of this Statement are consistent with the FASB’s proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own equity shares, depending on the nature of the relationship established between the holder and the issuer. This Statement is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003.

Item 7A. Quantitative and Qualitative Disclosures About Market Risks

At December 31, 2003, our investment portfolio included only cash and money market accounts and had no fixed-income securities. There would be no material impact to our investment portfolio, in the short term, associated with any change in interest rates and any decline in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest income.

Item 8. Consolidated Financial Statements and Supplementary Data

The financial statements and supplemental data required by this item are set forth at the pages indicated in Item 15(a)(1) of this annual report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9(A). Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-14(c) promulgated under the Securities Exchange Act of 1934, as amended, within 90 days prior to the filing date of

this report. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective as of the evaluation date.

(b) Changes in Internal Controls

There have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referenced in paragraph (a) above.

PART III

Item 10. Directors and Executive Officers of the Registrant

The following table sets forth information regarding our current directors and executive officers as of March 15, 2004:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Directors:</i>		
Howard E. ("Ted") Greene, Jr.	61	Chairman of the Board of Directors
William T. Comer, Ph.D.	68	Director
Georges Hibon	66	Director
Michael G. Grey	51	Director
Emile Loria, M.D.	54	Director, President and Chief Executive Officer
John P. McKearn, Ph.D.	50	Director
<i>Executive Officers:</i>		
Emile Loria, M.D.	54	Director, President and Chief Executive Officer
Robert J. De Vaere	46	Vice President, Finance and Administration, and Chief Financial Officer
Mark J. Newman, Ph.D.	48	Vice President, Research and Development

Directors

Mr. Greene, a founder of Epimmune, has served as a director since our inception. He was elected Chairman of the Board in January 1989 and served as President from July 1987 to January 1989. Mr. Greene is a director and founder of Amylin Pharmaceuticals, Inc., a biotechnology company involved in research and development of medicines for treating diabetes and served as Chairman of the Board from 1987 to 1998. He was a general partner of Biovest Partners, a seed venture capital firm specializing in medical technology companies from 1986 until 1993. Prior to Biovest, he was Chief Executive Officer of Hybritech Incorporated, a biotechnology company acquired by Eli Lilly & Company in 1986. Mr. Greene is a director of Amylin and Biosite Incorporated.

Dr. Comer has served as a director since January 1994. Since May 2000, he has been Chairman of the Board of Neurogenetics, Inc., a privately held biopharmaceutical company, where he also served as Interim Chief Executive Officer from March 2000 through March 2002. Dr. Comer served as President and Chief Executive Officer and a member of the Board of Directors of SIBIA Neurosciences, Inc., a biotechnology company, from April 1991 to November 1999. SIBIA was acquired by Merck & Co., Inc. in November 1999. Dr. Comer resigned in November 1999, but continued to serve as a consultant to Merck from December 1999 until August 2000. Dr. Comer previously served in various roles with Bristol-Myers Squibb, a pharmaceutical company, culminating in his position as Senior Vice President of Strategic Management, Pharmaceuticals and Nutritionals. He served as Chairman of Prescient Neuropharma, Inc. until December 17, 2002 and is currently a director of Innapharma, Inc.

Mr. Hibon has served as a director since August 2001. He currently serves as an advisor and has served since 1998 to several companies and organizations in Europe and North America. From 1990 to 1998, he was

with Pasteur Merieux Connaught, now Aventis Pasteur, a pharmaceutical company, most recently as Chairman and Chief Executive Officer of PMC North America, a vaccine focused business. From 1986 to 1989, he was with Gillette group as President Director General of ST Dupont, a luxury goods distributor. He was with Merck & Co., a pharmaceutical company, from 1968 to 1986 during which time he held various executive positions in their European and international operations. He currently serves on the Boards of Directors of Cerep, Aphton Corporation and Care France.

Mr. Grey has served as our director since July 1999. Since June 2003, he has served as President of Structural GenomiX, Inc., a privately held biotechnology company, and has been a member of the Board of Directors of Structural GenomiX since September 2001. From April 2001 until June 2003, he served as Chief Business Officer of Structural GenomiX. Between January 1999 and September 2001, he served as President and Chief Executive Officer of Trega Biosciences, Inc., a biotechnology company. Prior to joining Trega, Mr. Grey served as President of BioChem Therapeutics, Inc., a division of BioChem Pharma, Inc., a pharmaceutical company, from November 1994 to August 1998. During 1994, Mr. Grey served as President and Chief Operating Officer of Ansan, Inc., a biopharmaceutical Company. From 1974 to 1993, Mr. Grey served in various roles with Glaxo, Inc. and Glaxo Holdings, plc, a pharmaceutical company, culminating in his position as Vice President, Corporate Development. Mr. Grey serves on the Board of Directors of Achillion Pharmaceuticals, Inc.

Dr. Loria has served as our director since January 2001. He joined us as President and Chief Executive Officer in June 2001. From 1995 to 2000, he served as President and Chief Executive Officer of Biovector Therapeutics, a vaccine company. Prior to his appointment as Chief Executive Officer, he served as Senior Vice President, Business Development at Biovector from 1994 to 1995. From 1986 to 1993, he was founder and Managing Director of MS Medical Synergy, a company specialized in drug delivery. From 1978 to 1985, Dr. Loria held various positions with the pharmaceutical companies Hoffman La Roche-Kontron, Ciba-Geigy and Sanofi Pharma.

Dr. McKearn has served as our director since April 2000. Dr. McKearn has been the Chief Scientific Officer and a director of Kalypsys Inc., a privately held biotechnology company, since July 2003. Prior to that, he was with Pharmacia Corporation, formerly G.D. Searle and Co., a pharmaceutical company, since 1987. From August 2000 until June 2003, he served as Senior Vice President, Pharmacia Discovery Research, responsible for research activities in cardiovascular diseases, arthritis and oncology. Prior to that he served as Vice President, Searle Discovery Research from 1999 to 2000, Executive Director of Oncology from 1995 to 1999, and directed all arthritis, inflammation and oncology research from 1987 to 1995. Dr. McKearn was a Senior Scientist at E.I. DuPont de Nemours and Company, a pharmaceutical company, from 1985 to 1987 and a member of the Basel Institute for Immunology from 1982 to 1985.

Executive Officers

Mr. De Vaere has served as our Vice President, Finance and Chief Financial Officer since May 2000 and became our Vice President, Finance and Administration in December 2001. Prior to joining us in May 2000, Mr. De Vaere was with Vista Medical Technologies, Inc., a medical device company, since January 1996 where he served as Vice President of Finance and Administration and Chief Financial Officer. Prior to his employment with Vista, he was Director of Finance and Business Management for Kaiser Electro-Optics from April 1993 to January 1996 and Controller for Kaiser Rollmet, an aerospace company, from January 1991 to April 1993.

Dr. Newman has served as our Vice President, Infectious Disease Program since March 1999 and became our Vice President, Research and Development in September 2003. Prior to joining Epimmune, Dr. Newman served as Vice President of Research and Development of Vaxcel, Inc., a vaccine delivery/adjuvant company, from January 1995 to March 1999. Prior to joining Vaxcel, he was Associate Vice President, Research and Development for Apollon, Inc., a DNA vaccine company. He also previously held the position of Senior Director at Cambridge Biotech Corporation.

Board Committees and Meetings

During the fiscal year ended December 31, 2003, the Board held sixteen meetings. Our Board of Directors currently has an Audit Committee, a Compensation Committee and a Nominating Committee.

The Audit Committee is comprised of three independent non-employee directors: Mr. Greene; Mr. Grey; and Dr. Comer. The Board of Directors has adopted an Audit Committee Charter, which among other responsibilities, requires that this committee monitor our financial reporting process and internal control systems, review audit and management reports and review and approve the engagement of the independent auditors. The Audit Committee met two times prior to March 29, 2003 to plan for and discuss the 2002 annual audit with our independent auditors. The Audit Committee met four times after March 29, 2003, to review and discuss our first, second and third quarter financial results and financial statements to be included in our Form 10-Q filings and also acted by unanimous written consent one time during 2003. The Audit Committee met two times following the 2003 fiscal year end to discuss the 2003 annual audit with our independent auditors. The Audit Committee recommends the independent auditors to the Board and provides a direct line of communication between the auditors and the Board. The independent auditors separately meet with the Audit Committee, with and without our management present, to review and discuss various matters, including our financial statements, the report of the independent auditors on the results, scope and terms of their work and their recommendations concerning the Company's financial practices and procedures. All members of the Audit Committee are independent, as defined in Rule 4200(a)(14) of the National Association of Securities Dealers, Inc. ("NASD") listing standards. In addition, our Board of Directors believes that Mr. Greene is an audit committee financial expert. An audit committee financial expert is a person who has (i) an understanding of generally accepted accounting principles and financial statements, (ii) the ability to assess the general application of said principles in connection with the accounting for estimates, accruals and reserves, (iii) experience preparing, auditing, analyzing or evaluating financial statements of comparable breadth and complexity to ours or experience supervising others who do, and (iv) an understanding of internal controls and procedures.

The Compensation Committee is comprised of three independent non-employee directors: Mr. Greene; Dr. Comer; and Dr. McKearn. This Committee administers our stock option plans, stock purchase plan and 401(k) plan, approves salaries, bonuses and other compensation arrangements for our officers and performs such other functions regarding compensation as our Board of Directors may delegate. The Compensation Committee held six meetings and acted by unanimous written consent four times during 2003.

The Nominating Committee is composed of two independent non-employee directors: Mr. Grey and Dr. McKearn. The Board of Directors has adopted a Nominating Committee Charter, which among other responsibilities requires that the Nominating Committee interview, evaluate, nominate and recommend individuals for membership on our Board and committees thereof and nominates specific individuals to be elected as our officers by the Board.

During the fiscal year ended December 31, 2003, all of the Company's directors attended or participated in 75% or more of the aggregate of (i) the total number of meetings of the Board and (ii) the total number of meetings held by all committees of the Board on which such director served during the year.

On December 9, 2003, we adopted a Code of Business Conduct and Ethics applicable to all of our officers, directors and employees. The Code of Business Conduct is filed herewith as Exhibit 14.1. If we make any substantive amendments to the Code of Business Conduct or grant any waiver from a provision of the code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website at www.epimmune.com.

Item 11. Executive Compensation

Director Compensation

Non-employee directors are paid \$2,000 per meeting attended in person and \$500 per meeting attended by phone as compensation for their service on the Board. Directors are not compensated for actions taken by written consent. The members of the Board are eligible for reimbursement of expenses incurred in connection

with their service on the Board. Under the Directors' Deferred Compensation Plan, participating directors may elect on an annual basis to defer all of their cash compensation in a deferred compensation account pursuant to which the deferred fees are credited in the form of share units having a value equal to shares of our common stock share units, based on the market price of the stock at the time the deferred fees are earned. We will continue to credit share units to the participants' deferred compensation accounts on a quarterly basis. When a participant ceases serving as a director, the participant shall be entitled to receive the value of his or her account either in a single lump-sum payment or in equal annual installments, as determined by us, in our sole discretion. No participant entitled to receive a payment of benefits shall receive payment in the form of our common stock.

Directors are currently eligible to receive option grants under our stock option plan in accordance with the policy regarding non-employee director compensation adopted by the Board of Directors in 1999. This policy calls for each non-employee director to be granted annual options to purchase 5,000 shares of our common stock as of the date of each annual meeting of our stockholders. The shares subject to such option are to vest monthly over a twelve-month period, provided the director remains a director upon the date of his re-election to our Board. Newly appointed or elected non-employee directors are eligible for a 20,000-share option grant under this policy with monthly vesting over a forty-eight month period. In July 2003, the Board granted annual options to purchase 5,000 shares of our common stock in connection with the annual meeting of our stockholders to the following non-employee directors: Mr. Greene, Dr. Comer, Mr. Grey, Mr. Hixon, Dr. McKearn and former Board member Dr. Michael Ross at an exercise price of \$1.70 per share.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports in changes in ownership of our common stock and other of our equity securities. Specific due dates for these reports have been established, and we are required to disclose any failure to file by these dates during 2003. Our officers, directors and greater than 10% stockholders are required by the SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Compensation of Executive Officers

The following table shows for the fiscal years ended December 31, 2003, 2002 and 2001, compensation awarded or paid to, or earned by our Chief Executive Officer and our two other most highly compensated executive officers and two former officers, Dr. Chesnut and Mr. McClurg whose employment with us terminated in September 2003. These individuals are referred to as the "named executive officers." During the last three fiscal years, none of the executive officers received any restricted stock awards or long-term incentive payouts; provided, however, Dr. Loria purchased stock from us in 2001 that is subject to vesting.

Summary Compensation Table

Name and Principal Position	Annual Compensation			Long-Term Compensation Awards		All Other Compensation (\$)(2)
	Year	Salary(\$)	Bonus (\$)(1)	Restricted Stock Awards (\$)	Securities Underlying Options (#)	
Dr. Emile Loria(3)(4)	2003	350,000	25,000	0	500,000	3,568
President, Chief Executive Officer	2002	300,000	100,098	0	0	8,528
	2001	162,500	352,592	0	0	208,729
Dr. Mark J. Newman	2003	195,833	25,000	0	50,000	724
Vice President, Research and	2002	185,000	98	0	0	597
Development & Asst. Secretary	2001	168,000	50,000	0	95,000	602

Name and Principal Position	Year	Annual Compensation		Long-Term Compensation Awards		All Other Compensation (\$)(2)
		Salary(\$)	Bonus (\$)(1)	Restricted Stock Awards (\$)	Securities Underlying Options (#)	
Mr. Robert J. De Vaere Vice President, Finance and Administration, Chief Financial Officer and Secretary	2003	195,000	25,000	0	50,000	724
	2002	185,000	98	0	0	398
	2001	168,000	115,000	0	105,000	402
Dr. Robert W. Chesnut(5) Former Executive Vice President, Research and Development and Secretary	2003	168,044	0	0	0	171,726
	2002	245,000	98	0	0	2,150
	2001	231,008	120,000	0	120,000	2,419
Mr. Michael R. McClurg(6) Former Vice President, Business Development	2003	120,032	0	0	0	96,507
	2002	175,000	98	0	0	540
	2001	37,805	0	0	75,000	135

- (1) All officers of the Company were granted a stock bonus award during 2002 of 100 shares of our common stock in exchange for the termination of their participation in the 2002 Management Bonus Plan. The fair market value of our common stock on December 16, 2002, the issuance date, was \$0.98 per share, or \$98 for each award.
- (2) All other compensation consists of life insurance premiums paid by us unless otherwise noted.
- (3) Dr. Loria joined as our President and Chief Executive Officer in June 2001 at an annual salary of \$300,000. Dr. Loria received a signing bonus of \$125,000 and was eligible to earn a performance bonus equal to two percent of any proceeds received by us from any public or private equity financing or other transaction pursuant to which we received funding (other than research funding) that was completed by us between January 16, 2001 and January 16, 2002. During the period from January 16, 2001 and January 16, 2002, we completed transactions in which we received total funding of \$16,379,581 making Dr. Loria eligible for bonus payments of \$327,592 under the provisions of this agreement. Dr. Loria was paid a bonus of \$227,592 in 2001 and the remaining accrued balance of \$100,000 was paid in January 2002. Other compensation includes payments of \$2,181 and \$7,470 in 2003 and 2002, respectively, to independent tax accountants for the preparation of 2002 and 2001 foreign tax returns, and 2001 payments of \$204,427 for relocation to San Diego, California made by us to Dr. Loria.
- (4) Dr. Loria joined as our President and Chief Executive Officer in June 2001. In connection with his employment offer letter and joining our Board of Directors in January 2001, and as an inducement to accept the offer, we sold Dr. Loria 1,056,301 shares of our common stock at a purchase price of \$2.50 per share, the closing price of our common stock on the Nasdaq National Market on the date of purchase. The shares are subject to vesting in equal daily installments during the four-year period following the date of purchase, and we have a right to purchase any unvested shares at the purchase price paid by Dr. Loria in the event of termination of Dr. Loria's service to Epimmune. Dr. Loria issued us a promissory note for \$2,641,000, the aggregate purchase price of the shares, which is secured by a pledge of the shares. In September 2003, Dr. Loria surrendered an aggregate of 963,740 shares of our common stock at the fair market value of \$3.17 per share, in exchange for the prepayment of the outstanding principal and interest under the promissory note.
- (5) Dr. Chesnut was our Executive Vice President, Research and Development until his employment with Epimmune terminated in September 2003. Other compensation includes \$122,500 for severance and \$47,114 for accrued vacation paid to Dr. Chesnut upon his termination.
- (6) Mr. McClurg joined us as our Vice President, Business Development in October 2001. Mr. McClurg's employment with Epimmune terminated in September 2003. Other compensation includes \$87,500 for severance and \$8,647 for accrued vacation paid to him upon his termination.

Stock Option Grants and Exercises

We currently grant options to our executive officers under our 2000 Stock Plan and have previously granted options under our 1997 Stock Plan and our 1989 Stock Option Plan, which terminated in 1999. As of December 31, 2003, options to purchase a total of 154,213 shares were outstanding under the 1997 Stock Plan, options to purchase a total of 368,229 shares were outstanding under the 1989 Stock Option Plan, options to purchase a total of 7,140 shares were outstanding under the 1994 Non-Employee Directors' Stock Option Plan and options to purchase a total of 1,467,870 shares were outstanding under the 2000 Stock Plan. On December 16, 2002 we granted stock bonus awards of 600 shares to our executive officers from the 2000 Plan. There are no options available for grant under the 1997 Stock Plan, the 1989 Stock Option Plan or the 1994 Non-Employee Directors' Stock Option Plan. In December 2003, the Board approved an amendment to the 2000 Stock Plan to include a 1,000,000 increase in the number of shares reserved for issuance under the plan and instructed management to include a proposal on the ballot at its next annual shareholders meeting to approve the increase. As of December 31, 2003, options to purchase 1,467,870 shares of common stock were outstanding and 106,523 shares were available for future grant under the 2000 Stock Plan. In addition, as of December 31, 2003, options to purchase 1,000,000 shares of common stock had been granted, which are contingent on shareholder approval of the 1,000,000 shares increase in the number of shares reserved for issuance under the 2000 Stock Plan.

Options granted under the 1989 Stock Option Plan prior to 1996 generally vested 20% at the end of the first year of the optionee's employment and thereafter daily at the rate of 20% per year during such period of employment. Options granted under the 1989 Stock Option Plan after November 1996 and options granted under the 2000 Stock Plan generally vest 25% at the end of the first year of the optionee's employment and thereafter daily at the rate of 25% per year during such period of employment. Options granted under the subsidiary's plan which we assumed generally vest 25% at the end of the first year of the optionee's employment and thereafter monthly at the rate of 25% per year during such period of employment.

The potential realizable value shown in the table below is calculated based on the terms of the option at its time of grant (10 years in the case of all options). It is calculated by assuming that the stock price on the date of grant appreciates at the indicated annual rate, compounded annually for the entire term of the option and that the option is exercised and sold on the last day of its term for the appreciated stock price. These amounts represent certain assumed rates of appreciation, in accordance with rules of the SEC, and do not reflect our estimate or projection of future stock price performance. Actual gains, if any, are dependent on the actual future performance of our common stock, and no gain to the optionee is possible unless the stock price increases over the option term, which will benefit all stockholders.

The following tables show for the fiscal year ended December 31, 2003, certain information regarding options granted to, exercised by, and held at year-end by the Named Executive Officers:

Options Granted in Last Fiscal Year

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (2)	
	Number of Securities Underlying Options Granted	% Total Options Granted to Employees In Fiscal Year(1)	Exercise or Base Price (\$/Sh)	Expiration Date	5%(\$)	10%(\$)
Dr. Emile Loria	500,000	58.75%	1.54000	09/08/13	484,249	1,227,182
Dr. Mark J. Newman	35,000	4.11%	1.54000	09/08/13	33,897	85,903
	15,000	1.76%	2.11000	11/07/13	19,905	50,442
Mr. Robert J. De Vaere	50,000	5.88%	1.54000	09/08/13	48,425	122,718
Dr. Robert W. Chesnut(3)	—	—	—	—	—	—
Mr. Michael R. McClurg(4)	—	—	—	—	—	—

- (1) Based on 851,000 options granted in 2003 under the 2000 Plan, including grants to executive officers.
- (2) The potential realizable value is calculated based on the terms of the option at its time of grant (10 years in the case of all options). It is calculated by assuming that the stock price on the date of grant appreciates at the indicated annual rate, compounded annually for the entire term of the option and that the option is exercised and sold on the last day of its term for the appreciated stock price. These amounts represent certain assumed rates of appreciation, in accordance with rules of the SEC, and do not reflect the Company's estimate or projection of future stock price performance. Actual gains, if any, are dependent on the actual future performance of the Company's Common Stock, and no gain to the optionee is possible unless the stock price increases over the option term, which will benefit all stockholders.
- (3) Dr. Chesnut's employment as our Executive Vice President, Research and Development terminated in September 2003.
- (4) Mr. McClurg's employment as our Vice President, Business Development terminated in September 2003.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table sets forth summary information with respect to exercisable and unexercisable stock options held as of December 31, 2003 by each of the named executive officers. None of the named executive officers exercised options in fiscal year ended December 31, 2003. The value of the stock options is calculated using the fair market value of our common stock on December 31, 2003 (\$1.81 per share) minus the exercise price of the options.

Name	Shares Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at December 31, 2003	Value of Unexercised In-the-Money Options at December 31, 2003
			Exercisable/Unexercisable	Exercisable/Unexercisable
Dr. Emile Loria	—	—	77,975/422,025	\$21,053/\$113,947
Dr. Robert W. Chesnut(1)	—	—	140,416/140,416	—/—
Dr. Mark J. Newman	—	—	156,600/70,866	\$84,553/\$7,976
Mr. Robert J. De Vaere	—	—	94,610/85,390	\$ 2,105/\$11,395
Mr. Michael R. McClurg	—	—	—/—	—/—

- (1) Dr. Chesnut's employment as our Executive Vice President, Research and Development terminated in September 2003, at which time he signed a consent to amendment of his vested and outstanding incentive stock options, extending the post-termination exercise period and permitting him to exercise his options until September 5, 2004 pursuant to Sections 422(d) and 424(h) of the Internal Revenue Code of 1986.

Employment, Change of Control and Separation Agreements

In May 2000, we entered into severance benefits agreements with Dr. Newman, Vice President, Research and Development, and Mr. Robert De Vaere, Vice President, Finance and Administration and Chief Financial Officer. In March 2001, the severance agreements with Dr. Newman and Mr. De Vaere were amended. Under the agreements, as amended, in the event Dr. Newman or Mr. De Vaere is terminated without cause within one year following a change of control of us, he shall receive a lump-sum payment equal to twelve months of his annual base salary, and all of his unvested stock options shall immediately vest and become exercisable.

In January 2001, we entered into an employment agreement with Dr. Emile Loria, one of our directors, for the position of President and Chief Executive Officer, contingent upon obtaining satisfactory approval to work in the United States. Dr. Loria subsequently obtained such approval in June 2001. The agreement provided an annual salary of \$300,000 for Dr. Loria. In addition, Dr. Loria was eligible to earn a performance bonus equal to two percent of any proceeds received by us from any public or private equity financing or other transaction pursuant to which we received funding (other than research funding) that was completed by us

between January 16, 2001 and January 16, 2002. We also agreed to pay Dr. Loria a signing bonus of \$125,000, certain of his relocation expenses, including the costs of moving household goods to San Diego, temporary furnished living accommodations in San Diego for six months, automobile rental costs in San Diego for up to six months and cost of up to three trips for him and his family to and from France (such expenses were approximately \$200,000), and agreed to pay him \$60,000 to assist him in his relocation.

In addition, in January 2001, we sold Dr. Loria 1,056,301 shares of our common stock at the closing price of such common stock as reported by the Nasdaq National Market on the date of purchase, which was \$2.50 per share. These shares vest in equal daily installments over the four-year period following the purchase date and we have a right to purchase any unvested shares at the purchase price paid by Dr. Loria in the event of termination of Dr. Loria's service to us. Dr. Loria purchased the shares with a promissory note in the principal amount of \$2,641,000, which is secured by a pledge of the shares. The note bears interest at the rate of 5.61% per year, compounded annually. In September 2003, Dr. Loria surrendered an aggregate of 963,740 shares of our common stock at the fair market value of \$3.17 per share, in exchange for the prepayment of the outstanding principal and interest under the promissory note, a total of \$3,055,000.

Under the terms of the employment agreement, Dr. Loria is entitled to continued salary payments for twelve months in the event he is terminated without cause or voluntarily resigns for good reason. In addition, if Dr. Loria is terminated without cause or voluntarily resigns for good reason following a change in control of Epimmune, then Dr. Loria is entitled to receive a lump sum payment equal to one year of his base salary and all of the unvested shares he initially purchased from us will become fully vested.

In February 2004, we entered into an accelerated benefits agreement with Dr. Loria. Under the terms of the agreement, if Dr. Loria is terminated without cause or voluntarily resigns for good reason within one year following a change of control of Epimmune, then any stock options granted to him after December 9, 2003, which are unvested shall immediately vest and become exercisable.

In January 2004, the Compensation Committee of our Board of Directors approved a 2004 bonus plan for the officers of the Company under which the officers would be eligible for bonuses for service to the Company contingent upon the Company reaching certain milestones in accordance with guidelines approved by the Compensation Committee.

Compensation Committee Interlocks and Insider Participation

Mr. Greene, a member of the Compensation Committee, is Chairman of our Board of Directors.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2003 regarding our equity compensation plans.

Name of Plan	(a) Number of Securities to be Issued Upon Exercise of Options, Warrants and Rights	(b) Weighted-average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders.....	1,997,412	\$2.59	106,523
Equity compensation plans not approved by security holders	<u>4,960(1)</u>	<u>\$5.79</u>	<u>0</u>
Total	<u>2,002,412</u>	<u>\$2.60</u>	<u>106,523</u>

(1) This amount includes 4,960 shares of Common Stock that are issuable upon the exercise of warrants that were issued to two former executive officers of Epimmune as part of their severance arrangement pursuant to a severance benefits agreement. This arrangement was not required to be approved by Epimmune's stockholders.

The Company does not have in effect any equity compensation plans under which Epimmune's equity securities are authorized for issuance that were adopted without the approval of Epimmune's security holders, except as noted in the Footnote (1) above.

The following table sets forth certain information regarding the ownership of our common stock as of February 15, 2004 by (i) each director and nominee; (ii) each of the executive officers named in the summary compensation table; (iii) all executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock:

<u>Beneficial Owner</u>	<u>Beneficial Ownership(1)</u>	
	<u>Number of Shares</u>	<u>Percent of Shares</u>
Pharmacia Corporation(2) 5200 Old Orchard Road Skokie, IL 60077	2,020,758	13.3%
Genencor International, Inc. 200 Meridian Centre Blvd. Rochester, NY 14618	1,342,324	9.9%
International Biotechnology Trust plc 71 Kingsway London, WC2B 6ST, England	1,267,992	9.4%
RAM Trading Ltd.(3) 2100 Enterprise Avenue Geneva, IL 60134	1,004,150	7.3%
Mr. Peter Allard(4) Seaview, Chancery Lane Christ Church, Barbados, West Indies	837,716	6.2%
Dr. Robert W. Chesnut(5) (6)	327,050	2.4%
Dr. Emile Loria(6) (7)	243,140	1.8%
Dr. Mark J. Newman(6)	185,596	1.4%
Mr. Howard E. ("Ted") Greene, Jr.(6) (8)	174,350	1.3%
Mr. Robert J. De Vaere(6)	173,035	1.3%
Dr. William T. Comer(6)	44,662	*
Mr. Michael Grey(6)	38,750	*
Dr. John P. McKearn(6)	22,500	*
Mr. Georges Hibon(6)	21,667	*
Mr. Michael R. McClurg(6) (9)	100	*
All executive officers and directors as a group (10 persons) (10)	1,230,850	8.6%

* Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders and on any Schedules 13D or 13G filed with the Securities and Exchange Commission, or the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, each stockholder named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentage ownership is based on 13,525,622 shares of Common Stock outstanding on February 15, 2004, as adjusted by the rules promulgated by the SEC.

- (2) Includes 1,703,298 shares of Common Stock issuable upon conversion of shares of Series S Preferred Stock and Series S-1 Preferred Stock held by Pharmacia Corporation, formerly G.D. Searle, provided that Pharmacia is not entitled to vote such shares to the extent that the total number of shares of voting capital stock held by Pharmacia and its affiliates would exceed 19.9%. Pharmacia owns 100% of the outstanding shares of the Series S Preferred Stock and Series S-1 Preferred Stock. The Series S Preferred Stock and Series S-1 Preferred Stock are convertible into Common Stock at any time.
- (3) Includes 200,830 shares of common stock underlying currently exercisable warrants.
- (4) Includes 66,943 shares of common stock underlying currently exercisable warrants.
- (5) Dr. Chesnut's employment as our Executive Vice President, Research and Development terminated in September 2003, at which time he signed a consent to amendment of his vested and outstanding incentive stock options, extending the post-termination exercise period and permitting him to exercise his options until September 5, 2004 pursuant to Sections 422(d) and 424(h) of the Internal Revenue Code of 1986.
- (6) Includes shares, which certain executive officers and directors of the Company have the right to acquire within 60 days after February 15, 2004 pursuant to outstanding options, as follows:
 - Dr. Robert W. Chesnut, 140,416 shares;
 - Dr. William T. Comer, 43,748 shares;
 - Mr. Robert J. De Vaere, 167,679 shares;
 - Mr. Howard E. ("Ted") Greene, Jr., 42,320 shares;
 - Mr. Michael G. Grey, 38,750 shares;
 - Mr. Georges Hibon, 21,667 shares;
 - Dr. Emile Loria, 150,479 shares;
 - Dr. John P. McKearn, 22,500 shares;
 - Dr. Mark J. Newman, 169,657 shares;
 - All executive officers and directors as a group, 797,216 shares.
- (7) Of the shares held by Dr. Loria, 65,280 shares were subject to a right of repurchase in favor of the Company as of February 15, 2004. Dr. Loria's 65,280 shares vest ratably in equal daily installments until January 16, 2005, at which point all of Dr. Loria's shares will be vested, provided Dr. Loria's service to the Company is not terminated.
- (8) Includes 129,745 shares held in trust for the benefit of Mr. Greene and his wife and 2,285 shares held in trust for the benefit of Mr. Greene's children. Mr. Greene is a trustee of both trusts. Mr. Greene acting as trustee has voting and investment power with respect to such shares and may be deemed to be the beneficial owner of such shares.
- (9) Mr. McClurg's employment as our Vice President, Business Development terminated in September 2003.
- (10) Includes shares described in notes (5) through (8) above.

Item 13. *Certain Relationships and Related Transactions*

Our bylaws provide that we will indemnify our directors and executive officers and may indemnify our other officers, employees and other agents to the fullest extent permitted by Delaware law. We are also empowered under our bylaws to enter into indemnification contracts with our directors and officers and to purchase insurance on behalf of any person whom it is required or permitted to indemnify. Pursuant to this provision, we have entered into indemnity agreements with each of our directors and executive officers.

In addition, our certificate of incorporation provides that to the fullest extent permitted by Delaware law, our directors will not be liable for monetary damages for breach of the directors' fiduciary duty of care to us and our stockholders. This provision in the certificate of incorporation does not eliminate the duty of care, and in appropriate circumstances equitable remedies such as an injunction or other forms of non-monetary relief would remain available under Delaware law. Each director will continue to be subject to liability for breach of the director's duty of loyalty to us, for acts or omissions not in good faith or involving intentional misconduct or

knowing violations of law, for acts or omissions that the director believes to be contrary to our best interests or our stockholders, for any transaction from which the director derived an improper personal benefit, for acts or omissions involving a reckless disregard for the director's duty to us or our stockholders when the director was aware or should have been aware of a risk of serious injury to us or our stockholders, for acts or omissions that constitute an unexcused pattern of inattention that amounts to an abdication of the director's duty to us or our stockholders, for improper transactions between the director and us, and for improper distributions to stockholders and loans to directors and officers. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

We have entered into certain additional transactions with our directors and officers, as described under the captions "Executive Compensation" and "Employment Agreements."

As of December 31, 2003, Genencor held approximately 10.0% of our common stock.

Item 14. Principal Accountant Fees and Services

The following table sets forth the aggregate fees billed or to be billed by Ernst & Young LLP to us for the fiscal year ended December 31, 2003:

	<u>2003</u>	<u>2002</u>
Audit Fees(1)	\$127,000	\$159,000
Audit Related Fees(2)	9,000	—
Tax Related Fees(3)	27,000	28,000
All Other Fees	<u>—</u>	<u>—</u>
	<u>\$163,000</u>	<u>\$187,000</u>

- (1) Audit fees relate to the audit of our consolidated financial statements, reviews of our consolidated financial statements included in our Form 10-Q's for 2003, accounting consultations and review of documents filed with the SEC.
- (2) Audit related fees relate primarily to due diligence associated with a proposed business combination.
- (3) Tax related fees are for services related to tax compliance, tax advice and tax planning.

All fees described above were approved in advance by our Audit Committee.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by Ernst & Young. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services, and tax services up to specified amounts. Pre-approval may also be given as part of our Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual explicit case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of our Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) (1) Index to Financial Statements

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

	Page
Report of Ernst & Young LLP, Independent Auditors	F-2
Consolidated Balance Sheets as of December 31, 2003 and 2002	F-3
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2003	F-4
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2003	F-5
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2003	F-6
Notes to Consolidated Financial Statements	F-7 - F-23

(2) Index to Financial Statement Schedules

The consolidated financial statement schedules required by this item are omitted because they are not applicable or the required information is shown in the Financial Statements or the notes thereto.

(3) Exhibits

The response to this portion of Item 15 is submitted as Item 15(c).

(b) Reports on Form 8-K

Form 8-K filed on November 10, 2003 attaching a press release announcing our financial results for the third quarter ended September 30, 2003.

(c) Listing of Exhibits

Exhibit Number	Document Description
3.1	Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on December 2, 1991.(1)
3.2	Certificate of Designation of Series A Junior Participating Preferred Stock filed with the Secretary of State of Delaware on April 2, 1993.
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on July 5, 1995.
3.4	Certificate of Increase of Series A Junior Participating Preferred Stock filed with the Secretary of State of Delaware on July 5, 1995.
3.5	Certificate of Increase of Series A Junior Participating Preferred Stock filed with the Secretary of State of Delaware on July 2, 1998.(5)
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on July 2, 1998.(5)
3.7	Certificate of Amendment of Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on November 12, 1998.(6)
3.8	Certificate of Designations of the Series S and Series S-1 Preferred Stock filed with the Secretary of State of Delaware on June 29, 1999.(8)

<u>Exhibit Number</u>	<u>Document Description</u>
3.9	Certificate of Amendment of Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on July 1, 1999.(8A)
3.10	Certificate of Amendment of Amended and Restated Certificate of Incorporation filed with the Secretary of State of Delaware on September 23, 1999.(9)
3.11	Certificate of Decrease of Series A Junior Participating Preferred Stock filed with the Secretary of State of Delaware on September 23, 1999.(9)
3.12	Amended and Restated Bylaws of the Registration.(18)
3.13	Rights Agreement dated March 19, 1993 between Registrant and American Stock Transfer & Trust Company, as amended on June 29, 1999, February 15, 2000, July 9, 2001 and December 18, 2001.(18)
4.1	Reference is made to Exhibits 3.1 through 3.13.
4.2	Specimen certificate of the Common stock.(1)
10.1	Form of Indemnification Agreement entered into between Epimmune and its directors and officers.(1)(*)
10.2	Registrant's 1989 Stock Plan, as amended through June 12, 1998 (the "1989 Plan").(5)
10.3	Forms of Incentive Stock Option Agreement under the 1989 Plan.(1)
10.4	Form of Nonstatutory Stock Option Agreement under the 1989 Plan.(1)
10.5	Research Agreement, between Epimmune and The Scripps Research Institute, formerly Scripps Clinic and Research Foundation ("Scripps"), dated as of September 1, 1990, as amended August 5, 1991 (with certain confidential portions deleted).(1)(A)
10.6	License Agreement, between Epimmune and Scripps, dated as of September 23, 1991 (with certain confidential portions deleted).(1)(A)
10.7	Research and Option Agreement, between Epimmune and Scripps, dated October 1, 1991 (with certain confidential portions deleted).(1)(A)
10.8	Amendment to License Agreement between Epimmune and Scripps dated as of June 17, 1992 (with certain confidential portions deleted).(1)(B)
10.9	Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended through June 12, 1998.(5)(*)
10.10	Second Amendment to License Agreement between Epimmune and Scripps dated as of June 17, 1992 (with certain confidential portions deleted).(1)(B)
10.11	Directors' Deferred Compensation Plan, effective as of March 17, 1995, as amended September 20, 1996 and July 13, 1999.(22)(*)
10.12	Lease Agreement between Epimmune Inc. and Nexus Equity LLC VIII, dated as of November 1, 1998, as amended February 1, 1999.(7)
10.13	Preferred Stock Exchange Agreement, dated July 1, 1999, by and between the Company and G.D. Searle & Co.(8)
10.14	Investor Rights Agreement, dated as of July 1, 1999, by and between the Company and G.D. Searle & Co.(8)
10.15	Form of Common Stock Purchase agreement dated February 15, 2000.(10)
10.16	Letter Agreement between Epimmune and Robert De Vaere dated May 4, 2000.(11)(*)
10.17	Letter Agreement between Epimmune and Mark Newman dated May 4, 2000.(11)(*)
10.18	Form of Common Stock Purchase Agreement dated October 16, 2000.(12)
10.19	Non-Exclusive License Agreement between Epimmune and Valentis, Inc., dated November 27, 2000 (with certain confidential portions deleted).(12)(C)
10.20	Letter Agreement between Epimmune and Dr. Emile Loria regarding employment terms dated January 16, 2001.(13)(*)
10.21	Form of Restricted Stock Purchase Agreement between Epimmune and Dr. Emile Loria dated January 16, 2001.(13)(*)

<u>Exhibit Number</u>	<u>Document Description</u>
10.22	Amendment to Severance Benefits Agreement between Epimmune and Dr. Mark Newman dated March 8, 2001.(13)(*)
10.23	Amendment to Severance Benefits Agreement between Epimmune and Robert De Vaere dated March 8, 2001.(13)(*)
10.24	Non-exclusive License Agreement between Epimmune and Pharmexa A/S dated June 25, 2001 (with certain confidential portions deleted).(15)(D)
10.25	License Agreement between Epimmune and Genencor International Inc. dated July 9, 2001 (with certain confidential portions deleted).(15)(D)
10.26	Collaboration Agreement between Epimmune and Genencor International Inc. dated July 9, 2001 (with certain confidential portions deleted).(16)(E)
10.27	Securities Purchase Agreement between Epimmune and Genencor International Inc. dated July 9, 2001 (with certain confidential portions deleted).(16)(E)
10.28	Non-exclusive License Agreement between Epimmune and Biosite Incorporated dated August 17, 2001 (with certain confidential portions deleted).(16)(E)
10.29	Non-exclusive License Agreement between Epimmune and Anosys Inc. dated August 31, 2001 (with certain confidential portions deleted).(16)(E)
10.30	Non-exclusive License Agreement between Epimmune and Bavarian Nordic A/S dated November 28, 2001 (with certain confidential portions deleted).(18)(F)
10.31	Form of Share Purchase Agreement dated December 18, 2001.(17)
10.32	2000 Stock Plan as amended.(18)(*)
10.33	2001 Employee Stock Purchase Plan.(14)(*)
10.34	Letter Agreement between Epimmune and Michael McClurg dated March 29, 2002.(19)(*)
10.35	Letter Agreement between Epimmune and Dr. John Fikes dated March 29, 2002.(19)(*)
10.36	Separation Agreement dated October 14, 2002 between Epimmune and Dr. Sette.(20)(*)
10.37	Material Transfer Agreement dated October 14, 2002 between Epimmune and Dr. Sette.(20)
10.38	First Amendment to the Collaboration Agreement dated October 16, 2002 between Epimmune and Genencor International, Inc.(21)(G)
10.39	First Amendment to the License Agreement dated October 16, 2002 between Epimmune and Genencor International, Inc.(22)
10.40	First Amendment to the Non-Exclusive License Agreement dated October 18, 2002 between Epimmune and Valentis, Inc.(22)(G)
10.41	Non-Exclusive License Agreement dated October 28, 2002 between Epimmune and Valentis, Inc.(22)(G)
10.42	Amendment to Letter Agreement between Epimmune and Dr. Emile Loria dated June 20, 2003.(23)(*)
10.43	Non-Exclusive License Agreement between Epimmune and Immuno-Designed Molecules dated July 7, 2003.(23)(H)
10.44	Form of Unit Purchase Agreement dated September 18, 2003.(24)
10.45	Form of Warrant to Purchase Common Stock dated September 18, 2003.(24)
10.46	Termination of Amendment to Letter Agreement between Epimmune and Dr. Emile Loria dated September 8, 2003.(25)(*)
10.47	Accelerated Benefits Agreement between Epimmune and Dr. Emile Loria dated February 27, 2004.(*)
14.1	Code of Business Conduct and Ethics dated December 9, 2003.
21.1	Subsidiaries of Epimmune.(I)
23.1	Consent of Ernst & Young, LLP, Independent Auditors.
25.1	Power of Attorney. Reference is made to the signature page of this report.

<u>Exhibit Number</u>	<u>Document Description</u>
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted)
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted)
32.1	Certification pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted)

* Executive Compensation Plans and Arrangements

- (1) Incorporated by reference to the Company's Form S-1 Registration Statement and Amendments thereto (File No. 33-43356).
- (2) Incorporated by reference to the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 1992, filed on March 26, 1993.
- (3) Incorporated by reference to the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 1995, filed on March 22, 1996.
- (4) Incorporated by reference to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1997 filed on March 31, 1998.
- (5) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 1998, filed on August 14, 1998.
- (6) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 1998, filed on November 16, 1998.
- (7) Incorporated by reference to the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 1998, filed on April 15, 1999.
- (8) Incorporated by reference to the Company's Form 8-K, filed on July 16, 1999.
- (8A) Incorporated by reference to the Company's Definitive Proxy Statement filed on Form DEF 14A on July 28, 1999.
- (9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 1999, filed on November 15, 1999.
- (10) Incorporated by reference to the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 1999, filed on March 17, 2000.
- (11) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2000, filed on August 14, 2000.
- (12) Incorporated by reference to the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 2000, filed on March 29, 2001.
- (13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended March 31, 2001, filed on May 11, 2001.
- (14) Incorporated by reference to the Company's Form S-8 filed on June 27, 2001 (File No. 333-63950).
- (15) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2001, filed on August 13, 2001.
- (16) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2001, filed on November 14, 2001.
- (17) Incorporated by reference to the Company's Form S-3, filed on January 10, 2002.
- (18) Incorporated by reference to the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 2001, filed on March 29, 2002.

- (19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended March 31, 2002, filed on May 13, 2002.
- (20) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2002, filed on October 16, 2002.
- (21) Incorporated by reference to the Company's Registration Statement on Form S-1, filed on October 24, 2002.
- (22) Incorporated by reference to Amendment No. 1 to the Company's Registration Statement on Form S-1/A, filed on November 6, 2002.
- (23) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2003, filed on August 14, 2003.
- (24) Incorporated by reference to the Company's Current Report on Form 8-K, filed on September 19, 2003.
- (25) Incorporated by reference to the Company's Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2003, filed on November 10, 2003.
- (A) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on November 21, 1991.
- (B) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on May 15, 1996.
- (C) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on July 5, 2001.
- (D) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on September 4, 2001.
- (E) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on January 29, 2002.
- (F) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on May 14, 2002.
- (G) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on November 5, 2002.
- (H) Portions of this exhibit have been granted confidential treatment pursuant to an order granted by the Securities and Exchange Commission on October 22, 2003.
- (I) Previously filed.

(This page intentionally left blank)

EPIMMUNE INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Report of Ernst & Young LLP, Independent Auditors	F-2
Consolidated Balance Sheets as of December 31, 2003 and 2002	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2003, 2002 and 2001 ...	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2003, 2002, and 2001	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2003, 2002 and 2001 ...	F-6
Notes to Consolidated Financial Statements	F-7

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Epimmune Inc.

We have audited the accompanying consolidated balance sheets of Epimmune Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Epimmune Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

San Diego, California

February 20, 2004,

except for the third paragraph of Note 1, the first paragraph of Note 7 and Note 11, as to which the date is April 20, 2004

EPIMMUNE INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2003	2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,416,000	\$ 9,745,000
Accounts Receivable	1,012,000	516,000
Prepays and other current assets	186,000	192,000
Total current assets	7,614,000	10,453,000
Restricted cash	472,000	472,000
Property and equipment, net	1,145,000	1,363,000
Patents, net	3,462,000	3,240,000
	\$ 12,693,000	\$ 15,528,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 1,446,000	\$ 1,336,000
Deferred contract revenues	1,151,000	1,114,000
Accrued payroll and related expenses	173,000	252,000
Current portion of notes payable	—	43,000
Total current liabilities	2,770,000	2,745,000
Deferred rent	212,000	197,000
Stockholders' equity:		
Preferred stock, \$.01 par value, 10,000,000 shares authorized, 1,409,288 shares issued and outstanding at December 31, 2003 and 2002. Liquidation preference of \$10,000,000 at December 31, 2003 and 2002	14,000	14,000
Common stock, \$.01 par value, 25,000,000 shares authorized at December 31, 2003 and 2002; 13,490,618 and 12,153,462 shares issued and outstanding at December 31, 2003 and 2002, respectively	135,000	122,000
Additional paid-in capital	167,537,000	166,454,000
Note receivable from employee	—	(2,932,000)
Deferred compensation	(50,000)	(203,000)
Accumulated deficit	(157,925,000)	(150,869,000)
Total stockholders' equity	9,711,000	12,586,000
	\$ 12,693,000	\$ 15,528,000

See accompanying notes.

EPIMMUNE INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2003	2002	2001
Revenues:			
Research grants and contract revenue	\$ 2,521,000	\$ 1,899,000	\$ 1,831,000
License fees and milestones	1,118,000	487,000	3,750,000
Related party revenue	<u>3,519,000</u>	<u>4,684,000</u>	<u>2,585,000</u>
Total revenues	7,158,000	7,070,000	8,166,000
Costs and expenses:			
Research and development	10,495,000	11,257,000	7,870,000
General and administrative	3,567,000	2,887,000	3,363,000
Restructuring costs	<u>336,000</u>	<u>—</u>	<u>—</u>
Total costs and expenses	<u>14,398,000</u>	<u>14,144,000</u>	<u>11,233,000</u>
Loss from operations	(7,240,000)	(7,074,000)	(3,067,000)
Interest income, net	191,000	587,000	424,000
Other (expense) income, net	<u>(7,000)</u>	<u>(13,000)</u>	<u>(1,000)</u>
Net loss	<u><u>\$ (7,056,000)</u></u>	<u><u>\$ (6,500,000)</u></u>	<u><u>\$ (2,644,000)</u></u>
Net loss per share-basic and diluted	<u><u>\$ (0.58)</u></u>	<u><u>\$ (0.57)</u></u>	<u><u>\$ (0.31)</u></u>
Shares used in computing net loss per share-basic and diluted	<u><u>12,238,745</u></u>	<u><u>11,446,387</u></u>	<u><u>8,533,968</u></u>

See accompanying notes.

EPIMMUNE INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three Years Ended December 31, 2003

	Preferred Stock		Common Stock		Additional Paid-in Capital	Note Receivable from Employee	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Other Comprehensive Loss
	Shares	Amount	Shares	Amount							
Balance at December 31, 2000	1,409,288	\$14,000	7,847,343	\$ 78,000	\$153,726,000	\$ —	\$ (6,000)	\$(141,725,000)	\$ 4,000	\$12,091,000	\$(4,676,000)
Exercise of stock options	—	—	27,753	—	11,000	—	—	—	—	11,000	—
Repurchase of restricted stock	—	—	(20,041)	—	(3,000)	—	—	—	—	(3,000)	—
Issuance of common stock for cash, net of issuance costs of \$61,000	—	—	2,000,000	20,000	4,919,000	—	—	—	—	4,939,000	—
Issuance of common stock in connection with collaboration agreement	—	—	1,154,797	12,000	4,618,000	—	—	—	—	4,630,000	—
Issuance of common stock for the employee stock purchase plan	—	—	28,604	—	73,000	—	—	—	—	73,000	—
Issuance of restricted stock for note	—	—	1,056,301	11,000	2,630,000	(2,641,000)	—	—	—	—	—
Deferred compensation in connection with the issuance of stock options to employees	—	—	—	—	785,000	—	(785,000)	—	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	222,000	—	—	222,000	—
Deferred compensation related to consultant stock options	—	—	—	—	13,000	—	—	—	—	13,000	—
Unrealized gains on available-for-sale securities	—	—	—	—	—	—	—	19,000	—	19,000	19,000
Net loss	—	—	—	—	—	—	—	(2,644,000)	—	(2,644,000)	(2,644,000)
Balance at December 31, 2001	1,409,288	14,000	12,094,757	121,000	166,772,000	(2,641,000)	(569,000)	(144,369,000)	23,000	19,351,000	\$(2,625,000)
Issuance costs related to private placement	—	—	—	—	(14,000)	—	—	—	—	(14,000)	—
Exercise of stock options	—	—	14,764	—	4,000	—	—	—	—	4,000	—
Issuance of common stock in connection with employee stock purchase plan	—	—	43,341	1,000	59,000	—	—	—	—	60,000	—
Issuance of common stock in connection with stock bonus award	—	—	600	—	1,000	—	—	—	—	1,000	—
Interest on note receivable from employee	—	—	—	—	—	(291,000)	—	—	—	(291,000)	—
Deferred compensation in connection with the issuance of stock options to employees	—	—	—	—	(395,000)	—	267,000	—	—	(128,000)	—
Amortization of deferred compensation	—	—	—	—	—	—	99,000	—	—	99,000	—
Deferred compensation related to consultant stock options	—	—	—	—	27,000	—	—	—	—	27,000	—
Unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	(23,000)	—	(23,000)	(23,000)
Net loss	—	—	—	—	—	—	—	(6,500,000)	—	(6,500,000)	(6,500,000)
Balance at December 31, 2002	1,409,288	14,000	12,153,462	122,000	166,454,000	(2,932,000)	(203,000)	(150,869,000)	—	12,586,000	\$(6,523,000)
Issuance of common stock in connection with employee stock purchase plan	—	—	69,300	1,000	55,000	—	—	—	—	56,000	—
Exercise of stock options	—	—	62,635	—	61,000	—	—	—	—	61,000	—
Issuance of common stock in connection with private placement (net)	—	—	2,168,961	22,000	3,588,000	—	—	—	—	3,610,000	—
Amortization of deferred compensation related to note on restricted stock	—	—	—	—	—	—	66,000	—	—	66,000	—
Interest on note receivable from employee	—	—	—	—	—	(123,000)	—	—	—	(123,000)	—
Retirement of common stock in connection with restricted stock buyback	—	—	(963,740)	(10,000)	(2,400,000)	3,055,000	—	—	—	645,000	—
Reversal of deferred compensation related to restricted stock buyback	—	—	—	—	(75,000)	—	75,000	—	—	—	—
Deferred compensation related to restricted stock vesting	—	—	—	—	—	—	12,000	—	—	12,000	—
Net reclass of vested shares from liability to equity	—	—	—	—	(186,000)	—	—	—	—	(186,000)	—
Deferred compensation related to consultant stock options	—	—	—	—	34,000	—	—	—	—	34,000	—
Stock based compensation related to force reduction	—	—	—	—	6,000	—	—	—	—	6,000	—
Net loss	—	—	—	—	—	—	—	(7,056,000)	—	(7,056,000)	(7,056,000)
Balance at December 31, 2003	1,409,288	\$14,000	13,490,618	\$135,000	\$167,537,000	\$ —	\$ (50,000)	\$(157,925,000)	\$ —	\$ 9,711,000	\$(7,056,000)

See accompanying notes.

EPIMMUNE INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2003	2002	2001
Operating activities			
Net loss.....	\$(7,056,000)	\$(6,500,000)	\$(2,644,000)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	866,000	777,000	578,000
Stock based compensation	764,000	(1,000)	235,000
Deferred rent	15,000	31,000	47,000
Write-off of abandoned patents	76,000	232,000	625,000
Interest on note held by stock holder	(123,000)	(291,000)	—
Loss on disposal of assets	2,000	3,000	—
Changes in operating assets and liabilities:			
Prepays and other current assets	(490,000)	(1,000)	(200,000)
Accounts payable and accrued liabilities	(76,000)	(140,000)	471,000
Deferred revenue	37,000	(1,194,000)	2,079,000
Accrued payroll and related expense	(79,000)	30,000	(19,000)
Net cash (used in) provided by operating activities	(6,064,000)	(7,054,000)	1,172,000
Investing activities			
Purchases of property and equipment	(131,000)	(735,000)	(293,000)
Patents	(817,000)	(1,183,000)	(682,000)
Purchases of available-for-sale securities	—	(1,614,000)	(7,626,000)
Maturities of available-for-sale securities	—	12,588,000	2,059,000
Construction in progress	—	—	(10,000)
Net cash (used in) provided by investing activities	(948,000)	9,056,000	(6,552,000)
Financing activities			
Principal payments under equipment notes payable and note payable to bank	(43,000)	(345,000)	(413,000)
Net proceeds from issuance of common stock	3,726,000	50,000	9,650,000
Net cash provided by (used in) financing activities	3,683,000	(295,000)	9,237,000
(Decrease) increase in cash and cash equivalents	(3,329,000)	1,707,000	3,857,000
Cash and cash equivalents at beginning of year	9,745,000	8,038,000	4,181,000
Cash and cash equivalents at end of year	<u>\$ 6,416,000</u>	<u>\$ 9,745,000</u>	<u>\$ 8,038,000</u>
Supplemental disclosure of cash flow information			
Interest paid	<u>\$ 5,000</u>	<u>\$ 22,000</u>	<u>\$ 59,000</u>
Supplemental disclosure of non-cash investing and financing activities			
Unrealized (losses) gains on available-for-sale securities	<u>\$ —</u>	<u>\$ 23,000</u>	<u>\$ 19,000</u>
Sale of restricted common stock for stockholder note receivable	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,641,000</u>
Return of common stock in connection with restricted stock buyback	<u>\$ 2,410,000</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes.

EPIMMUNE INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2003

1. Summary of Significant Accounting Policies

Organization and Business Activity

Epimmune Inc. (the "Company") was incorporated in Delaware on July 10, 1987 as Cytel Corporation. On July 1, 1999, Cytel merged with its majority-owned subsidiary, Epimmune Inc., and changed its name from Cytel Corporation to Epimmune Inc. The Company is focused on the development of therapeutic and prophylactic vaccines for the treatment and prevention of infectious diseases and cancer.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and Cytel Corporation. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of its liabilities in the normal course of business. Through December 31, 2003, the Company has an accumulated deficit of \$157.9 million. Successful completion of the Company's transition to commercialization and to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure and, if necessary, obtaining additional financing and/or reducing expenditures. With existing cash and interest earned thereon, along with receipts from existing contracts and its recent financing in April 2004, the Company expects to be able to maintain its current level of operations through 2005, based on anticipated expenditures.

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of cash, certificates of deposit, treasury securities and repurchase agreements with original maturities at the date of acquisition of less than three months.

Short-term Investments

The Company has classified its investments as available-for-sale and accordingly carries them at fair value. Unrealized holding gains or losses on these securities are included in comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses are also included in interest income. The cost of securities sold is based on the specific-identification method. At December 31, 2003, the Company had no short-term investments in its portfolio.

Concentration of Credit Risk

The Company invests its excess cash in United States government securities and debt instruments of financial institutions and corporations with strong credit ratings. The Company has established guidelines

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

1. Summary of Significant Accounting Policies — (Continued)

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. Management attempts to schedule the maturities of the Company's investments to coincide with the Company's expected cash requirements.

Property and Equipment

Property and equipment is stated at cost and depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the assets or the lease term.

Patent Costs

Patent costs are amortized on a straight-line basis over ten years. The patent costs are shown net of accumulated amortization of \$1,553,000 and \$1,166,000 at December 31, 2003 and 2002, respectively.

Impairment of Long-lived Assets

If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company values the assets at fair value.

Research Grants and Contract Revenue

Research grants and contract revenue represent research and development revenues primarily from the National Institutes of Health. Revenues from grants are recognized on a percentage-of-completion basis as related costs are incurred.

License Revenues and Expenses

The Company recognizes revenues pursuant to Staff Accounting Bulletin No. 101, "Revenue Recognition." Collaboration revenues are earned and recognized as research costs are incurred in accordance with the provisions of each agreement. License fees are earned and recognized in accordance with the provisions of each agreement. Upfront license fees for perpetual licenses where the Company has no performance obligations are recognized when received. License fees with ongoing involvement or performance obligations are recognized over the term of the agreement. For example, in connection with the Company's collaboration with Genencor, because the Company received an upfront license fee, it is being amortized into revenue over the collaboration term. Fees paid to initiate research projects are deferred and recognized over the project period. Milestone payments are recognized as revenue upon the completion of the milestone when the milestone event was substantive, its achievability was not reasonably assured at inception and the Company's performance obligations after milestone achievement will continue to be funded at a comparable level before the milestone achievement. The Company defers revenue recognition until performance obligations have been completed and collectibility is reasonably assured.

Research and development costs are expensed as incurred. Expenses under research grants and contracts, which are included in research and development and for which the Company is reimbursed, were approximately \$5.2 million, \$5.1 million and \$4.3 million for 2003, 2002 and 2001, respectively.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

1. Summary of Significant Accounting Policies — (Continued)

Net Loss Per Share

Basic and diluted net loss per common share is presented in conformity with SFAS No. 128, *Earnings per Share*. In accordance with SFAS No. 128, basic and diluted loss per share has been computed using the weighted average number of shares outstanding during the period, less shares subject to repurchase.

The following table presents the calculation of net loss per share:

	Years Ended December 31,		
	2003	2002	2001
Net loss applicable to common stockholders	\$(7,056,000)	\$(6,500,000)	\$(2,644,000)
Weighted average shares used in computing net loss per share, basic and diluted	12,238,745	11,446,387	8,533,968
Net loss per common share, basic and diluted	\$ (0.58)	\$ (0.57)	\$ (0.31)

The Company has excluded all preferred stock, outstanding stock options and warrants, and shares subject to repurchase from the calculation of diluted loss per common share because all such securities are antidilutive for all periods presented. The total number of shares excluded from the calculation of diluted net loss per share, prior to the application of the treasury stock method for options and warrants, was 4,572,195, 4,078,664, and 4,197,277 for the years ended December 31, 2003, 2002, and 2001, respectively.

Accounting for Stock-based Compensation

The Company has elected to follow Accounting Principles Board (“APB”) Opinion No. 25 “*Accounting for Stock Issued to Employees*” and related interpretations in accounting for its employee stock options because the alternative fair value accounting provided for under SFAS No. 123, “*Accounting for Stock-Based Compensation*” requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB Opinion No. 25, because the exercise price of the Company’s employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

Deferred compensation for options granted to non-employees has been determined in accordance with SFAS No. 123 and Emerging Issues Task Force No. 96-18 as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. Deferred charges for options granted to non-employees are periodically re-measured as the underlying options vest.

Adjusted pro forma information regarding net income or loss is required by SFAS No. 123, and has been determined as if the Company had accounted for its employee stock options under the fair-value method of that Statement. The fair value for these options was estimated at the date of grant using the “Black-Scholes” method for option pricing with the following weighted average assumptions for 2003, 2002, and 2001: risk-free interest rates of 4.5%, 6% and 6%, respectively; dividend yield of 0 for all periods; and a weighted average expected life for all options of six years. The volatility factor assumptions of the expected market price of the Company’s common stock were 112%, 135%, and 139% for 2003, 2002, and 2001, respectively.

For purposes of adjusted pro forma disclosures, the estimated fair value of the option is amortized to expense over the option’s vesting period. The effect of applying SFAS No. 123 for pro forma information is not likely to be representative of the effects on pro forma income (loss) in future years.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

1. Summary of Significant Accounting Policies — (Continued)

The Company's adjusted pro forma information is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Pro forma net loss	\$(7,807,000)	\$(7,258,000)	\$(3,391,000)
Pro forma net loss per share	\$ (0.64)	\$ (0.63)	\$ (0.40)

Comprehensive Income

The Company follows the provisions of SFAS No. 130, "Reporting Comprehensive Income." SFAS No. 130, which provides rules for the reporting and display of comprehensive income (loss) and its components. The Company has disclosed its comprehensive income (loss) in the statement of stockholders' equity.

Restructuring Charges

On September 3, 2003, the Company announced a reduction of its work force aimed at focusing the Company's efforts on its most advanced clinical programs and its sponsored and partnered programs. The Company reduced its research and administrative staff by 11 individuals or 23%, which resulted in a one-time restructuring charge of approximately \$336,000 in the third quarter ended September 30, 2003. As of December 31, 2003, the Company had made payments of \$336,000 related to the work force reduction and no balances were included in accounts payables or accrued liabilities.

Non-recurring Charges

On August 12, 2003, the Company announced that the merger agreement between the Company and Anosys, Inc., entered into on May 9, 2003, was terminated. In connection with the termination of the merger agreement, the Company recorded a charge of \$0.5 million during the second quarter ended June 30, 2003, which is included in General and Administrative costs, to write-off costs it had previously capitalized in connection with the proposed merger.

During the fourth quarter of 2001, the Company recorded a charge of \$492,000 to Research and Development to write off certain patent costs previously capitalized. The write-off was comprised of certain patent costs for which the Company had abandoned the underlying patent due to its evolving business focus as well as certain costs no longer specifically attributable to identifiable patents.

Recently Issued Accounting Standards

In June 2002, the FASB issued SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities". This statement supercedes Emerging Issues Task Force ("EITF") Issue No. 94-3 "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF Issue No. 94-3, a liability is recognized at the date an entity commits to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. The provisions of SFAS No. 146 will be effective for any exit and disposal activities initiated after December 31, 2002. The Company adopted these provisions during 2003 and accounted for its work force reduction in September 2003 based on the provisions of SFAS No. 146.

In December 2002, the FASB issued SFAS No. 148 "Accounting for Stock-Based Compensation — Transition and Disclosure — an amendment of FASB Statement No. 123". This statement amends SFAS No. 123 "Accounting for Stock Based Compensation" to provide alternative methods of voluntarily

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

1. Summary of Significant Accounting Policies — (Continued)

transitioning to the fair value based method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure requirements of SFAS No. 123 to require disclosure of the method used to account for stock-based employee compensation and the effect of the method on reported results in both annual and interim financial statements. The disclosure provisions are effective for the Company beginning with its year ended December 31, 2002. The Company elected to continue to follow the provisions of APB 25 in accounting for stock based compensation.

In November 2002, the EITF reached consensus on EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, which addresses how to account for arrangements that may involve the delivery or performance of multiple products, services, and/or rights to use assets. The final consensus of EITF Issue No. 00-21 will be applicable to agreements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. Additionally, companies will be permitted to apply the consensus guidance to all existing arrangements as the cumulative effect of a change in accounting principle in accordance with APB Opinion No. 20, *Accounting Changes*. The adoption of EITF Issue No. 00-21 had no impact on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes standards for how we classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires that we classify a financial instrument within its scope as a liability. Some of the provisions of this Statement are consistent with the current definition of liabilities in FASB Concepts Statement No. 6, "Elements of Financial Statements." The remaining provisions of this Statement are consistent with the FASB's proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own equity shares, depending on the nature of the relationship established between the holder and the issuer. This Statement is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 had no material impact on our financial position or results of operations.

2. Short-term Investments

The Company did not hold any short-term investments at December 31, 2003 or 2002.

The gross realized gains and losses on sales of available-for-sale securities, which are included in investment income, are as follows:

	Year Ended December 31,		
	2003	2002	2001
Gross gains	\$ —	\$ —	\$ 2,000
Gross losses	—	(18,000)	—
Total net realized (loss) gains	\$ —	\$(18,000)	\$ 2,000

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

3. Balance Sheet Information

Prepays and other current assets consist of the following:

	December 31,	
	2003	2002
Prepaid expenses	\$181,000	\$181,000
Investment interest receivable	5,000	11,000
	\$186,000	\$192,000

Property and equipment consist of the following:

	December 31,	
	2003	2002
Furniture and equipment	\$1,960,000	\$1,869,000
Leasehold improvements	473,000	455,000
	2,433,000	2,324,000
Less accumulated depreciation and amortization	(1,288,000)	(961,000)
	\$1,145,000	\$1,363,000

Depreciation expense for the years ended December 31, 2003, 2002 and 2001 was \$346,000, \$354,000 and \$286,000, respectively.

Accounts payable and accrued liabilities consist of the following:

	December 31,	
	2003	2002
Trade accounts payable and accrued liabilities	\$1,213,000	\$1,272,000
Directors deferred compensation	233,000	64,000
	\$1,446,000	\$1,336,000

4. Stockholders' Equity

Preferred Stock

As of December 31, 2003, the Company had 10,000,000 preferred shares authorized and 859,666 shares of Series S Preferred and 549,622 shares of Series S-1 Preferred issued and outstanding. The Series S and Series S-1 Preferred is convertible into common stock at the option of the holder or will automatically convert upon the closing of a financing in which the Company receives gross proceeds of at least \$15,000,000. The number of common shares into which such Series S and Series S-1 Preferred will convert is determined by dividing the original issue price by the then conversion price. The conversion price of the Series S Preferred is adjusted for any sales of securities below the then conversion price while the Series S-1 Preferred conversion price is fixed. As of December 31, 2003, the Series S Preferred conversion price was \$5.2875 and the Series S-1 Preferred conversion price was \$7.0958. As of December 31, 2003, the Series S Preferred would convert into 1,153,676 shares of common stock and the Series S-1 Preferred would convert into 549,622 shares of common stock. The Company cannot pay dividends on any common stock if any of the Series S or Series S-1 Preferred stock is outstanding unless such dividend is also paid on the Preferred stock on an as-converted basis. The Series S and Series S-1 Preferred shares have a liquidation preference over the common stock of the Company, which was equal to \$10,000,000 at December 31, 2003.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Stockholders' Equity — (Continued)

Common Stock

In September 2003, the Company completed a private placement of 2,168,961 shares of common stock and warrants to purchase up to 542,238 shares of common stock to selected institutional and accredited investors, including current shareholders, for a total purchase price of \$4.05 million. The Company received net proceeds of \$3.6 million. The purchase price of each security, which was the combination of one share of common stock and a warrant to purchase 25% of one share of common stock, was priced at the market value of \$1.86725, which was the sum of the average of the closing bid price of Epimmune common stock as quoted on the Nasdaq National Market for the five days up to and including September 17, 2003, and \$0.03125, the imputed value of a warrant to purchase 25% of one share of common stock. In addition, we issued warrants to purchase an aggregate of 250,000 shares of our common stock to a placement agent for services rendered in connection with the private placement. Each warrant, including the warrant issued to the placement agent, has a three-year term and an exercise price equal to 125% of \$1.86725 or \$2.33406 per share. The Company filed a registration statement to permit registered resales of the common stock and the common stock issuable upon exercise of the warrants sold in the transaction. The registration statement was declared effective on October 21, 2003.

Stock Warrants

In May 2000, the Company issued warrants to purchase 4,960 shares of its common stock with an exercise price of \$1.875 to former officers of Cytel. The warrants were issued in connection with severance agreements and were recorded at their fair value on the date of grant. The expense associated with the issuance of the warrants was included as part of the restructuring charge. The warrants issued in May 2000 will expire May 2004.

In September 2003, the Company issued warrants to purchase 542,238 shares of common stock in connection with its private placement to selected institutional and accredited investors. Each warrant was priced at \$0.03125, the imputed value of a warrant to purchase 25% of one share of common stock. In addition, we issued warrants to purchase an aggregate of 250,000 shares of our common stock to a placement agent for services rendered in connection with the private placement. Each warrant, including the warrant issued to the placement agent, has a three-year term and an exercise price equal to 125% of \$1.86725 or \$2.33406 per share.

Employee Stock Purchase Plan

In October 1991, Cytel adopted an Employee Stock Purchase Plan (the "ESPP") whereby employees, at their option, could purchase shares of Cytel common stock through payroll deductions at the lower of 85% of the fair market value on the plan offering date or 85% of the fair market value of the common stock at the purchase date. The ESPP was terminated in July 1999. As of the termination date of the ESPP, 85,558 shares of common stock had been issued under the Stock Plan.

In March 2001, the Company reserved 300,000 shares of common stock upon the adoption of the Employee Stock Purchase Plan (the "Purchase Plan") whereby employees, at their option, could purchase annually up to 5,000 shares of Epimmune common stock through payroll deductions at the lower of 85% of the fair market value on the plan offering date or 85% of the fair market value of the common stock at the purchase date. As of December 31, 2003, 141,245 shares of common stock had been issued under the Purchase Plan.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Stockholders' Equity — (Continued)

Directors' Deferred Compensation Plan

Under the Directors' Deferred Compensation Plan, participating directors may elect on an annual basis, to defer all of their cash compensation, for service on the Company's Board, in a deferred compensation account pursuant to which the deferred fees are credited in the form of share units having a value equal to shares of the Company's common stock ("Share Units"), based on the market price of the stock at the time the deferred fees are earned. The Company will continue to credit Share Units to the participants' deferred compensation accounts on a quarterly basis. When a participant ceases serving as a director, the participant shall be entitled to receive the value of his or her account either in a single lump-sum payment or in equal annual installments, as determined by the Company in its sole discretion. No participant entitled to receive a payment of benefits shall receive payment in the form of the Company's common stock. For the years ended December 31, 2003, 2002 and 2001 the Company recorded an (expense) benefit of (\$169,000), \$68,000 and (\$72,000), respectively, related to the Directors' Deferred Compensation Plan.

Stock Plans

1989 Stock Plan

In November 1989, the Company adopted a Stock Plan (the "1989 Plan"), under which options may be granted to employees, directors, consultants or advisors. The 1989 Plan provided for the grant of both incentive stock options and nonstatutory stock options. The exercise price of an incentive stock option is not less than the fair market value of the common stock on the date of grant. The exercise price of nonstatutory options is not less than 85% of the fair market value of the common stock on the date of grant. No options granted under the 1989 Plan have a term in excess of ten years from the date of grant. Shares and options issued under the 1989 Plan vest over varying periods of one to six years. Effective June 9, 2000 with the approval of the Company's 2000 Plan, the 1989 Plan was discontinued resulting in cancellation of remaining available shares, and any shares granted under the 1989 Plan that in the future are cancelled or expire will not be available for re-grant. As of December 31, 2003, options to purchase 375,369 shares of common stock were outstanding under the 1989 Plan.

1997 Stock Plan

In December 1997, the Company adopted a Stock Plan (the "1997 Plan"), under which options were granted to employees, directors, and consultants of the Company. The 1997 Plan provided for the grant of both incentive stock options and nonstatutory stock options. The exercise price of an incentive stock option was not less than the fair market value of the common stock on the date of grant. The exercise price of nonstatutory options was not less than 85% of the fair market value of the common stock on the date of grant. No options granted under the 1997 Plan have a term in excess of ten years from the date of grant. Options issued under the 1997 Plan vest over varying periods of one to four years. Options that terminate will not be available for future grant. As of December 31, 2003, options to purchase 154,213 shares of common stock were outstanding under the 1997 Plan.

2000 Stock Plan

In June 2000, the Company adopted a Stock Plan (the "2000 Stock Plan"), and reserved 700,000 shares for issuance under the plan. Options under the plan may be granted to employees, directors, consultants or advisors of the Company. The 2000 Stock Plan provides for the grant of both incentive stock options and nonstatutory stock options. The exercise price of an incentive stock option is not less than the fair market value of the common stock on the date of the grant. The exercise price of nonstatutory options is also not less than the fair market value of the common stock on the date of grant. No options granted under the 2000 Stock Plan

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Stockholders' Equity — (Continued)

have a term in excess of ten years from the date of grant. Options issued under the 2000 Stock Plan may vest over varying periods of up to four years. In December 2001 the Board amended, and the Epimmune stockholders subsequently approved, the 2000 Plan to include a 500,000 increase in the number of shares reserved for issuance under the 2000 Stock Plan to a total of one million two hundred thousand (1,200,000) shares. On December 16, 2002 the Company granted stock bonus awards of 600 shares to its executive officers from the 2000 Plan. In June 2003 the Board amended, and the Epimmune stockholders subsequently approved, the 2000 Plan to include a 400,000 increase in the number of shares reserved for issuance under the 2000 Stock Plan to a total of one million six hundred thousand (1,600,000) shares. In December 2003, the Board approved an amendment to the 2000 Stock Plan to include a 1,000,000 increase in the number of shares reserved for issuance under the plan and instructed management to include a proposal on the ballot at its next annual shareholders meeting to approve the increase. As of December 31, 2003, options to purchase 1,467,870 shares of common stock were outstanding and 106,523 shares were available for future grant under the 2000 Stock Plan. In addition, as of December 31, 2003, options to purchase 1,000,000 shares of common stock had been granted, which are contingent on shareholder approval of the 1,000,000 shares increase in the number of shares reserved for issuance under the 2000 Stock Plan.

Stock Option Repricing

In June 1998, the stockholders approved an Option Exchange Program for certain options under the 1989 Plan. These options vest over a six-year period in accordance with a schedule developed by management, in conjunction with the State of Wisconsin Investment Board, a major stockholder of the Company. On the date of approval, all current employees were eligible to participate; however, options granted to outside directors and consultants to the Company were excluded from the exchange. There were 546,962 options eligible for participation, of which 303,145 options were repriced. The effective exchange price was \$10.7188. Eligible employees who elected to participate forfeited a total of 42,879 shares. These shares were permanently canceled and not returned to the Plan for future grant. The Option Exchange Program imposes restrictive vesting provisions. If the holder exercises vested options before the sixth year, then the remaining unvested options do not vest until the end of the sixth year, at which time all remaining shares will be fully vested.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Stockholders' Equity — (Continued)

The following table summarizes stock option activity under all stock option plans for the three years ended December 31, 2003:

	<u>Shares</u>	<u>Weighted Average Price</u>
Balance at December 31, 2000	1,015,032	\$5.10
Granted	786,000	\$2.65
Exercised	(27,753)	\$0.40
Cancelled	<u>(233,665)</u>	\$4.21
Balance at December 31, 2001	1,539,614	\$4.07
Granted	194,520	\$2.03
Exercised	(15,364)	\$0.28
Cancelled	<u>(33,874)</u>	\$4.74
Balance at December 31, 2002	1,684,896	\$3.86
Granted	851,000	\$1.57
Exercised	(62,635)	\$0.97
Cancelled	<u>(475,809)</u>	\$5.47
Balance at December 31, 2003	<u>1,997,452</u>	\$2.59

The following is a summary of the options outstanding under all of the Company's stock option plans as of December 31, 2003:

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>	<u>Weighted Average Remaining Life in Years</u>	<u>Weighted Average Exercise Price</u>	<u>Options Exercisable</u>	<u>Weighted Average Exercise Price of Options Exercisable</u>
\$ 0.16	66,724	3.96	\$0.16	66,724	\$0.16
\$ 0.48	87,489	4.99	0.48	87,489	0.48
\$ 1.35 - \$ 3.37	1,615,872	8.39	2.13	801,500	2.54
\$ 3.75 - \$ 6.00	175,500	6.11	5.01	165,014	4.97
\$10.50 - \$16.25	40,251	4.63	11.31	40,112	11.31
\$18.82 - \$42.88	<u>11,616</u>	1.18	29.84	<u>11,616</u>	29.84
Total	<u>1,997,452</u>			<u>1,172,455</u>	
Weighted averages		7.78	\$2.59		\$3.16

The weighted average fair value of options granted during 2003, 2002 and 2001 was \$1.51, \$1.87 and \$2.47, respectively.

In March 1993, the Company adopted a Stockholder Rights Plan. The Plan provides for the distribution of a preferred stock purchase right ("Rights") as a dividend for each share of the Company's common stock held as of the record date at the close of business on April 8, 1993. Under certain conditions involving an acquisition by any person or group of 15% or more of the common stock, the Rights permit the holders (other than the 15% holder) to purchase one one-hundredth of a share of Series A Preferred Stock at a price of \$80 per one one-hundredth of a preferred share per Right. Each one one-hundredth of a share of preferred stock has rights, privileges and preferences which make its value approximately equal to the value of a common share. In addition, in the event of certain business combinations, the Rights permit the purchase of

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

4. Stockholders' Equity — (Continued)

the common stock of an acquirer at a 50% discount. Under certain conditions, the Rights may be redeemed by the Board of Directors at a price of \$.01 per Right. The Rights have no voting privileges and are attached to and automatically trade with the Company's common stock. The Rights expired on March 19, 2003.

On January 16, 2001, the Company entered into an employment agreement with Dr. Emile Loria for the position of President and Chief Executive Officer. Dr. Loria was elected to the Company's Board of Directors. Also on January 16, 2001, the Company entered into a Restricted Stock Purchase agreement with Dr. Loria for the purchase of 1,056,301 common shares at \$2.50 per share. The shares vest daily over a four-year period and unvested shares are subject to a repurchase option in favor of the Company. A promissory note with an interest rate of 5.61% was issued for the purchase price of the shares. In September 2003, Dr. Loria surrendered an aggregate of 963,740 shares of our common stock at the fair market value of \$3.17 per share, in exchange for the prepayment of the outstanding principal and interest under the promissory note, a total of \$3,055,000. At the time of the transaction, the Company included \$231,000 associated with the remaining 92,561 unvested shares in accrued liabilities as the Company has a repurchase option on the unvested shares at the original exercise price. As the remaining 92,561 unvested shares vest between September 29, 2003 and January 15, 2005, the liability will be reclassified into equity in equal installments. At December 31, 2003, 74,247 shares were unvested and subject to the repurchase option.

In connection with the prepayment of the note, the Company recorded a non-cash, stock-based compensation charge of approximately \$645,000 in the third quarter of 2003 based on the difference between the fair market price on September 29, 2003 and the exercise price of the shares surrendered by Dr. Loria. The Company also accrued an additional \$62,000 in non-cash, stock-based compensation charges associated with the 92,561 remaining unvested shares, which it will amortize to expense as the unvested shares vest between September 29, 2003 and January 15, 2005. The Company had approximately \$50,000 of accrued deferred compensation at December 31, 2003.

Prior to the prepayment of the promissory note, the Company recorded monthly compensation expense related to the shares sold to Dr. Loria based on the provisions of EITF 95-16, "Accounting for Stock Compensation Arrangements with Employer Loan features under APB 25." For the years ended December 31, 2003, 2002 and 2001, the Company recorded a charge of \$66,000, a benefit of \$127,000 and a charge of \$127,000 of compensation expense respectively.

The Company also recorded compensation expense related to the below market interest rate the promissory note bears. For the years ended December 31, 2003 and 2002, the Company recorded \$66,000 and \$99,000 of compensation expense related to the note respectively. In addition, the Company had \$50,000 and \$203,000 of accrued, deferred compensation expense for the years ended December 31, 2003 and 2002 respectively.

Shares Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at December 31, 2003:

Options granted and outstanding	1,997,452
Options authorized for future grants	106,523
Employee stock purchase plan for future purchases	158,755
Stock warrants	797,198
Stock acquisition rights under existing agreements	1,000,000
Conversion of preferred stock	<u>1,703,298</u>
	<u>5,763,226</u>

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

5. Equipment Loans and Notes Payable

In August 1998, Epimmune entered into a \$1,150,000 loan and security agreement, as amended for capital equipment purchases and certain tenant improvements. These funds were used primarily for enhancement and upgrades of our scientific information management systems databases. Total cumulative advances drawn under the credit line totaled \$1,032,000 at December 31, 2003 and 2002. The capital equipment financed collateralizes all borrowings. The line of credit was paid in-full in March 2003.

Equipment loans and notes payable consist of the following:

	December 31,	
	2003	2002
Equipment loan payable in monthly installments of principal and interest of \$14,600, at 9.44% interest, due March 2003	\$ —	\$43,000
	\$ —	\$43,000

6. Commitments

The Company leases its office and research facility under an operating lease that expires in March 2009. Under this operating lease, the Company pays taxes, insurance and maintenance expenses related to the premises. Epimmune's facility lease requires a letter of credit of \$472,000 to secure the performance of the Company's lease obligation and is reflected as restricted cash. Rent expense was \$582,000 for each the years ended December 31, 2003, 2002 and 2001.

Future minimum lease payments under operating leases at December 31, 2003 are as follows:

<u>Year</u>	<u>Operating Leases</u>
2004	\$ 585,000
2005	602,000
2006	620,000
2007	639,000
2008	658,000
Thereafter	166,000
Total minimum lease payments	\$3,270,000

7. Revenues Under Collaborative Research and Development Agreements

Genencor International, Inc.

In July 2001, the Company entered into a collaboration with Genencor International, Inc. for vaccines to treat or prevent hepatitis B virus, hepatitis C virus and human papilloma virus. Pursuant to the agreement, Epimmune exclusively licensed to Genencor its PADRE and epitope technologies for vaccines to treat or prevent hepatitis B, hepatitis C and human papilloma virus. In connection with this collaboration, the Company received an upfront license fee, which is being amortized over the collaboration term. In addition, Genencor made an initial ten percent equity investment in Epimmune common stock at a premium to the market price. Under the agreement with Genencor, the Company may receive a total of approximately \$60 million in payments, including the initial equity investment but excluding royalties. In January 2002, Epimmune received a payment from Genencor for achievement of the first milestone, identification of a product candidate to treat chronic hepatitis B infection. In February 2004, the Company announced it had earned a milestone payment from Genencor as a result of Genencor filing an IND for a vaccine to Hepatitis B.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. Revenues Under Collaborative Research and Development Agreements — (Continued)

The milestone payments were recognized as revenue when received. The collaboration revenues are being recognized as incurred. In addition, Genencor fully funds Epimmune's research in these specific indications and is obligated to pay the Company royalties on sales of any products that may be developed under the collaboration. The initial collaboration had a term through September 2003, and in October 2002, was extended to September 2004. In March 2004, Genencor assigned its rights under the collaboration to Innogenetics NV. In connection with the assignment by Genencor, the Company extended the collaboration term with Innogenetics through September 2005. In addition, Genencor agreed not to sell or otherwise dispose of any of the Company's common stock it held, without the Company's prior approval, for a minimum of twelve months. Innogenetics has the right to terminate the collaboration early, upon three months written notice, if Epimmune breaches its obligations under the collaboration agreement or upon certain force majeure events. All revenues from Genencor are included in related party revenue.

Bavarian Nordic A/S

In November 2001, the Company entered into a collaboration agreement with Bavarian Nordic A/S to combine its technology and expertise in the fields of T cell epitope identification and vaccine design with Bavarian Nordic's vaccine delivery technology and manufacturing expertise to develop vaccines for the treatment or prevention of HIV infection. The Company did not record revenue on Bavarian Nordic for the years ended December 31, 2003 and 2002.

Beckman Coulter, Inc.

In January 2003, the Company entered into an option and license agreement with Beckman Coulter, Inc. under which Beckman Coulter may acquire a non-exclusive, worldwide license to certain Epimmune epitopes on an epitope-by-epitope basis for certain infectious diseases and cancer indications. Beckman Coulter may use these epitopes for research and diagnostic applications in connection with their MHC Tetramer and other immune response monitoring technologies. Under the terms of the agreement, the Company is entitled to annual option fees, which are being amortized into revenue over the term of the agreement. In the event that Beckman Coulter exercises its option to acquire a license to any specific epitope, the Company will be entitled to additional license fees for each epitope and royalties on product sales in the event any products are commercialized using our technology.

Merck & Co., Inc.

In April 2003, the Company entered into an agreement with Merck & Co., Inc. under which Merck will evaluate select Epimmune epitopes in connection with technology controlled by Merck for the development of certain vaccines. Under the terms of the agreement, the Company will provide Merck a limited number of its proprietary analog, or modified, epitopes, which will then be evaluated in connection with delivery technologies owned or controlled by Merck to determine the activity of the Epimmune epitopes. The Company received an evaluation license fee in connection with the agreement, which is being amortized into revenue over the term of the agreement. Merck has an option to enter into licensing discussions with the Company for the development of the Epimmune epitopes for use in vaccines for the treatment of certain diseases.

Pharmexa A/S

In June 2001, the Company entered into a license agreement with Pharmexa A/S granting Pharmexa a non-exclusive license to the Company's PADRE technology for use in connection with Pharmexa's AutoVac™ technology for controlling autoimmune diseases. In connection with the agreement, the Company received an upfront license fee and is also entitled to receive milestones and royalties on product sales, if any

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. Revenues Under Collaborative Research and Development Agreements — (Continued)

products are ever developed. The upfront license fee was recognized as revenue during 2001 as the Company had no on-going obligations.

Biosite Incorporated

In August 2001, the Company entered into a license agreement with Biosite Incorporated granting Biosite a non-exclusive license to the Company's PADRE technology for use in connection with Biosite's antibody technology which can be used to determine a new molecule's function and its utility as a target for diagnostic or therapeutic products. In connection with the agreement, the Company received an upfront license fee, which was recognized as revenue during 2001, as the Company had no on-going obligations.

Anosys Inc.

In August 2001, the Company entered into a license agreement with Anosys Inc., formerly AP Cells, granting Anosys a non-exclusive license to certain cancer antigens and associated technology for use in *ex vivo* cell therapy. In connection with the agreement, the Company received an upfront license fee, which was recognized as revenue during 2001, as the Company had no on-going obligations. The Company is also entitled to receive milestones and royalties on product sales, if any products are ever developed. In September 2003, the Company announced it had received a milestone payment under the agreement as a result of Anosys filing an IND for a product incorporating technology licensed to them. In addition, the Company announced that it had received payment of additional license fees under the terms of the original agreement as a result of Epimmune regaining all rights to the technology covered by the agreement in Japan. Both the milestone payment and the additional license fees were recognized as revenue in the third quarter ended September 30, 2003. In the event Anosys elects to exercise its rights to include Japan in the territory covered by the agreement, Epimmune will be entitled to an additional license fee payment.

Immuno-Designed Molecules, S.A.

In October 2002, the Company entered into an evaluation and license option agreement with Immuno-Designed Molecules, S.A. for certain cancer antigens for use in IDM's *ex vivo* cancer therapy program. Under the terms of the agreement, IDM had 120 days from the date of the option agreement to evaluate the epitopes and exercise its option to license certain patented and non-patented rights to Epimmune's universal cancer epitope packages for use in *ex vivo* cancer therapy. In February 2003, IDM exercised its option and now has a non-exclusive license to use the epitopes in connection with its Dendritophage™ *ex vivo* technology. The Company received an evaluation license fee when it entered into the evaluation, which is being amortized into revenue over the evaluation period. The Company also received a license fee when IDM exercised its option. The parties have now negotiated and entered into a license agreement and the Company may be entitled to receive commercialization milestone payments and royalties on product sales if IDM develops products using Epimmune's technology.

Amgen Inc.

In September 2003, the Company entered into an agreement with Amgen Inc. under which Amgen acquired a non-exclusive license to Epimmune's PADRE technology for research use. Under the terms of the agreement, Epimmune received a license fee that will be amortized into revenue over the term of the agreement.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. Revenues Under Collaborative Research and Development Agreements — (Continued)

Aventis Pasteur

In July 2002, the Company entered into an evaluation and license option agreement with Aventis Pasteur Limited, which gives Aventis, for twelve months, the right to exercise its option to license from Epimmune certain epitopes from two cancer associated antigens. Aventis will evaluate the epitopes for possible integration into its pox virus therapeutic cancer vaccine program. The Company received an evaluation license fee, which was amortized into revenue over the evaluation period. In June 2003, the end of the evaluation period, Aventis Pasteur chose not to exercise its rights under the agreement.

National Institutes of Health

In September 2003, the Company received a five-year, \$16.7 million contract from the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) for the design and development of prophylactic HIV vaccines for clinical evaluation. The Company will recognize revenue under the contract as reimbursable expenses under the contract are incurred.

In July 2003, the Company received a grant from the National Cancer Institute, or NCI, an institute of the NIH, to support continued epitope analog identification and preclinical development of multi-epitope, analog based cancer vaccines. The grant has a total potential value of approximately \$0.6 million over two years. The activities funded by this grant complement current studies and Phase I/II clinical trials the Company is conducting by providing analog epitopes that extend vaccine coverage to larger segments of the population. The grant was made under the NCI's Flexible System to Advance Innovative Research for Cancer Drug Discovery by Small Business, or FLAIR program.

In October 2002, the Company was awarded a contract from NIAID to conduct research and development aimed at developing a malaria vaccine. The award is part of the NIAID's Millennium Vaccine Initiative that solicits vaccine technology from the private sector to accelerate the development of effective vaccines for malaria and tuberculosis. The program is composed of a Phase A feasibility study and an option for a Phase B development program for a total potential value of \$3.5 million over five years. The Company is working with investigators at the Naval Medical Research Center on the program.

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

8. Income Taxes

Significant components of the Company's deferred tax assets as of December 31, 2003 and 2002 are shown below. A valuation allowance of \$65,668,000 at December 31, 2003 and \$64,187,000 at December 31, 2002 has been recognized to offset the deferred tax assets as realization of such assets is uncertain.

	2003	2002
Deferred tax liabilities:		
Patents expensed for tax	\$ (1,162,000)	\$ (1,098,000)
Total deferred tax liabilities	(1,162,000)	(1,098,000)
Deferred tax assets:		
Capitalized research expenses	1,476,000	605,000
Net operating loss carryforwards	55,167,000	54,732,000
Research and development credits	9,698,000	9,410,000
Other, net	489,000	538,000
Total deferred tax assets	66,830,000	65,285,000
Valuation allowance for deferred tax assets	(65,668,000)	(64,187,000)
Net deferred tax assets	\$ —	\$ —

At December 31, 2003, the Company has federal and California net operating loss carryforwards of approximately \$144,712,000 and \$103,813,000, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for California tax purposes and expiration of the California tax loss carryforwards. The federal tax loss carryforwards will begin expiring in 2004, unless previously utilized. The California tax loss carryforwards will continue to expire in 2004. The Company also has federal and California research and development tax credit carryforwards of \$7,444,000 and \$3,468,000, respectively. The federal research and development tax credit carryforwards will begin expiring in 2004 unless previously utilized. The California research and development tax credit carryforwards do not expire and will carry forward indefinitely until utilized.

Pursuant to Internal Revenue Code Sections 382 and 383, the annual use of the Company's net operating loss and credit carryforwards will be limited because of greater than 50% cumulative changes in ownership, which occurred during 1989 and 1994. However, the Company believes that these limitations will not have a material impact on the financial statements.

9. 401(k) Plan

The Company has a defined contribution plan, the Epimmune Inc. 401(k) Plan, which covers all full-time employees of the Company. This plan allows each eligible employee to voluntarily make pre-tax deferred salary contributions. The Company may make contributions in amounts as determined by the Board of Directors. The Company did not make any matching contributions for the years ended December 31, 2003, 2002 and 2001.

10. Unaudited Quarterly Financial Information

The following tables present unaudited quarterly financial information, for the eight quarters ended December 31, 2002. We believe this information reflects all adjustments (consisting only of normal recurring adjustments) that we consider necessary for a fair presentation of such information in accordance with

EPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

10. Unaudited Quarterly Financial Information — (Continued)

accounting principles generally accepted in the United States. The results for any quarter are not necessarily indicative of results for any future period (in millions, except per share data):

	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
Year Ended December 31, 2003				
Revenues	\$ 1.4	\$ 1.8	\$ 2.0	\$ 1.9
Loss from operations	(1.9)	(2.1)	(2.1)	(1.2)
Net loss	(1.8)	(2.0)	(2.0)	(1.2)
Basic and diluted net loss per share	(0.15)	(0.17)	(0.17)	(0.09)
	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
Year Ended December 31, 2002				
Revenues	\$ 2.0	\$ 1.8	\$ 1.7	\$ 1.6
Loss from operations	(1.3)	(2.3)	(1.6)	(1.8)
Net loss	(1.1)	(2.2)	(1.5)	(1.7)
Basic and diluted net loss per share	(0.09)	(0.19)	(0.13)	(0.15)

11. Subsequent Events

In March 2004, Genencor assigned its rights under the collaboration to Innogenetics NV. In connection with the assignment by Genencor, the Company extended the collaboration term with Innogenetics through September 2005. In addition, Genencor agreed not to sell or otherwise dispose of any of the Company's common stock it held, without the Company's prior approval, for a minimum of twelve months. Innogenetics has the right to terminate the collaboration early, upon three months written notice, if Epimmune breaches its obligations under the collaboration agreement or upon certain force majeure events.

In April 2004, the Company completed a private placement of 2,466,379 shares of common stock and warrants to purchase up to 1,233,188 shares of common stock to selected institutional and accredited investors, including current shareholders, for a total purchase price of \$5.5 million. The Company received net proceeds of \$5.1 million. The purchase price of each security, which is the combination of one share of common stock and, for each two shares of common stock purchased, a warrant to purchase one share of common stock, was priced at the market value of \$2.2125, which was equal to or greater than the sum of the closing bid price of Epimmune common stock as quoted on the Nasdaq National Market on the date of execution of the purchase agreements, and \$0.0625, the imputed value of a warrant to purchase one share of common stock. In addition, the Company issued warrants to purchase an aggregate of 250,000 shares of its common stock to a placement agent for services rendered in connection with the private placement. Each warrant, including the warrant issued to the placement agent, has a three-year term and an exercise price equal to 120% of \$2.2125 or \$2.655 per share.

(This page intentionally left blank)

CORPORATE INFORMATION

BOARD OF DIRECTORS

Howard E. (Ted) Greene, Jr.
Chairman of the Board

William T. Comer, Ph.D.
Chairman of the Board, Neurogenetics, Inc.

Michael G. Grey
President, Structural GenomiX

Georges Hibon
Consultant, Aventis Pasteur, Merck

Emile Loria, M.D.
President & Chief Executive Officer, Epimmune

John P. McKearn, Ph.D.
Chief Scientific Officer and Director,
Kalypsys, Inc.

MANAGEMENT:

Emile Loria, M.D.
President & Chief Executive Officer

Robert J. De Vaere
Vice President, Finance & Administration,
Chief Financial Officer, Secretary

Mark J. Newman, Ph.D.
Vice President, Research & Development,
Assistant Secretary

CORPORATE HEADQUARTERS:

5820 Nancy Ridge Drive
San Diego, California 92121
Phone: (858) 860-2500
Web Address: www.epimmune.com

STOCK LISTING:

Our common stock is traded on the NASDAQ
National Market under the symbol, "EPMN."

INDEPENDENT AUDITORS:

Ernst & Young LLP
501 West Broadway, Suite 1100
San Diego, California 92101

TRANSFER AGENT & REGISTRAR:

American Stock Transfer & Trust
59 Maiden Lane
New York, New York 10038
Phone: (800) 937-5449, or (718) 921-8200
Web address: www.amstock.com

CORPORATE COUNSEL:

Cooley Godward LLP
4401 Eastgate Mall
San Diego, California 92121

INVESTOR RELATIONS CONTACT:

Robert J. De Vaere
Vice President, Finance & Administration,
Chief Financial Officer
Epimmune Inc.
Phone: (858) 860-2553

SEC FORM 10-K:

A copy of our annual report filed with the
Securities and Exchange Commission on
Form 10-K is available without charge by calling
or writing to the address provided above.

ANNUAL MEETING:

Our annual meeting of stockholders will be held at
10:00a.m. on June 15, 2004 at Epimmune
headquarters.

FORWARD-LOOKING STATEMENT

This report includes forward-looking statements
that reflect management's current views of future
events. Actual results may differ materially from
the forward-looking statements due to a number
of important factors described in the most recent
Forms 10-K and 10-Q.

Epimmune® and *PADRE*® are trademarks of
Epimmune Inc.



Epimmune Inc.
5820 Nancy Ridge Drive
San Diego, CA 92121
Tel: 858.860.2500
Fax: 858.860.2600