ANNUAL REPORT

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2002

AUTOIMMUNE INC.

AUTOIMMUNE™

To Our Shareholders:

AutoImmune Inc. had a successful 2002. While continuing to operate in a virtual mode to minimize expenses, we made considerable progress in building a foundation for increasing shareholder value.

Most importantly, we created the potential for additional revenue through the formation of a joint venture with Deseret Laboratories, Inc. to manufacture, market and sell Colloral®, a product for nutritional support of patients with rheumatoid arthritis. The product was launched in February 2003 and we are hopeful it will produce meaningful income for the company in future years.

AutoImmune has licenses for two aspects of its intellectual property with capable partners in deals that could generate significant value for the Company if and when products are approved for sale. The first of these is with Teva Pharmaceutical Industries, Ltd., which is working on an oral formulation of Copaxone® (glatiramer acetate), its injectable product for the treatment of relapsing–remitting multiple sclerosis. After completing additional pharmacological and immunological studies on the oral formulation, Teva has begun planning for the next human clinical trial and seems committed to successful development of this product. The second license is with BioMS Medical Corporation, which has said it will start a Phase III trial of its MBP8298 product for the treatment of chronic progressive multiple sclerosis during 2003. We are pleased with the progress of our licensees this past year and look forward to the results of their clinical studies.

Recruitment has ended for the oral insulin arm of the NIH sponsored diabetes prevention trial (DPT-1), which is testing a therapeutic method covered by AutoImmune's patents, and preliminary results are expected toward the middle of 2003. If the results are positive, it could open the door to an additional licensing opportunity for the company.

The success of our licensing efforts is dependent on expanding and defending AutoImmune's intellectual property. At year end we had 154 issued US and foreign patents, plus nine original and continuation-in-part patent applications with numerous foreign counterparts. The majority of these relate to methods and products that induce immunological tolerance for the treatment of disease. We hope to see more patents issued and continue to support limited research efforts at The Brigham and Women's Hospital.

With adequate financial reserves to wait for results from the clinical trials of our products and the prospect of positive cash flows in the future, we believe we are well positioned for success and remain confident that our technology will be proven of significant therapeutic value.

Your interest in AutoImmune is greatly appreciated. We hope you share our vision for the future.

Sincerely,

Robert C. Bishop
Chairman of the Board
March 24, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2002.

AUTOIMMUNE INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-348-9062**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1199 Madia Street, Pasadena, CA	**91103**
(Address of principal executive offices)	**(Zip Code)**

(626) 792-1235

(Registrant's telephone number, including area code)

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

Title of each Class	Name of each exchange on which registered.
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 is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

On June 28, 2002, the aggregate market value of the voting stock held by non- affiliates of the registrant was $6,227,043(1). As of March 20, 2003, there were outstanding 16,919,623 shares of the registrant's Common Stock, $0.01 par value.

(1) Non-affiliates of the registrant include all shareholders other than directors, executive officers and holders of 5% or more of the registrant's Common Stock.

Documents Incorporated by Reference

Portions of the Company's definitive proxy statement for its annual meeting of shareholders which the Company intends to file within 120 days after the end of the Company's fiscal year ended December 31, 2002 are incorporated by reference into Part III hereof as provided therein.

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PART I

Item 1. Business.

Overview

AutoImmune Inc. (the "Company" or "AutoImmune") is a biopharmaceutical company that owns or has rights to technology that the Company believes could lead to the development of a new class of therapeutics for the treatment of autoimmune and other cell-mediated inflammatory diseases and conditions. The Company believes, based on preclinical and clinical data, that its proprietary approach to therapy can induce tissue-specific immunosuppression without toxicity or significant side effects. Additional clinical and commercial advantages of this approach include the possibility of administering products orally (the preferred method of treating chronic diseases) and the potential for application to a variety of inflammatory diseases and conditions.

Most of the Company's products are based upon the principles of mucosal tolerance. When proteins are administered by a mucosal route (e.g., oral, nasal, or by aerosol to the lungs) the body's natural immune system mechanisms suppress the response that would otherwise arise against a foreign substance. This immune suppression can be directed toward a specific tissue through appropriate selection and dosing of the protein in a mucosally delivered product.

AutoImmune believes it is the leading company for the development of therapeutics based upon the concepts of mucosal tolerance. The status of each of AutoImmune's principal products is as follows:

Colloral®—Between 1991 and 1999, AutoImmune completed ten human clinical trials involving over 1,900 patients to investigate the use of Colloral® as a pharmaceutical for treating the signs and symptoms of rheumatoid arthritis. The data from these trails demonstrated that Colloral is very safe and that patients treated with Colloral often show substantial improvements from baseline in a wide variety of clinical efficacy measures, but not with the consistency needed to justify development of Colloral as a pharmaceutical product. As a result, AutoImmune began exploring the possibility of repositioning Colloral as a nutraceutical. In 2000, the Company completed a market analysis of Colloral as a nutritional supplement and filed a "Notice of New Dietary Ingredient" with the Food and Drug Administration (the "FDA") that was accepted by the FDA without comment.

In August 2002, AutoImmune and Deseret Laboratories, Inc. (a private company headquartered in St. George, Utah) entered into a joint venture by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. AutoImmune's interest in Colloral LLC is greater than 50%, but AutoImmune does not have control of Colloral LLC. Therefore, the investment is accounted for using the equity method. AutoImmune contributed equipment used to manufacture bulk product and a license to certain Colloral-related intellectual property to Colloral LLC. Deseret contributed cash and is committed to providing additional amounts, which additional amounts are refundable if the board of directors of Colloral LLC determines that the money is no longer needed. AutoImmune has no obligation to make additional capital contributions. Colloral LLC began marketing Colloral as a nutraceutical product in February 2003.

AI 401—Under a non-exclusive license for research purposes only which has since been terminated, Eli Lilly and Company supported three different Phase II clinical trials to demonstrate human proof of principle for AI 401 in patients newly diagnosed with Type 1 diabetes. The results from the last of these studies are reported to be positive, but have not yet been published. In addition, Eli Lilly provided AI 401 for the Diabetes Prevention Trial (DPT-1) being conducted by the National Institute for Health ("NIH"). The oral arm of this trial, which completed patient enrollment in November 2002, is designed to determine whether AI 401 can delay or prevent the clinical onset of Type 1 diabetes. AutoImmune currently expects the results from DPT-1 to be announced during the American Diabetes Association meetings in June 2003.

Products for Multiple Sclerosis—In February 1999, AutoImmune entered into an exclusive agreement with Teva Pharmaceutical Industries, Ltd. covering the development by Teva of an oral formulation of Copaxone® (glatiramer acetate), Teva's currently available, injectable drug for multiple sclerosis. This oral formulation uses AutoImmune's proprietary technology for oral tolerance. After an unsuccessful efficacy trail, Teva conducted both immunologic and pharmacological studies on oral formulations and is now preparing to start additional human trials.

In August 2000, the Company entered into an agreement with BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp.), under which it granted BioMS an exclusive license to AutoImmune's patents pertaining to an injectable therapy for the treatment of multiple sclerosis. BioMS has advised AutoImmune that it anticipates starting a Phase III clinical trial during the first half of 2003 on its MBP8298 treatment for chronic progressive multiple sclerosis.

Autoimmune diseases represent a major worldwide health care problem in terms of the number of people affected. The Company believes that each of these products under development offers the potential for a therapeutic breakthrough.

The Company was incorporated in Delaware in September 1988 as AutoImmune Technologies, Inc. The Company changed its name to AutoImmune Inc. in July 1991. The principal executive address of AutoImmune is 1199 Madia Street, Pasadena, CA 91103, and its telephone number is (626) 792-1235.

Strategy

The Company's objective is to become a leading provider of therapeutic technology and products to treat immune system disorders. The key elements of the Company's strategy include the following:

Leveraging the Company's Technology Platform. The Company believes its technology is applicable to a variety of autoimmune and other cell-mediated diseases and conditions. In addition to the development efforts on the products described above, the Company continues to support research on other potential applications of its technology and is currently studying an immunologic approach to decrease myocardial ischemia-reperfusion injury. The Company has, and plans to continue to seek, licensing arrangements, joint ventures or other collaborative arrangements to assist in financing the development and commercialization of its products. This strategy has resulted in the Company's collaboration with Eli Lilly for clinical testing of its products to treat autoimmune-mediated diabetes, the Company's agreement with Teva relating to the development of an oral formulation of Copaxone, the Company's agreement with a subsidiary of Elan Plc relating to its purchase of all of AutoImmune's rights to certain patent applications involving the treatment of Alzheimer's Disease, and the Company's agreement with BioMS relating to the Company's patents pertaining to an injectable therapy for the treatment of multiple sclerosis. It has also resulted in an agreement with OraGen Corporation, under which AutoImmune received an equity position in OraGen in consideration of consulting services related to the development of products using mucosal tolerance for the treatment of certain sequelae of infectious diseases. Most recently, this strategy has resulted in the Company entering into a joint venture with Deseret Laboratories, Inc. to manufacture, market and sell Colloral as a nutraceutical.

The Company continues to develop the technology underlying mucosal tolerance therapy through research conducted primarily at The Brigham and Women's Hospital, a teaching hospital affiliated with Harvard Medical School. This research is designed to further the Company's understanding of the mechanisms of mucosal tolerance with the goal of increasing the effectiveness of the Company's products and exploring new therapeutic applications for this technology. The Company currently has no internal research and development activities or capabilities.

In March, 2000, the Company entered into an agreement under which a subsidiary of Elan Plc purchased all of AutoImmune's rights to certain patent applications involving the treatment of Alzheimer's Disease. Under the

terms of the agreement, AutoImmune has received $7.0 million in cash, and Elan Plc has received warrants to purchase 375,000 shares of AutoImmune Common Stock at $3.13 per share and 375,000 shares of AutoImmune Common Stock at $.7275 per share.

Protecting the Company's Competitive Position. From its inception, the Company has sought to establish a strong proprietary position. As of December 31, 2002, the Company had pending nine original and continuation-in-part United States patent applications and numerous foreign counterparts. The Company has received or has exclusive rights to 154 U.S. and foreign patents, including seven U.S. patents covering the use of oral Type I, II, or III collagen (or fragments of collagen) to treat rheumatoid arthritis in humans; five U.S. patents covering the treatment of cell-mediated autoimmune disease by nasal or by inhalation administration of autoantigens, and in particular covering treatment of multiple sclerosis or rheumatoid arthritis by nasal or inhalation administration of compositions containing myelin basic protein or collagen, respectively, or active fragments thereof; three U.S. patents covering suppression of allograft rejection by oral administration of a major histocompatibility complex Class II antigen or an active fragment thereof; four U.S. patents covering the treatment, or prevention of the onset of, Type 1 diabetes by oral or nasal administration of a composition containing insulin or a fragment of insulin; four U.S. patents covering treatment of multiple sclerosis by oral administration of bovine myelin; one U.S. patent covering the treatment of uveoretinitis using oral S-antigen; one U.S. patent covering the combination of oral tolerance and methotrexate in the treatment of multiple sclerosis; four U.S. patents directed to peptide fragments of myelin basic protein and the use of such fragments in suppressing proliferation of T cells activated in multiple sclerosis patents; and one U.S. patent covering a method for preparing Type II collagen. The U.S. Patent Office has also allowed an application covering bystander suppression of Type 1 diabetes by oral administration of glucagon. The European and Japanese Patent Offices have each granted a patent to the Company covering the use of compositions containing autoantigens to treat a group of human autoimmune diseases. Oppositions (proceedings challenging the patent's validity) were filed against each of the European and Japanese patents by a third party, but both proceedings have now been concluded. Although the Japanese Patent Office initially issued a decision adverse to the patent, AutoImmune eventually prevailed, and the Japanese patent has been reinstated with narrower claims. The Company prevailed in the opposition to its European Patent and that patent remains in force essentially as issued. The European Patent Office has also granted one patent covering bystander suppression of autoimmune disease and one patent covering use of myelin basic protein in the treatment of multiple sclerosis.

Minimizing Costly Infrastructure and Capital Investment. From its inception, the Company has sought to conserve its financial resources. The Company has historically made extensive use of external resources, such as clinical research organizations and consultants. Currently, the Company anticipates it will operate as a "virtual" company to the maximum extent possible by operating without office space and full-time employees as it awaits the results of ongoing clinical trials and business development activities.

Autoimmune Diseases

The human immune system is the major biological defense mechanism responsible for recognizing and fighting disease. The immune system distinguishes foreign substances (antigens) from the body's tissue and rids the body of a wide variety of disease-causing antigens such as bacteria and viruses. T cells, which circulate in the blood, are a major component of this system. There are several types of T cells which play a critical role in recognizing antigens, carrying out the immune response, and regulating the resulting chain of events. These include "helper" T cells, which release factors to amplify the immune response, "killer" T cells, which attack and destroy other cells displaying the targeted antigen, and "regulatory" T cells, which release factors to down-regulate or suppress the immune response and keep it in control.

Autoimmune diseases are generally believed to be a result of an inappropriate response of the immune system. In many autoimmune diseases, the helper and killer T cells go awry and attack the body's healthy tissues. T cells which act in this manner are called autoreactive T cells. These T cells appear to target the antigenic substances present in specific tissues (autoantigens). The antigenic substances differ depending upon the disease

and may change over the course of a disease. In some diseases, the antigenic substances have not been characterized, while in others a number of substances have been found, but the particular role of each has not been identified.

Autoimmune diseases, which may be crippling or fatal, can strike virtually any tissue or organ. The particular disease that occurs depends upon which healthy tissue is attacked. For example, if the tissue attacked is the brain, multiple sclerosis results; if synovial tissue in joints is the target, rheumatoid arthritis results. Type 1 diabetes occurs when certain pancreatic cells are attacked and uveitis occurs when cells of the uvea, the middle, vascular layer in the eye, are attacked.

There is currently no known method for curing autoimmune diseases. These diseases are chronic and require lifelong treatment. Treatments tend to fall into two major categories. The first category involves compounds for palliative treatment, such as anti-inflammatory agents and pain killers for rheumatoid arthritis or insulin for diabetes. In some forms of the diseases, there is no acceptable method of treating even the symptoms. The second category involves the administration of immunosuppressants, which shut down single or multiple parts of the immune system. These immunosuppressants usually have serious toxicity and side effect problems with long-term use.

While there are numerous cell-mediated autoimmune diseases, the Company's technology is presently employed in the development of products for three of these diseases: rheumatoid arthritis, Type 1 diabetes and multiple sclerosis. Rheumatoid arthritis is a chronic disease in which the body's immune system attacks synovial tissue in joints, resulting in a progressive, painful inflammation of the joints, along with crippling deformation of the hands, feet, hips, knees and shoulders. In advanced phases of the disease, symptoms include severe pain, body disfiguration and loss of mobility. The autoimmune form of diabetes (Type I, also known as juvenile or insulin-dependent diabetes) occurs as a result of the body's immune system destroying the insulin-producing islet cells in the pancreas. Although the administration of insulin controls the metabolic abnormalities of the disease, it does not always prevent major debilitating effects, which can include neural degeneration, chronic pain, arteriosclerosis, loss of limbs due to peripheral vascular disease, blindness and kidney failure. In its most severe form, diabetes can result in death. Multiple sclerosis is a neurologic disease which in its most severe form is relentlessly progressive and can result in complete disability within ten years.

The Company has directed its efforts in these areas because each of these diseases and conditions is mediated by the T cells in the immune system, and thus is well suited to AutoImmune's mucosal tolerance approach. No completely satisfactory treatment currently exists for any of these conditions.

The Company's Technology

Most of AutoImmune's products are based upon the principles of mucosal tolerance. Mucosal tolerance utilizes the natural immune system mechanisms associated with the gut (the small intestine), nasal passages, lungs and other mucosally lined tissues. These mechanisms allow the body to accept, or "tolerate", proteins (antigens) absorbed through the mucosal tissue without stimulating an immune response that would otherwise arise against a foreign substance. In a series of extensive research studies directed by Dr. Howard Weiner, who is one of the Company's principal scientific advisors, it was shown that, when properly activated, these mechanisms can be used to treat autoimmune disorders by selectively suppressing the immune system. This discovery forms the basis of the Company's products and patent claims. See "Patents and Proprietary Rights."

The Company's method uses therapeutic substances—antigenic proteins (or derivatives and analogs thereof) found in organs attacked by each disease—which, for example, if delivered orally are disassembled in the gut by the normal digestive processes. Specific fragments of these substances (peptides) attach to antigen-presenting cells on the surface of the gut. The cells involved are those associated with Peyer's Patches, which are groupings of immune system cells surrounding the gut that have been reported to induce immune tolerance. This triggers the immune system to initiate a chain of events that results in the creation of regulatory T cells which migrate

through the blood and lymph system to suppress or down-regulate the immune response at the targeted organ, thereby mitigating the disease. This suppression can be directed toward the tissue under attack in an autoimmune disease by appropriate selection and dosing of the protein in a mucosally-delivered product.

AutoImmune has completed a wide range of human, animal and in vitro tests relating to the mucosal administration of its products in a variety of disease indications. The Company believes these experiments have demonstrated that selective immune system tolerance can be induced by mucosal administration of antigens, suppressing undesirable immune system attacks against healthy tissue without suppressing the entire immune system.

AutoImmune's research has indicated that identification of the precise autoantigen for a disease may not be necessary to develop an effective treatment based on oral tolerance. Research has shown that mucosal tolerance induced by one organ-specific protein is capable of suppressing autoreactive T cells that are attacking a different protein in the same organ. The Company refers to this phenomenon as "bystander suppression," and has filed patents to protect its rights to this discovery. In particular, bystander suppression allows a mucosal tolerance treatment to be effective even if the autoantigen is not precisely identified or changes during the course of a disease, an effect known as "determinant spreading".

In contrast to existing treatments, which are limited to treating only the symptoms of autoimmune disease or which run the risks and side effects of shutting down the entire immune system, the Company's products are intended to interrupt the disease process and be specific to each disease. Moreover, because of the apparent freedom from significant side effects enjoyed by AutoImmune's products, the Company believes they may be prescribed earlier in the disease process than is now customary, and thus may allow patients to avoid most or all of the debilitating effects of autoimmune diseases. The Company believes its approach of inducing the activation of regulatory T cells in order to suppress disease distinguishes it from most others currently conducting autoimmune disease research.

The Company's approach offers a number of important clinical and commercial advantages:

Adverse Reactions Unlikely. The Company believes that since the therapeutic substances used in the products under development employing the Company's technology are protein-based products taken in small quantities and stimulate natural functions, they are unlikely to cause adverse reactions. AutoImmune's human studies to date have shown a lack of both toxicity and significant side effects, which the Company believes may expedite the regulatory process.

Tissue-Specific Immunosuppression. The Company's mucosal tolerance technique utilizes the immune system itself to generate natural immunosuppression in the specific tissue(s) attacked by a disease. It does not down-regulate the entire immune system.

Oral Delivery. Several of the products in development by the Company and its licensees are administered orally, the preferred method of treating chronic diseases. Other forms of immunotherapy that are being marketed require or that are known by the Company to be in development by competitors are likely to require chronic intravenous, sub-cutaneous or intra-muscular administration.

Broad Application. The Company believes that, in addition to the diseases and conditions on which it has been working to date, its mucosal tolerance approach potentially could be applied to the treatment of a variety of other inflammatory diseases and other clinical conditions, including psoriasis and atherosclerosis.

Products

AutoImmune has one product on the market for nutritional support of patients with rheumatoid arthritis. The chart set forth below describes the status of that product.

PRODUCTS ON THE MARKET

Product	Disease/Condition	Status
Colloral®	Rheumatoid Arthritis	Market launched in February 2003 by Colloral LLC, a joint venture between AutoImmune Inc. and Deseret Laboratories, Inc.

Colloral®. Between 1991 and 1999, AutoImmune completed ten human clinical trials involving over 1,900 patients to investigate the use of Colloral® as a pharmaceutical for treating the signs and symptoms of rheumatoid arthritis. The data from these trials demonstrated that Colloral is very safe and that patients treated with Colloral often show substantial improvements from baseline in a wide variety of clinical efficacy measures, but not with the level of consistency needed to justify development of Colloral as a pharmaceutical product. As a result, AutoImmune began exploring the possibility of repositioning Colloral as a nutraceutical. In 2000, the Company completed a market analysis of Colloral as a nutritional supplement and filed a "Notice of New Dietary Ingredient" with the Food and Drug Administration (the "FDA") that was accepted by the FDA without comment. In August 2002, AutoImmune and Deseret Laboratories, Inc. (a private company headquartered in St. George, Utah) entered into a joint venture by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. AutoImmune's interest in Colloral LLC is greater than 50%, but AutoImmune does not have control of Colloral LLC. Therefore, the investment is accounted for using the equity method. AutoImmune contributed equipment used to manufacture bulk product and a license to certain Colloral-related intellectual property to Colloral LLC. Deseret contributed cash and is committed to providing additional amounts, which additional amounts are refundable if the board of directors of Colloral LLC determines that the money is no longer needed. AutoImmune has no obligation to make additional capital contributions. Colloral LLC began marketing Colloral as a nutraceutical product in February 2003.

It is estimated that 1% of the worldwide population suffers from rheumatoid arthritis. In the United States, there are 2.1 million patients with rheumatoid arthritis, including more than 70,000 patients with juvenile rheumatoid arthritis. There is no known cure, but several approaches are used in an attempt to alleviate two major symptoms of the disorder, pain and inflammation. A number of pain relievers are widely used, but most have undesirable side effects. Similarly, a wide variety of anti-inflammatory agents, ranging from aspirin to non-steroidal anti-inflammatory drugs ("NSAIDs"), are used with varying degrees of success. The NSAIDs used to alleviate pain and inflammation have undesirable gastrointestinal side effects that limit their use. None of the available NSAIDs work with consistent efficacy on all types of patients. Several companies have introduced a new class of NSAIDs described as COX-2 inhibitors. These products, which began to enter the market in 1999, alleviate some of the gastrointestinal side effects currently seen with traditional NSAIDS. Broad immunosuppressants are also used to treat rheumatoid arthritis but toxicity limits their use. Additionally, there are several biologic products which have been approved by the FDA for the treatment of rheumatoid arthritis. Most of these biologic products, which are injectables, are TNF (tumor necrosis factor) inhibitors. Several different types of non-pharmaceutical preparations are also used by patients with rheumatoid arthritis, including a number of nutraceutical products.

Principal Products in Development

AutoImmune has products in development for the treatment of Type 1 diabetes and multiple sclerosis. The chart set forth below describes the stage of development of each of the Company's principal products.

PRINCIPAL PRODUCTS IN DEVELOPMENT

Product	Disease/Condition	Development Status
AI 401	Type 1 diabetes	Phase II trials in progress (conducted by the NIH).
Coral®	Multiple sclerosis	Preparing to start Phase II trials (conducted by Teva).
MBP8298	Multiple sclerosis	Preparing to start Phase III trials (conducted by BioMS).

Type 1 Diabetes. In December 1994, the Company entered into a collaborative agreement with Eli Lilly and Company under which Eli Lilly provided support for clinical testing of the Company's autoimmune-mediated (Type 1) diabetes product. This agreement was terminated in the first quarter of 1999 as a result of Eli Lilly's failure to make a required milestone payment. Eli Lilly, however, remained obligated to complete the trials then underway and to provide the Company with full access to the data therefrom, including the right to use such data for any purpose. Under a non-exclusive license for research purposes only, investigators sponsored by Lilly have completed three different Phase II clinical trials to demonstrate human proof of principle for AI 401. The U.S. study was a one-year, double-blind, placebo-controlled trial with more than 200 patients, designed to measure immunological changes, preservation of pancreatic function and time to insulin dependence. Interim data reported in June 1997 showed AI-401 to benefit adult patients who were diagnosed with Type 1 diabetes at age 20 and greater. The final results of this trial are reportedly positive, but have not yet been published. A second Phase II trial, involving approximately 150 patients, was conducted in France. The third trial was conducted in Italy with approximately 80 patients. The results of these latter two trials have been published and show no therapeutic effect in younger patient populations. In addition, Eli Lilly provided AI 401 for the Diabetes Prevention Trial (DPT-1) being conducted by the NIH. This oral arm of this trial, which began in September 1996 and completed patient enrollment in November 2002, is designed to determine whether AI 401 can delay or prevent the clinical onset of Type 1 diabetes. AutoImmune currently expects the results from DPT-1 to be announced during the American Diabetes Association meetings in June 2003.

Approximately 1,000,000 people in the United States suffer from Type 1 diabetes. It is estimated that worldwide there are 180,000 new patients diagnosed with this disease each year. There is no known cure for Type 1 diabetes; at best it can be controlled. In addition, because insulin is a large protein that is not appreciably absorbed through the gut, it must be administered intravenously or intra-muscularly, rather than orally. The limitations of the treatment delivery system and the inconsistency of the therapeutic results have led to major efforts to discover effective new methods of treatment. The Company believes that the preferred therapeutic approach would be an oral treatment such as the Company's which could prevent the onset of the disease (and the related destruction of the insulin-producing cells) in susceptible populations. Methods to pre-screen persons who are genetically susceptible to Type 1 diabetes are being developed by others. AutoImmune expects that individuals who have been diagnosed in the early stages of Type 1 diabetes, as well as those who may be identified through such pre-screening, would constitute the primary market for AutoImmune's diabetes product.

Multiple Sclerosis. In the second quarter of 1997, the Company ceased independent efforts to develop a product for the treatment of multiple sclerosis and began evaluating opportunities to collaborate with third parties in the development of such a product. In this regard, the Company has entered into an exclusive agreement with Teva Pharmaceutical Industries, Ltd. The agreement covers the development by Teva of an oral formulation of Copaxone® (glatiramer acetate), Teva's currently available, injectable drug for multiple sclerosis. This oral formulation, called Coral®, uses the Company's proprietary technology for oral tolerance. After an unsuccessful efficacy trial, Teva conducted both immunologic and pharmacologic studies on oral formulations and is now in preparing to start additional human trials. AutoImmune will receive a $10 million milestone payment if product approval is received and escalating royalties on cumulative sales of all products covered by the Teva agreement.

In August 2000, the Company entered into an agreement with BioMS Medical Corporation under which it granted BioMS an exclusive license to AutoImmune's patents pertaining to an injectable therapy for the treatment of multiple sclerosis. BioMS has advised AutoImmune that it anticipates starting a Phase III clinical trial during the first half of 2003 on its MBP8298 treatment for chronic progressive multiple sclerosis. If the trial is successful and regulatory approval for commercial sale of the product is received, AutoImmune will receive an escalating royalty on cumulative sales of all products covered by the BioMS agreement.

Approximately 350,000 persons in the United States suffer from multiple sclerosis. Approximately one-third of individuals with multiple sclerosis stabilize and never reach a severe stage; others have multiple acute attacks as frequently as two to three times a year. In its most severe form, the disease is relentlessly progressive and can result in complete disability within ten years. Since the early 1980s, non-specific immunosuppressants, such as

cyclophosphamide and azothioprine, have been used with occasional success to slow the progression of this disease in some patients. None of these treatments is capable of stopping multiple sclerosis attacks or halting the progression of the disease without exposing patients to potentially serious side effects. Since 1993, three products have been approved by the FDA for the treatment of relapsing/remitting multiple sclerosis. All three are indicated for reduction of the frequency of multiple sclerosis exacerbations (one is also approved for slowing the progression of disability associated with sclerosis). Each of these drugs is administered by injection and each has side effects, including injection site reactions, flu-like symptoms and shortness of breath.

Additional Products and Research Programs

The Company's additional research and development efforts are currently focused on expanding the applications of mucosal tolerance therapy. The Company believes its mucosal tolerance approach may lead to treatments for cell-mediated inflammatory diseases including atherosclerosis, psoriasis and myocardial ischemic-reperfusion injury.

Raw Materials

The Company is not on its own currently producing any products for clinical or commercial use and has no plans to manufacture products. Colloral LLC, the joint venture between AutoImmune Inc. and Deseret Laboratories, Inc., contracts with Deseret for the manufacturing of Colloral. All of the raw materials used in the manufacture of Colloral are at the present time widely available in the marketplace.

Manufacturing

All of the Company's pharmaceutical products for clinical and commercial use have to be produced under controlled conditions and under current FDA Good Manufacturing Practices. If the Company decides to self-manufacture products, the Company will be required to obtain sufficient technical staff to oversee all production operations, including quality control, quality assurance, technical support and manufacturing management in order to ensure compliance with GMP requirements. If the Company decides to rely upon contract manufacturing arrangements, the Company will depend upon third parties to produce and deliver products in accordance with GMP.

The Company is not on its own currently producing any products for clinical or commercial use and has no plans to manufacture products.

In August 2002, AutoImmune and Deseret Laboratories, Inc. entered into a joint venture by forming Colloral LLC to manufacture, market and sell Colloral® as a nutraceutical. As part of its capital contribution to Colloral LLC, AutoImmune has contributed all of the equipment and procedures previously used to manufacture Colloral to the joint venture. Colloral LLC has contracted with Deseret for the manufacture of Colloral using this equipment and these procedures in accordance with current FDA Good Manufacturing Practices.

Marketing and Sales

In order to market any of its products directly, the Company would need to develop a marketing and sales organization. The Company has no plans to develop its own marketing and sales organization, but rather plans to market and sell its products by entering into agreements or joint ventures with established companies. Such arrangements may be exclusive or non-exclusive and may provide for marketing rights worldwide or in specific markets.

In August 2002, AutoImmune and Deseret Laboratories, Inc. entered into a joint venture by forming Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. Colloral LLC has contracted with Deseret for sales and marketing of Colloral. Colloral LLC began marketing Colloral through direct mail solicitation of individuals who had previously expressed interest in obtaining the product in February 2003. It is anticipated that sales channels and promotional support will be expanded in the future.

Collaborative Research Agreements

During the early stages of its development, the Company chose to operate through a variety of agreements with medical research institutions. AutoImmune's agreements with The Brigham and Women's Hospital ("BWH") and other leading medical research institutions, together with the advantages of the mucosal tolerance mechanism, allowed the Company to conduct pilot human studies and demonstrate the potential utility of its technique in a number of diseases at a comparatively early stage of the Company's development.

The Brigham and Women's Hospital. BWH, a teaching hospital affiliated with Harvard Medical School, has been performing sponsored research for the Company since 1988. The Company's current agreement with BWH extends until June 30, 2003 and is renewable for additional one year periods by mutual consent. The research budget at BWH provides for expenditures by AutoImmune of approximately $48,000 during the twelve months ending June 30, 2003. Under certain circumstances, the Company may reduce its level of expenditures. The Company will own or have exclusive rights to all inventions, improvements and discoveries made at BWH and resulting from the research program, subject to certain rights retained by the U.S. government in any patentable invention conceived or first reduced to practice using federal funds. The Company will pay to BWH (i) a royalty on all products sold by the Company that are subject to a patent covering an invention developed under the research program or as to which rights were acquired by the Company from BWH, and (ii) a percentage of any upfront payments and/or royalties received by AutoImmune with respect to sales of such products by others. BWH also may receive a percentage of any milestone payments the Company receives from licensees or other transferees of such patent after the first commercial sale of a product covered by a patent. If the Company defaults in the payment of any amount due to BWH, BWH will have an option to purchase all technology developed under the research program at a purchase price equal to the sum of all amounts previously paid by the Company to BWH.

The research at BWH constitutes the only ongoing AutoImmune sponsored research activity involving the Company's technology. Other medical research institutions and firms are conducting research in this area and the extent to which they may require a license from AutoImmune to commercialize their efforts can not be determined at this time.

BWH is a shareholder of the Company. Both of the scientists who made the discoveries which led to the founding of AutoImmune are affiliated with BWH.

Patents and Proprietary Rights

The establishment of a strong proprietary position is an important element of AutoImmune's strategy. As of December 31, 2002, the Company had pending nine original and continuation-in-part United States patent applications and numerous foreign counterparts. The Company has received or has exclusive rights to 154 U.S. and foreign patents, including seven U.S. patents covering the use of oral Type I, II, or III collagen (or fragments of collagen) to treat rheumatoid arthritis in humans; five U.S. patents covering the treatment of cell-mediated autoimmune disease by nasal or by inhalation administration of autoantigens, and in particular covering treatment of multiple sclerosis or rheumatoid arthritis using nasal or by inhalation administration of compositions containing myelin basic protein or collagen, respectively, or active fragments thereof; three U.S. patents covering suppression of allograft rejection by oral administration of a major histocompatibility complex Class II antigen or an active fragment thereof; four U.S. patents covering the treatment, or prevention of the onset of, Type 1 diabetes by oral or nasal administration of a composition containing insulin or a fragment of insulin; four U.S. patents covering treatment of multiple sclerosis by oral administration of bovine myelin; one U.S. patent covering the treatment of uveoretinitis using oral S-antigen; one U.S. patent covering the combination of oral tolerance and methotrexate in the treatment of multiple sclerosis; four U.S. patents directed to peptide fragments of myelin basic protein and the use of such fragments in suppressing proliferation of T cells activated in multiple sclerosis patents; and one U.S. patent covering a method for preparing Type II collagen. The U.S. Patent Office has also allowed an application covering bystander suppression of Type 1 diabetes by oral administration of glucagon.

The European and Japanese Patent Offices have each granted a patent to the Company covering the use of compositions containing autoantigens to treat a group of human autoimmune diseases. Oppositions (proceedings challenging their validity) were filed against these patents by a third party, but both have now been successfully concluded. Although the Japanese Patent Office initially issued a decision adverse to the patent, the Company eventually prevailed, and the Japanese patent has been reinstated with narrower claims. The Company prevailed in the opposition to its European patent and that patent remains in force essentially as issued. The European Patent Office has also granted one patent covering bystander suppression of autoimmune disease and one patent covering use of myelin basic protein in the treatment of multiple sclerosis.

The Company owns a patent application originally filed by BWH for the treatment of autoimmune diseases by oral administration of autoantigens, which includes a number of specific claims directed to the treatment of multiple sclerosis. The disclosure contained in this initial patent application has been significantly expanded in a chain of successor applications. There can be no assurance, however, that patents will be granted on these applications or that the Company will succeed in developing additional products that are patentable.

The Company has applied for patents, or acquired rights to patent applications, covering oral or more broadly mucosal tolerance methods of treating or preventing other specific autoimmune diseases and related conditions, including uveitis, Type 1 diabetes, transplant rejection, Alzheimer's disease and vascular disease. It has filed applications that claim tolerization treatment of autoimmune diseases by inhalation of autoantigens, specific peptides thought to be involved in multiple sclerosis, and bystander suppression, by which tolerance can be induced without identifying the specific antigen causing an autoimmune disease.

There can be no assurance that patent applications owned by, or licensed to, the Company will issue as patents or that, if issued, the Company's patents will be valid or that they will provide the Company with meaningful protection against competitors or with a competitive advantage. There can be no assurance that the Company will not need to acquire licenses under patents belonging to others for technology potentially useful or necessary to the Company and there can be no assurance that such licenses will be available to the Company, if at all, on terms acceptable to the Company. Moreover, there can be no assurance that any patent issued to or licensed by the Company will not be infringed or circumvented by others. In particular, if the Company is unable to obtain issuance of a patent with broad claims with respect to oral tolerance treatment of autoimmune diseases or if the Company is unable to prevail in oppositions against foreign patents of the Company with similar claim scope a competitor may be able to design around the Company's patent rights by employing a treatment that is not covered by the Company's subsisting patents.

Much of the Company's know-how and technology may not be patentable. To protect its rights, the Company requires employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for the Company's trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. In addition, the Company's business may be adversely affected by competitors who independently develop competing technologies, especially if the Company obtains no, or only narrow, patent protection.

Lastly, there can be no assurance that third-parties will not bring suit against the Company for patent infringement by the Company or a licensee of the company or for declaratory judgment to have the Company's patents declared invalid.

Competition

The pharmaceutical and nutraceutical industries are highly competitive, and research on the causes of and possible treatments for autoimmune and other cell-mediated inflammatory diseases is developing rapidly. The Company competes with a number of pharmaceutical and biotechnology companies which have financial, technical and marketing resources significantly greater than those of the Company. Companies with established positions in the pharmaceutical and nutraceutical industries are better equipped than the Company to develop and

market products based on the application of new technologies to the treatment of autoimmune diseases. A significant amount of research in the field is also being conducted at universities and other not-for-profit research organizations. These institutions are becoming increasingly aware of the commercial value of their findings and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. These institutions also may market competitive commercial products on their own or through joint ventures.

The Company's competitors may succeed in developing products that are more effective than those of the Company. Rapid technological change or developments by others may result in the Company's products and potential products becoming obsolete or non-competitive.

For additional information concerning products developed and under development by the Company's competitors to treat rheumatoid arthritis, see "Products – Colloral®."

Government Regulation

The manufacturing and marketing of the Company's products and certain areas of its research are subject to regulation for safety and efficacy by numerous government authorities in the United States and other countries. Domestically, the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of the Company's products. There can be no assurance that the Company will ever obtain the government approval necessary to make commercial sales of any of its products currently in research or development.

AutoImmune believes that some of its pharmaceutical products under development will be classified by the FDA as "biologic products," while others may be classified as "drug products." While both biologics and drugs can qualify for Orphan Drug status, biologics, once approved, have no current provision for subsequent competitors to market generic versions. Each biologic, even if it has the same composition and is for the same indication as a regulatory approved biologic, must undergo the entire development process in order for a competitive firm to obtain FDA approval for it.

New drug or biological products require several steps in order to receive regulatory approval, including (i) preclinical laboratory and animal tests; (ii) submission by the Company or an individual physician to the FDA of an application for an Investigational and New Drug Application ("IND"), or submission to a research institution of an Institutional Review Board for approval of intrastate trials, one of which must become effective before human clinical trials may start; (iii) the performance of well-controlled clinical trials; and (iv) the submission of a New Drug Application ("NDA") or Biologics License Application ("BLA") containing the results of clinical trials and methods of manufacture of the product prior to commercial sale or shipment of the product. During the approval process, the FDA must confirm that good laboratory and clinical practices were maintained during product testing as well as good manufacturing practices were employed in product manufacture.

Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess potential product safety and efficacy. The results of the preclinical tests are submitted to the FDA as part of an IND, and, unless the FDA objects, the IND becomes effective and clinical trials may begin 30 days after the FDA receives the filing.

The initial clinical evaluation, Phase I trials, generally involve administration of a product to a small number of persons. The product is tested for safety, dosage tolerance, metabolism, and pharmacokinetic properties. Phase II trials generally involve administration of a product to a limited number of patients with a particular disease to determine dose level, efficacy and safety. Phase III trials generally examine the clinical efficacy and safety in an expanded patient population at multiple clinical sites. The FDA reviews the clinical plans and the results of trials and can discontinue the trials at any time if there are significant safety issues or if there is convincing evidence

that a drug is not effective for the purpose for which it is being investigated. Each of AutoImmune's clinical trials will be conducted with the approval of an Institutional Review Board at the institution where the trial will be conducted. The Institutional Review Board considers, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. Pivotal Phase III trials are designed to demonstrate definitive efficacy. More than one trial is usually required for FDA approval to market a drug. The results of the preclinical and clinical trials are submitted after completion of the pivotal Phase III trials in the form of a BLA or NDA for approval to commence commercial sales. The approval process is affected by several factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may also require post-marketing surveillance to monitor potential adverse effects of the product. The regulatory process can be modified by Congress or the FDA in specific situations.

The length of the regulatory review process cannot be predicted with certainty for new individual products. The Drug Price Competition and Patent Term Restoration Act, however, defines the original period of enforceability for a product or use patent to be 17 years from issuance or 20 years from filing. Under certain circumstances, to compensate the patent holder for the time required for FDA regulatory review, this period may be extended for up to 5 years. This Act also establishes a period following FDA approval of a product during which the FDA may not accept or approve short-form applications for generic versions of the drug from other sponsors.

AutoImmune's nutraceutical product is classified by the FDA as a dietary supplement and is subject to regulation under the Dietary Supplement Health and Education Act of 1994.

The Company also will be subject to government regulations enforced under the Occupational Safety and Health Act, the Environmental Protection Act, the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other national, state or local restrictions.

In addition, the ability to successfully commercialize the Company's human therapeutic 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 coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and there can be no assurance that adequate third-party coverage will be available for the Company to maintain price levels sufficient for realization of an appropriate return on its investment in product development.

Employees

As of March 20, 2003, AutoImmune has no full-time employees. The President and the Director of Finance are currently working for the Company on a part-time basis and are deemed to be common law employees.

Factors To Be Considered

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which involve risks and uncertainties. The Company's actual results may differ significantly from results discussed in the forward-looking statements due to a number of important factors, including, but not limited to the Company's extremely limited operations, uncertainties of clinical trial results and product development, the Company's dependence on third parties for licensing revenue and the risks of technological change and competition. Set forth below is a discussion of certain factors that could cause the Company's actual results to differ materially from the results projected in such forward looking statements.

A "Virtual Company". Since January 2000, the Company has operated as a virtual company. It has no full-time employees and its activities, conducted through the Company's President and Director of Finance, who

work part-time for the Company, are primarily directed toward finding companies that will license the Company's technology and develop, manufacture and sell products based upon this technology. Consequently, the Company's prospects are entirely dependent upon its efforts to find commercial partners on terms acceptable to the Company and upon the efforts and success of these partners and the Company's existing partners.

Developmental Stage of the Company's Products. The Company has not completed the development of any product except Colloral®. The Company's pharmaceutical products require significant additional clinical testing and/or investment prior to commercialization. Products for therapeutic use in human health care must be evaluated in extensive human clinical trials to determine their safety and efficacy as part of a lengthy process to obtain government approval. Positive results for a product in a clinical trial do not necessarily assure that future clinical trials will yield positive results or that the government will approve the commercialization of the product. Clinical trials may be terminated at any time for many reasons, including toxicity or a lack of efficacy based upon mid-trial examinations of clinical trial data or adverse event reporting. There can be no assurance that the Company will successfully develop additional products or that the Company's products will prove to be safe and efficacious in clinical trials, meet applicable regulatory standards, receive required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed.

Lack of Product Revenues. From its inception in 1988 through December 31, 2002, the Company accumulated net losses of $108,359,000. The Company may incur additional losses as the Company continues to sponsor research and to pursue opportunities to license and otherwise exploit its technology. The Company's ability to achieve profitable operations depends in part on successful completion of the development by the Company and others of products utilizing the Company's technology, the ability to obtain any required regulatory approvals and the ability to manufacture and market these products. There can be no assurance that the Company will achieve profitable operations at any time.

The Company's revenues to date have been earned in connection with collaborative/licensing agreements and the granting of short term rights (see "Dependence upon Collaborative Agreements" below). Payments to the Company under these arrangements generally depend upon royalties based upon sales of products, the achievement of certain milestones or the satisfaction of other conditions. For example, the Company granted certain patent rights to Teva Pharmaceutical Industries, Ltd. in return for future payments based upon the achievement of certain milestones and royalties based on sales, if any, and the Company entered into an agreement with BioMS Medical Corporation which provides for the payment of royalties based on sales of a product, if any. To date, there have been no sales under either of these arrangements. Because revenues under these agreements are contingent upon the achievement of certain conditions, there can be no assurance that the Company will derive any additional revenues from these agreements.

In August 2002, AutoImmune and Deseret Laboratories, Inc. (a private company headquartered in St. George, Utah) entered into a joint venture by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. AutoImmune's interest in Colloral LLC is greater than 50%, but AutoImmune does not have control of Colloral LLC. Therefore, the investment is accounted for using the equity method. To the extent that Colloral LLC generates revenues in excess of cumulative losses, AutoImmune will record income. During February 2003, Colloral LLC began marketing Colloral through direct mail solicitation of individuals who had previously expressed interest in obtaining the product. It is anticipated that sales channels and promotional support will be expanded in the future, but there can be no assurance that the Company will derive revenues from this arrangement.

Additional Financing Requirements and Access to Capital. Since inception, the Company has raised net proceeds of $116,000,000 from the sale of equity securities in private placements and public stock offerings. The Company does not believe it currently has the ability to raise significant additional funds. Based upon its budget for calendar year 2003, the Company believes that current cash and marketable securities and the interest earned from the investment thereof will be sufficient to meet the Company's operating expenses and capital

requirements for at least five years. Thereafter, or if the Company's operations change substantially, the Company will need to raise substantial additional capital to fund its operations, including clinical trials and commercialization efforts.

Dependence on Collaborative Agreements. Currently, the Company is wholly dependent upon collaborative agreements with others. The Company has granted Teva Pharmaceutical Industries, Ltd. exclusive worldwide rights to certain of its patents covering multiple sclerosis and myasthenia gravis applications of its technology. These rights were granted in return for payments based upon the achievement of certain milestones and royalties based on sales, if any. The Company also has granted BioMS Medical Corporation exclusive worldwide rights to certain patents covering a product to treat multiple sclerosis. The agreement with BioMS provides for monthly diligence payments which escalate annually and royalties based on sales, if any, which obligations to make such diligence payments will cease if BioMS terminates the agreement. Most recently, the Company entered into a joint venture with Deseret Laboratories, Inc. by forming Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. There can be no assurance that the Company will be able to negotiate other acceptable arrangements in the future or that such arrangements will be successful.

The majority of the Company's basic research to date has been done through agreements with BWH and other medical research institutions. Between 1993 and 1999, the Company conducted some of its research and most of its development activities internally. Currently, the Company has no employees engaged in research and product development. Therefore, the Company expects to continue to be dependent upon research performed under contract with BWH. If the Company is unable to maintain this relationship, the Company would be adversely affected and the Company's ability to commercialize future products may be delayed.

Patents and Proprietary Rights. The Company's success will depend, in part, on its ability to obtain patents, maintain trade secret protection and operate or enable others to operate without infringing on the proprietary rights of third parties or having third parties circumvent the Company's rights. The Company has received or has exclusive rights to 154 U.S. and foreign patents. The Company has filed and is actively pursuing numerous applications for additional U.S. and foreign patents, and is an assignee or licensee of the rights to other patent applications. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. For example, the emerging policy of the United States Patent Office and the federal courts appears to favor narrowing claims in biotechnology patents. Thus, there can be no assurance that any patents issued to the Company will provide the Company with any competitive advantages or will not be challenged by any third parties, that the patents of others will not impede the ability of the Company to do business or that third parties will not be able to circumvent the Company's patents, that the Company's licensees will not terminate their licenses or that they will be successful in producing and marketing products that trigger the payment of royalties to the Company, or that any of the Company's patent applications will result in the issuance of patents. Furthermore, there can be no assurance that others will not develop independently similar products, duplicate any of the Company's product, or those of the Company's licensees, or, if patents are issued to the Company, design around the patented products developed by the Company.

The Company or its licensees may be required or may desire to obtain licenses from third parties to avoid infringing patents or other proprietary rights owned by third parties or to avoid third party patents blocking the activities of the Company's licensees. No assurance can be given that any license required or desired under any such patents or proprietary rights would be available, if at all, on terms acceptable to the Company or to its licensees. If the Company or its licensees do not obtain such licenses, the Company or its licensees could encounter delays in product introductions, or could find that the development, manufacture or sale of products requiring such licenses could be prohibited. In addition, the Company could incur substantial costs in defending itself in suits for patent infringement brought against the Company or a licensee of the Company or in filing suits against others to have such patents declared invalid.

Much of the Company's know-how and technology may not be patentable. To protect its rights, the Company requires employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for the

Company's trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Furthermore, the Company's business and that of its licensees may be adversely affected by competitors who independently develop competing technologies, especially if the Company obtains no, or only narrow, patent protection.

Technological Change and Competition. The biotechnology, pharmaceutical and nutraceutical industries are subject to rapid and significant technological change. The Company's competitors are numerous and include, among others, major pharmaceutical companies, biotechnology firms, nutraceutical firms, universities and other research institutions in the United States and abroad. There can be no assurance that the Company's competitors will not develop technologies and products that would render the Company's technology and products obsolete or noncompetitive. Most of these competitors have substantially greater financial and technical resources and production and marketing capabilities than the Company. In addition, most of the Company's competitors have significantly greater experience than the Company in conducting preclinical testing and clinical trials of pharmaceutical products and obtaining FDA and other regulatory approvals of products for use in health care. Accordingly, the Company's competitors may obtain FDA approval for products more rapidly than the Company.

The Company currently has no internal research and development activities or capabilities. The Company relies upon sponsored research with BWH for its research and development activities. The research budget at BWH for Company sponsored research during the twelve months ended June 30, 2003 is approximately $48,000.

Government Regulation. Prior to marketing, any pharmaceutical product utilizing the Company's technology must undergo rigorous preclinical testing and clinical trials, as well as an extensive regulatory approval process mandated by the FDA and foreign regulatory agencies. These processes can take many years and require the expenditure of substantial resources. Delays in obtaining regulatory approvals would adversely affect the marketing of the Company's products and the Company's ability to receive product royalties. There can be no assurance that the clearances and approvals necessary for the clinical testing or manufacturing and marketing of these products can be obtained. Existing or additional government regulation could prevent or delay regulatory approval of these products or affect the pricing or marketing of these products.

AutoImmune's nutraceutical product is classified by the FDA as a dietary supplement and is subject to regulation under the Dietary Supplement Health and Education Act of 1994. Failure to comply with these regulations could result in the product being withdrawn from the market.

Item 2. Properties.

The Company is currently operating in a virtual mode utilizing the personal office spaces of the President and the Director of Finance and therefore has no leases. The principal executive office of the Company is located at the President's personal office in Pasadena, California.

Item 3. Legal Proceedings.

The Company is not a party to any litigation or legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to a vote of the Company's shareholders during the fourth quarter of fiscal year 2002.

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

The Company's common stock is traded on the Nasdaq SmallCap Market under the symbol AIMM. The following table shows the quarterly high and low closing price on Nasdaq for a share of the Company's common stock for the fiscal years ended December 31, 2001 and 2002.

	Price range of common stock	
	High	Low
Fiscal year ending December 31, 2001		
First quarter	$2.65	$1.47
Second quarter	$4.00	$2.04
Third quarter	$3.80	$0.62
Fourth quarter	$1.39	$0.84
Fiscal year ending December 31, 2002		
First quarter	$1.35	$1.03
Second quarter	$1.09	$0.60
Third quarter	$1.09	$0.49
Fourth quarter	$0.93	$0.63

As of March 20, 2003, there were 203 record holders and approximately 5,000 total shareholders of the Company's common stock.

AutoImmune has never declared or paid any cash dividends on its capital stock. The Company currently intends to retain its earnings, if any, and therefore does not anticipate paying any cash dividends on its capital stock in the foreseeable future.

Item 6. Selected Financial Data.

The selected financial data set forth below are derived from financial statements that have been audited by PricewaterhouseCoopers LLP, independent accountants. The balance sheets at December 31, 2001 and December 31, 2002 and the related statements of operations and of cash flows for the three years ended December 31, 2000, December 31, 2001 and December 31, 2002 and notes thereto appear elsewhere in this Form 10-K. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Company's financial statements and related notes included elsewhere in this Form 10-K.

	For the year ended December 31,				
	1998	1999	2000	2001	2002
Statement of Operations Data:					
Revenue:					
License rights	$ —	$ —	$ 4,010,000	$ 1,348,000	$ 70,000
Total revenue	—	—	4,010,000	1,348,000	70,000
Costs and expenses:					
Research and development:					
Related party	1,314,000	1,170,000	260,000	135,000	61,000
All other	11,496,000	7,649,000	522,000	237,000	327,000
General and administrative	1,712,000	2,416,000	679,000	589,000	661,000
Total costs and expenses	14,522,000	11,235,000	1,461,000	961,000	1,049,000
Income (loss) from operations	(14,522,000)	(11,235,000)	2,549,000	387,000	(979,000)
Interest income, net	1,337,000	570,000	599,000	461,000	190,000
Other expense	—	—	—	—	(100,000)
Net income (loss)	$(13,185,000)	$(10,665,000)	$ 3,148,000	$ 848,000	$ (889,000)
Net income (loss) per share—basic	$ (0.80)	$ (0.64)	$ 0.19	$ 0.05	$ (0.05)
Net income (loss) per share—diluted	$ (0.80)	$ (0.64)	$ 0.18	$ 0.05	$ (0.05)
Weighted average common shares outstanding—basic	16,491,701	16,602,911	16,743,349	16,909,541	16,919,623
Weighted average common shares outstanding—diluted	16,491,701	16,602,911	17,288,172	17,253,299	16,919,623

	December 31,				
	1998	1999	2001	2000	2002
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 17,528,000	$ 6,973,000	$ 9,883,000	$ 10,792,000	$ 10,018,000
Working capital	16,325,000	6,411,000	9,753,000	10,697,000	9,912,000
Total assets	18,326,000	7,082,000	9,955,000	10,934,000	10,099,000
Capital lease obligations less current maturities	—	—	—	—	—
Deficit accumulated during development stage	(100,805,000	(111,470,000)	(108,322,000	(107,474,000)	(108,363,000)
Total stockholders' equity	16,917,000	6,411,000	9,753,000	10,797,000	9,912,000

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

Results of Operations

Overview

The sections of "Management's Discussion and Analysis of Financial Condition and Results of Operations" contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 which involve risks and uncertainties. The Company's actual results may differ significantly from results discussed in the forward-looking statements due to a number of important factors, including, but not limited to the Company's extremely limited operations, the uncertainties of clinical trial results and product development, the Company's dependence on third parties for licensing and other revenue and risks of technological change and competition.

Since its inception through December 31, 2002, the Company has incurred ongoing losses from operations and has cumulative losses as of December 31, 2002 totaling $108,359,000. Through year end 2002, the Company has not recorded any revenue from the sale of products. Revenue recorded through December 31, 2002 was earned in connection with license rights, contract research and the granting of certain short-term rights. As a result, inflation has not materially affected the Company's revenues and income from continuing operations.

In August 2002, AutoImmune and Deseret Laboratories, Inc. entered into a joint venture by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. AutoImmune's interest in Colloral LLC is greater than 50%, but AutoImmune does not have control of Colloral LLC. Therefore, the investment is accounted for using the equity method. To the extent that Colloral LLC generates revenues in excess of cumulative losses, AutoImmune will record income. In February 2003, Colloral LLC began marketing Colloral through direct mail solicitation of individuals who had previously expressed interest in obtaining the product. It is anticipated that sales channels and promotional support will be expanded in the future, but there can be no assurance that the Company will derive revenues from this arrangement. Accordingly, the Company might remain in the development stage in the future and may continue to incur substantial losses.

Years Ended December 31, 2001 and 2002

Revenue was $1,348,000 and $70,000 for the years ended December 31, 2001 and 2002, respectively. In 2001, revenue was comprised of $1,308,000 in payments by a subsidiary of Elan Plc for the purchase of certain patent rights related to Alzheimer's disease and monthly license payments from BioMS Medical Corporation. The revenue in 2002 was comprised of monthly license payments from BioMS.

Research and development expenses were $372,000 and $388,000 for the years ended December 31, 2001 and 2002, respectively. The increase is primarily due to $80,000 in higher patent-related legal costs which were offset in part by the $74,000 reduction of contractual payments to The Brigham and Women's Hospital.

General and administrative expenses were $589,000 and $661,000 for the years ended December 31, 2001 and 2002, respectively. The increase is due to a $42,000 increase in corporate activity and a $30,000 increase in insurance costs.

Net interest income was $461,000 and $190,000 for the years ended December 31, 2001 and 2002, respectively. The decrease is primarily due to reductions in market interest rates and returns on investment for US Treasury obligations and other short term instruments.

Other expense was $100,000 for the year ended December 31, 2002. This expense reflects an impairment of the Company's investment in Oragen Corporation. In the fourth quarter of 2002, the Company determined that the entire value of its investment in Oragen should be reduced to zero to reflect Oragen's continued difficulty in obtaining funding for its operations.

Years Ended December 31, 2000 and 2001

Revenue was $4,010,000 and $1,348,000 for the years ended December 31, 2000 and 2001, respectively. Of that total revenue, $4,000,000 in 2000 and $1,308,000 in 2001 represent payments by a subsidiary of Elan Plc for the purchase of certain patent rights related to Alzheimer's disease. The remaining amounts represent monthly license payments from BioMS Medical Corporation.

Research and development expenses were $782,000 and $372,000 for the years ended December 31, 2000 and 2001, respectively. The decrease is primarily due to the $125,000 reduction of contractual payments to The Brigham and Women's Hospital and $290,000 in lower patent-related legal costs.

General and administrative expenses were $679,000 and $589,000 for the years ended December 31, 2000 and 2001, respectively. The decrease is due to a reduction of corporate activity.

Net interest income was $599,000 and $461,000 for the years ended December 31, 2000 and 2001, respectively. The decrease is due to reductions in market interest rates and returns on investment for US Treasury obligations and other short term instruments.

Liquidity and Capital Resources

The Company's needs for funds have historically fluctuated from period to period as it has increased or decreased the scope of its research and development activities. Since inception, the Company has funded these needs almost entirely through sales of its equity securities. Its current needs have been significantly reduced as a result of the termination of research, development and administrative employees and other operating expenses in 1999.

As of December 31, 2002, the Company had an outstanding contractual obligation to The Brigham and Women's Hospital to sponsor research totaling $24,000. In addition, AutoImmune holds an interest in an entity called Colloral LLC, which is manufacturing, marketing and selling Colloral as a nutraceutical. AutoImmune has no obligation to make additional capital contributions to Colloral LLC. To the extent that Colloral LLC generates revenues in excess of cumulative losses and makes distributions, AutoImmune will obtain income.

The Company's working capital and capital requirements will depend on numerous factors, including the strategic direction that the Company and its shareholders choose, the level of resources that the Company devotes to the development of its patented products, the extent to which it proceeds by means of collaborative relationships with pharmaceutical or nutraceutical companies and its competitive environment. Based upon its budget for the calendar year 2003, the Company believes that current cash and marketable securities and the interest earned from the investment thereof will be sufficient to meet the Company's operating expenses and capital requirements for at least five years. At the appropriate time, the Company may seek additional funding through public or private equity or debt financings, collaborative arrangements with pharmaceutical companies or from other sources. If additional funds are necessary but not available, the Company will have to reduce certain activities, which could include areas of research, product development, manufacturing or marketing activity, or otherwise modify its business strategy. Such a reduction would have a material adverse effect on the Company.

In order to preserve principal and maintain liquidity, the Company's funds through year end 2002 have been invested in U.S. Treasury obligations and other short-term instruments. As of December 31, 2002, the Company's cash and cash equivalents and marketable securities totaled $10,018,000. Current liabilities at December 31, 2002 were $187,000. In the future, the Company plans to invest a portion of its funds in high-grade corporate bonds to increase the yield it receives on its investments.

Off-Balance Sheet Arrangements

AutoImmune has not created, and is not party to, any special-purpose or off-balance sheet entities for the purpose of raising capital, incurring debt or operating parts of its business that are not consolidated into its financial statements.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Management bases its 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.

The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its financial statements:

Revenue is recognized in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements ("SAB 101"). Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable, and collectibility is reasonably assured.

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, or royalties on net product sales. Revenue arrangements where multiple products or services are sold together under one contract are evaluated to determine if each element represents a separate earnings process. In the event that an element of such multiple element arrangement does not represent a separate earnings process, revenue from this element is recognized over the term of the related contract.

Where the Company has continuing performance obligations under the terms of a collaborative arrangement or associated with non-refundable license fees, revenue is recognized over the period the Company completes its performance obligations. Under the terms of one agreement, the Company and Brigham & Women's Hospital have indemnified a subsidiary of Elan against any claim, demand or action arising from any misrepresentation made to the subsidiary Elan about patent rights and warranties, up to the amounts previously received by the Company under the agreement. The Company does not consider this a performance obligation that would preclude or defer revenue recognition. Option fees representing payments to be made to the Company for a right to evaluate and negotiate the terms of a potential licensing arrangement are recognized when the options are granted because such fees are non-refundable and the Company has no further obligations.

Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Revenue from service contracts is earned as the related services are performed.

Marketable securities are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. The Company employs a methodology in evaluating whether a decline in fair value below cost basis is other than temporary that considers available evidence regarding its marketable securities. In the event that the cost basis of a security exceeds its fair value, the Company evaluates, among

other factors: the duration of the period that, and extent to which, the fair value is less than the cost basis; the financial health of and business outlook for the issuer of the securities, including industry and sector performance, changes in technology and operational and financing cash flow factors; overall market conditions and trends; and the Company's intent and ability to hold the investment. Once a decline in fair value is determined to be other than temporary, a write-down is recorded and a new cost basis in the security is established. Assessing the above factors involves inherent uncertainty. Accordingly, write-downs, if recorded, could be materially different from the actual market performance of marketable securities in the Company's portfolio, if, among other things, relevant information related to its marketable securities was not publicly available or other factors not considered would have been relevant to the determination of impairment.

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51." FIN 46 requires certain variable interest entities ("VIE"), to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all VIE created or acquired after January 31, 2003. For VIE created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company believes Colloral LLC would be considered a VIE and has included transitional disclosures required by FIN 46. The Company is currently assessing the impact that the adoption of FIN 46 will have on its financial position and results of operation.

On December 31, 2002, the FASB issued FASB Statement No. 148 (FAS 148), *Accounting for Stock-Based Compensation—Transition and Disclosure*, which amends FAS 123, *Accounting for Stock-Based Compensation.* FAS 148 provides specific guidance for companies choosing to transition from employee stock option accounting under the provisions of APB 25 to employee stock option accounting under FAS 123. The Company currently accounts for employee stock option grants under APB 25 and will continue to do so during fiscal 2003.

In addition, the provisions of FAS 148 require that, in all annual and interim financial statements, companies disclose for each period for which an income statement is presented an accounting policy footnote that includes: the method of accounting for stock options; total stock compensation cost that is recognized in the income statement and would have been recognized had FAS 123 been adopted for recognition purposes as of its effective date; and pro forma net income and earnings per share that would have been reported had FAS 123 been adopted for recognition purposes as of its effective date. The Company currently provides these disclosures in the annual financial statements but, commencing in the first quarter of 2003, will be required to disclose this information in the interim financial statements.

In November 2002, the FASB issued FIN No. 45 "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others an interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34." The Interpretation requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken by issuing the guarantee. The Interpretation also requires additional disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees it has issued. The accounting requirements for the initial recognition of guarantees are applicable on a prospective basis for guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for all guarantees outstanding, regardless of when they were issued or modified, during the first quarter of fiscal 2003. The adoption of FIN No. 45 did not have a material effect on the Company's financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The Company has historically invested all of its cash in U.S. Treasury obligations and money market instruments. In the future, the Company plans to invest a portion of its funds in high-grade corporate bonds to

increase the yield it receives on its investments. These investments are denominated in U.S. dollars. Due to the conservative nature of these instruments, the Company does not believe that it has material exposure to interest rate or market risk.

Item 8. Financial Statements and Supplementary Data.

Information with respect to the Company's financial statements and financial statement schedules filed with this report is set forth in Item 15 of Part IV.

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

None.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The information called for by this Item and not provided below is incorporated by reference to the Company's proxy statement which the Company intends to file with the Securities and Exchange Commission and mail to shareholders within 120 days of the Company's fiscal year ended December 31, 2002.

Executive officer information is as follows:

Robert C. Bishop, Ph.D., age 60, is the Company's President, Chief Executive Officer and Chairman of the Board. Dr. Bishop was elected President and Chief Executive Officer in May 1992. He also became a director of the Company in May 1992. In May 1999, Dr. Bishop was elected Chairman of the Board. Effective December 31, 1999, Dr. Bishop ceased being a full-time employee of AutoImmune and began working in the same capacity on a part-time basis. For more than five years prior to joining the Company, Dr. Bishop held senior management positions at Allergan, Inc., an eye and skin care company, including President of Allergan Medical Optics from 1986 to 1988, Senior Vice President of Corporate Development of Allergan, Inc. from 1988 to 1989, President of Allergan Pharmaceuticals, Inc. from 1989 to 1991 and Group President of Allergan Therapeutics Group for Allergan's worldwide pharmaceutical, surgical and neurotoxin businesses from February 1991 to May 1992. From 1976 through 1986, Dr. Bishop served as an executive of American Hospital Supply Corporation. Dr. Bishop received his B.A. degree in psychology and a Ph.D. in biochemistry from the University of Southern California and his M.B.A. from the University of Miami. Dr. Bishop is a director of Quintiles Transnational Corp., a contract research, sales and marketing company serving the health care industry, a director of Millipore Corporation, a purification technologies/systems company serving the biopharmaceutical and analytical laboratories markets, a director of Caliper Technologies Corporation, a microfluidics company developing lab-on-a-chip instrument systems, and a director of Optobionics Corporation, a developer of ophthalmic device products. Dr. Bishop is also a member of the Board of Managers/Trustees for the MFS/Sun Life Series Trust and Compass Accounts at MFS Investment Management.

Heather A. Ellerkamp, CPA, age 38, joined the Company in February 1994. Ms. Ellerkamp has been Director of Finance and Treasurer of the Company since June 1997, and from February 1994 to June 1997, she held various financial positions with the Company, including controller. Ms. Ellerkamp received her B.A. degree in Management Science from the University of California, San Diego and her M.B.A. from the University of Michigan. Effective November 19, 1999, Ms. Ellerkamp ceased being a full time employee of AutoImmune and is currently working in the same capacity on a part-time basis.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to the Company's proxy statement which the Company intends to file with the Securities and Exchange Commission and mail to shareholders within 120 days of the Company's fiscal year ended December 31, 2002.

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

The information required by this Item is incorporated by reference to the Company's proxy statement which the Company intends to file with the Securities and Exchange Commission and mail to shareholders within 120 days of the Company's fiscal year ended December 31, 2002.

Item 13. Certain Relationships and Related Transactions.

The information required by this Item is incorporated by reference to the Company's proxy statement which the Company intends to file with the Securities and Exchange Commission and mail to shareholders within 120 days of the Company's fiscal year ended December 31, 2002.

Item 14. Controls and Procedures.

Within 90 days prior to the filing of this Form 10-K, the Company's Chief Executive Officer and Director of Finance reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures. The Chief Executive Officer and Director of Finance have concluded that the Company's disclosure controls and procedures are effective and adequately designed to ensure that the information required to be disclosed in this Form 10-K has been accumulated and disclosed.

There have been no significant changes in the Company's internal controls or in other factors that could significantly affect those internal controls subsequent to the date on which they were last evaluated.

PART IV

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

(a)(1) Financial Statements

(a)(2) Financial Statement Schedule

All schedules are omitted because they are not applicable or the required information is shown in the financial statements.

(a)(3) Exhibits

Exhibit Number	Exhibit Description
3.1	—Restated Certificate of Incorporation(1)
3.2	—By-Laws(2)
4.1	—Specimen Common Stock Certificate(2)
4.2	—Rights Agreement dated as of May 19, 1995(3)
10.1	—Amended and Restated 1988 Stock Option Plan effective December 14, 1992(1)
10.2	—Agreement, dated March 18, 1992, between AutoImmune Inc. and Schering Corporation(2)+
10.3	—Lease Agreement, dated November 1992, between AutoImmune Inc. and Ledgemont Realty Trust(2)
10.4	—Amended and Restated Research and Development Agreement, dated July 1, 1992, between AutoImmune Inc. and The Brigham and Women's Hospital, Inc.(2)
10.5	—Research Agreement, dated October 21, 1992, and Royalty Agreement, dated 1992, between AutoImmune Inc. and Joslin Diabetes Center(2)
10.6	—Research Agreement, dated July 1, 1992, Royalty Agreement, dated June 6, 1990, and Research Agreement, dated July 1990, between AutoImmune Inc. and the Beth Israel Hospital(2)
10.7	—Cooperative Research and Development Agreement, effective July 1, 1990, among the National Eye Institute of the National Institutes of Health, The Brigham and Women's Hospital and AutoImmune Inc.(2)
10.8	—Retainer Agreement, dated June 1, 1992, between AutoImmune Inc. and Cato Research Ltd.(2)
10.9	—Employment Agreement, dated April 2, 1992, between AutoImmune Inc. and Robert C. Bishop(2)
10.10	—Amended Consulting Agreement, dated July 1992, and Amended and Restated Consulting Agreement, dated November 1988, between AutoImmune Inc. and Howard L. Weiner, M.D.(2)
10.11	—Amended Consulting Agreement, dated July 1992, and Amended and Restated Consulting Agreement, dated November 1988, between AutoImmune Inc. and David A. Hafler, M.D.(2)
10.12	—Consulting Agreement, dated February 1, 1989, between AutoImmune Inc. and James P. Tam, Ph.D.(2)
10.13	—Scientific Advisory Board Agreement, dated August 5, 1992, and Consulting Service Agreement, dated August 5, 1992, between AutoImmune Inc. and Jack L. Strominger, M.D.(2)
10.14	—Scientific Advisory Board Agreement, dated August 11, 1992, between AutoImmune Inc. and Herman N. Eisen, M.D.(2)
10.15	—Scientific Consultant Agreement, dated July 16, 1992, between AutoImmune Inc. and Henry Oettinger, Ph.D.(2)
10.16	—Nonemployee Director Stock Option Plan(4)
10.17	—Employee Stock Purchase Plan(5)
10.18	—License and Collaboration Agreement dated December 1, 1994 between AutoImmune Inc. and Eli Lilly and Company(6)+
10.19	—First Amendment to Lease dated October 31, 1993 between AutoImmune Inc. and Ledgemont Realty Trust(7)
10.20	—Second Amendment to Lease dated February 1, 1996 between AutoImmune Inc. and Ledgemont Realty Trust(7)

Exhibit Number	Exhibit Description
10.21	—Third Amendment to Lease dated October 23, 1996 between AutoImmune Inc. and Ledgemont Realty Trust(8)
10.22	—Sublease agreement dated November 1, 1997 between AutoImmune Inc. and Antigenics, LLC(8)
10.23	—Consent to Sublease Agreement dated November 1, 1997 between AutoImmune Inc., Antigenics, LLC, and Ledgemont Realty Trust(8)
10.24	—1998 Stock Option Plan(9)
10.25	—Development and License Agreement dated as of December 4, 1998 between AutoImmune Inc. and Teva Pharmaceutical Industries Ltd.(10)+
10.26	—Sublease Termination Agreement dated June 15, 1998 between AutoImmune Inc. and Antigenics, LLC (10)
10.27	—Fourth Amendment to Lease dated July 17, 1998 between AutoImmune Inc. and Ledgemont Realty Trust(10)
10.28	—Consulting Agreement dated January 3, 2000 between AutoImmune Inc. and Robert C. Bishop, Ph.D.(11)
10.29	—Consulting Agreement dated November 20, 1999 between AutoImmune Inc. and Heather A. Ellerkamp(11)
10.30	—Consulting Agreement dated September 20, 1999 between AutoImmune Inc. and Fletcher Spaght, Inc.(11)
10.31	—Letter Agreement dated January 31, 2000 between AutoImmune Inc. and Fletcher Spaght, Inc.(12)+
10.32	—Agreement for Assignment of Patent Rights, dated effective as of January 29, 2000 among The Brigham and Women's Hospital, Inc., AutoImmune Inc. and Neuralab Limited(12)+
10.33	—Letter Agreement dated March 16, 2000 between AutoImmune Inc. and The Brigham and Women's Hospital Inc.(12)+
10.34	—Agreement dated August 1, 2000 between AutoImmune and Rycor Technology Instruments Corp. (now known as BioMS Medical Corporation)
10.35	—Limited Liability Company Operating Agreement of Colloral LLC, dated August 19, 2002 (13)+
10.36	—License Agreement, dated August 19, 2002 between AutoImmune Inc. and Colloral LLC (13)
10.37	—Trademark License Agreement, dated August 19, 2002, between AutoImmune Inc. and Colloral LLC (13)
23.1	—Consent of PricewaterhouseCoopers LLP
99.1	—Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350
99.2	—Certification of the Director of Finance and Treasurer pursuant to 18 U.S.C. Section 1350

(1) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1992 (File No. 0-20948).

(2) Incorporated by reference to the Company's Registration Statement on Form S-1 (File No. 33-55430).

(3) Incorporated by reference to the Company's Current Report in Form 8-K filed with the Securities and Exchange Commission on May 26, 1995 (File No. 0-20948).

(4) Incorporated by reference to Appendix A to the Company's definitive Proxy Statement dated April 6, 1994 for the Annual Meeting of Shareholders held on May 18, 1994 filed pursuant to Section 14 of the Exchange Act.

(5) Incorporated by reference to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on August 17, 1994 (Registration No. 33-82972).

(6) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1994, as amended.
(7) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1995.
(8) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1997.
(9) Incorporated by reference to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on December 3, 1998 (Registration No. 333-68309).
(10) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1998.
(11) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 1999.
(12) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
(13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
+ The Company has been granted confidential treatment of the redacted portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, and has separately filed a complete copy of this exhibit with the Securities and Exchange Commission.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the last quarter of 2002.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 24th day of March, 2003.

AUTOIMMUNE INC.

By: /s/ ROBERT C. BISHOP
Robert C. Bishop,
Chairman, President and Chief Executive Officer

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

/s/ ROBERT C. BISHOP **Robert C. Bishop** **Principal Executive Officer**	Director, Chairman, President and Chief Executive Officer	March 24, 2003
/s/ HEATHER A. ELLERKAMP **Heather A. Ellerkamp** **Principal Financial and Accounting Officer**	Director of Finance and Treasurer	March 24, 2003
/s/ HUGH A. D'ANDRADE **Hugh A. D'Andrade**	Director	March 24, 2003
/s/ ALLAN R. FERGUSON **Allan R. Ferguson**	Director	March 24, 2003
/s/ R. JOHN FLETCHER **R. John Fletcher**	Director	March 24, 2003
/s/ HENRI A. TERMEER **Henri A. Termeer**	Director	March 24, 2003

CERTIFICATIONS

I, Heather A Ellerkamp, certify that:

1. I have reviewed this annual report on Form 10-K of AutoImmune Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 24, 2003

/s/ HEATHER A. ELLERKAMP

Name: Heather A. Ellerkamp
Title: Director of Finance and Treasurer

I, Robert C. Bishop, certify that:

1. I have reviewed this annual report on Form 10-K of AutoImmune Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 24, 2003

/s/ ROBERT C. BISHOP

Name: Robert C. Bishop
Title: Chief Executive Officer

AutoImmune Inc.
(a development stage company)

Index to Financial Statements

Report of Independent Accountants

To the Board of Directors and Stockholders of
AutoImmune Inc.

In our opinion, the accompanying balance sheet and the related statement of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the financial position of AutoImmune Inc. (a development stage company) at December 31, 2001 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 and for the period from inception (September 9, 1988) through December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP
PricewaterhouseCoopers LLP

Boston, Massachusetts
March 17, 2003

AutoImmune Inc.
(a development stage company)

Balance Sheet

	December 31, 2001	2002
Assets		
Current assets:		
Cash and cash equivalents	$ 3,929,000	$ 5,033,000
Marketable securities	6,863,000	4,985,000
Prepaid expenses and other current assets	42,000	81,000
Total current assets	10,834,000	10,099,000
Fixed assets, net	—	—
Other assets	100,000	—
Total assets	$ 10,934,000	$ 10,099,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 47,000	$ 42,000
Accrued professional fees	90,000	145,000
Total current liabilities	137,000	187,000
Commitments and contingencies (Notes 6 and 12)		
Stockholders' equity:		
Common stock, $.01 par value: 25,000,000 shares authorized; 16,919,623 shares issued and outstanding at December 31, 2001 and 2002	169,000	169,000
Additional paid-in capital	118,102,000	118,102,000
Deficit accumulated during the development stage	(107,474,000	(108,363,000)
Accumulated other comprehensive income	—	4,000
Total stockholders' equity	10,797,000	9,912,000
Total liabilities and stockholders' equity	$ 10,934,000	$ 10,099,000

The accompanying notes are an integral part of these financial statements.

AutoImmune Inc.
(a development stage company)

Statement of Operations

	For the year ended December 31,			Period from inception (September 9, 1988) through December 31, 2002
	2000	2001	2002	
Revenue:				
License rights	$ 4,010,000	$ 1,348,000	$ 70,000	$ 5,428,000
Option fees	—	—	—	2,200,000
Research and development revenue under collaborative agreements	—	—	—	955,000
Total revenue	4,010,000	1,348,000	70,000	8,583,000
Costs and expenses:				
Research and development:				
Related party	260,000	135,000	61,000	19,788,000
All other	522,000	237,000	327,000	91,841,000
General and administrative	679,000	589,000	661,000	17,584,000
Total costs and expenses	1,461,000	961,000	1,049,000	129,213,000
Income (loss) from operations	2,549,000	387,000	(979,000)	(120,630,000)
Interest income	599,000	461,000	190,000	12,674,000
Interest expense	—	—	—	(303,000)
Other expense	—	—	(100,000)	(100,000)
	599,000	461,000	90,000	12,271,000
Net income (loss)	$ 3,148,000	$ 848,000	$ (889,000)	$(108,359,000)
Net income (loss) per share—basic	$ 0.19	$ 0.05	$ (0.05)	
Net income (loss) per share—diluted	$ 0.18	$ 0.05	$ (0.05)	
Weighted average shares outstanding—basic	16,743,349	16,909,541	16,919,623	
Weighted average shares outstanding—diluted	17,288,172	17,253,299	16,919,623	

The accompanying notes are an integral part of these financial statements.

AutoImmune Inc.
(a development stage company)

Statement of Changes In Stockholders' Equity
For the period from inception (September 9, 1988)
through December 31, 2002

	Common Stock						
	Number of shares	Par value	Additional paid-in capital	Comprehensive income (loss)	Deficit accumulated during the development stage	Accumulated other comprehensive income	Total stockholders' equity
Issuance of common stock during 1988	168,750	$ 2,000	$		$ (1,000)	$ —	$ 1,000
Conversion of junior convertible preferred stock to common stock during 1991	506,250	5,000			(3,000)		2,000
Issuance of common stock during 1992	91,116	1,000	100,000				101,000
Conversion of mandatorily redeemable convertible preferred stock to common stock during 1993	6,353,568	63,000	12,496,000				12,559,000
Issuance of common stock, net of issuance costs during 1993	3,022,000	30,000	35,669,000				35,699,000
Issuance of common stock during 1994	67,500	1,000	2,000				3,000
Issuance of common stock, net of issuance costs during 1995	6,072,883	61,000	68,530,000				68,591,000
Issuance of common stock during 1996	75,978	1,000	441,000				442,000
Issuance of common stock during 1997	34,851	—	92,000				92,000
Issuance of common stock during 1998	156,099	2,000	221,000				223,000
Issuance of common stock during 1999	108,877	1,000	163,000				164,000
Net loss for the period from inception (September 9, 1988) through December 31, 1999				$(111,466,000)	(111,466,000)		(111,466,000
Other comprehensive income (loss): Net unrealized gain on marketable securities during 1994 through 1999 (Note 11)				—		—	—
Comprehensive loss				$(111,466,000)			
Balance at December 31, 1999	16,657,872	167,000	117,714,000		(111,470,000)	—	6,411,000
Comprehensive income: Net income				$ 3,148,000	3,148,000		3,148,000
Other comprehensive income (loss): Net unrealized gain on marketable securities (Note 11)				—		—	—
Comprehensive income				$ 3,148,000			
Issuance of common stock	101,751	1,000	193,000				194,000
Balance at December 31, 2000	16,759,623	168,000	117,907,000		(108,322,000)	—	9,753,000
Comprehensive income: Net income				$ 848,000	848,000		848,000
Other comprehensive income (loss): Net unrealized gain on marketable securities (Note 11)				—		—	—
Comprehensive income				$ 848,000			
Valuation of warrants issued			192,000				192,000
Issuance of common stock	160,000	1,000	3,000				4,000
Balance at December 31, 2001	16,919,623	169,000	118,102,000		(107,474,000)	—	10,797,000
Comprehensive loss: Net loss				$ (889,000)	(889,000)		(889,000)
Other comprehensive income (loss): Net unrealized gain on marketable securities (Note 11)				4,000		4,000	4,000
Comprehensive loss				$ (885,000)			
Balance at December 31, 2002	16,919,623	$169,000	$118,102,000		$(108,363,000)	$ 4,000	$9,912,000

The accompanying notes are an integral part of these financial statements.

AutoImmune Inc.
(a development stage company)

Statement of Cash Flows

Increase (Decrease) in Cash and Cash Equivalents Cash flows from operating activities:	For the year ended December 31, 2000	2001	2002	Period from inception (September 9, 1988) through December 31, 2002
Net income (loss)	$ 3,148,000	$ 848,000	$ (889,000)	$(108,359,000)
Adjustments to reconcile net loss to net cash used by operating activities:				
Interest expense related to demand notes converted into mandatorily redeemable convertible preferred stock	—	—	—	48,000
Patent costs paid with junior convertible preferred and common stock	—	—	—	3,000
Valuation of warrants issued in conjunction with license revenue	—	192,000	—	192,000
Depreciation and amortization	—	—	—	4,464,000
Loss on sale/disposal of fixed assets	—	—	—	642,000
Decrease in patent costs	—	—	—	563,000
Impairment of investment in Oragen	—	—	100,000	100,000
(Increase) decrease in prepaid expenses and other current assets	37,000	30,000	(39,000)	(81,000)
Increase (decrease) in accounts payable	48,000	(65,000)	(5,000)	42,000
Increase (decrease) in accrued expenses	(517,000)	—	55,000	145,000
Net cash provided (used) by operating activities	2,716,000	1,005,000	(778,000)	(102,241,000)
Cash flows from investing activities:				
Purchase of available-for-sale marketable securities	(11,947,000)	(19,694,000)	(11,887,000)	(305,248,000)
Proceeds from sale/maturity of available-for-sale marketable securities	6,783,000	17,995,000	13,769,000	289,256,000
Proceeds from maturity of held-to-maturity marketable securities	—	—	—	11,011,000
Proceeds from sale of equipment	—	—	—	306,000
Investment in Oragen	—	(100,000)	—	(100,000)
Purchases of fixed assets	—	—	—	(5,288,000)
Increase in patent costs	—	—	—	(563,000)
Increase in other assets	—	—	—	(125,000)
Net cash provided (used) by investing activities	(5,164,000)	(1,799,000)	1,882,000	(10,751,000)
Cash flows from financing activities:				
Proceeds from sale-leaseback of fixed assets	—	—	—	2,872,000
Payments on obligations under capital leases	—	—	—	(2,872,000)
Net proceeds from issuance of mandatorily redeemable convertible preferred stock	—	—	—	10,011,000
Proceeds from bridge notes	—	—	—	300,000
Proceeds from issuance of common stock	194,000	4,000	—	105,514,000
Proceeds from issuance of convertible notes payable	—	—	—	2,200,000
Net cash provided by financing activities	194,000	4,000	—	118,025,000
Net increase (decrease) in cash and cash equivalents	(2,254,000)	(790,000)	1,104,000	5,033,000
Cash and cash equivalents at beginning of period	6,973,000	4,719,000	3,929,000	—
Cash and cash equivalents at end of period	$ 4,719,000	$ 3,929,000	$5,033,000	$ 5,033,000

See Note 2 for supplemental disclosure of non-cash financing activities.

The accompanying notes are an integral part of these financial statements.

1. Formation and Operations of the Company

AutoImmune was incorporated in Delaware on September 9, 1988. The Company is dedicated to the development of innovative therapeutics to treat people who suffer from immune systems disorders. The Company's therapeutic approach is based upon "mucosal tolerance," a method designed to control disease by using the body's natural immunosuppressive mechanisms. The Company is considered a development stage company as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises.*

The Company has not yet completed the development of any product, except Colloral®. The Company contributed all of the equipment used to manufacture Colloral and certain Colloral-related intellectual property to Colloral LLC, an entity created by a joint venture between AutoImmune and Deseret Laboratories, Inc. in August 2002. Colloral LLC is currently the exclusive manufacturer, marketer and seller of Colloral. The Company's other products will require significant additional clinical testing and investment prior to commercialization. To date the Company has been dependent on collaborative agreements for the majority of its basic research and has primarily used contract manufacturers to produce its products for clinical trials.

In addition, the Company faces risks and uncertainties similar to other life science companies in the development stage. These risks and uncertainties include, but are not limited to, the Company's extremely limited operations, the uncertainties of clinical trial results and product development, the Company's dependence on third parties for licensing and other revenue and risks of technological changes and competition.

Currently, the Company anticipates that it will operate as a "virtual" company to the maximum extent possible by operating without office space and full-time employees as it awaits the results of currently ongoing clinical trials and business development activities.

2. Summary of Significant Accounting Policies

Cash Equivalents and Marketable Securities

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company invests primarily in U.S. Government debt securities. These investments are subject to minimal credit and market risks. The Company specifically identifies securities for purposes of determining gains and losses on the sale of cash equivalents and marketable securities. At December 31, 2002, the Company had classified all of its marketable securities as available-for-sale as defined in SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* Accordingly, unrealized gains and losses on available-for-sale securities are recorded as a separate component of stockholders' equity. At December 31, 2001 and 2002, there were no significant unrealized gains or losses on the marketable securities.

Fair Value of Financial Instruments

At December 31, 2002, the Company's financial instruments consisted of cash equivalents, investments, accounts payable and accrued expenses. The carrying amount of these instruments approximate their fair values. In the fourth quarter of 2002, an impairment expense of $100,000 was recorded in other expense. The Company determined that the entire value of its investment in Oragen should be reduced to zero to reflect Oragen's continued difficulty in obtaining funding for its operations.

Fixed Assets

Fixed assets are stated at cost and depreciated using the straight-line method over the estimated useful life of the assets. Assets which were under capital leases and leasehold improvements were amortized over the shorter of their estimated useful lives or the term of the respective leases by use of the straight-line method.

Contingent Stock Purchase Warrants

The value of contingent stock purchase warrants issued by the Company in connection with clinical research agreements is determined on the date that the Company estimates that it is probable that such contingencies will be met. The fair value of the warrants on the measurement date is recorded as compensation expense. The Company periodically assesses whether it is probable and estimable that the compensation related to contingent warrants will be earned.

Revenue Recognition

Revenue is recognized in accordance with Securities and Exchange Commission's Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements ("SAB 101"). Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured.

Contract and license fee revenue is primarily generated through collaborative license and development agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, or royalties on net product sales. Revenue arrangements where multiple products or services are sold together under one contract are evaluated to determine if each element represents a separate earnings process. In the event that an element of such multiple element arrangement does not represent a separate earnings process, revenue from this element is recognized over the term of the related contract.

Where the Company has continuing performance obligations under the terms of a collaborative arrangement or associated with non-refundable license fees, revenue is recognized over the period the Company completes its performance obligations. Under the terms of one agreement, the Company and Brigham & Women's Hospital have indemnified a subsidiary of Elan against any claim, demand or action arising from any misrepresentation made to the subsidiary of Elan about patent rights and warranties, up to the amounts previously received by the Company under the agreement. The company does not consider this a performance obligation that would preclude or defer revenue recognition. Option fees representing payments to be made to the Company for a right to evaluate and negotiate the terms of a potential licensing arrangement are recognized when the options are granted because such fees are non-refundable and the Company has no further obligations.

Revenues from milestone payments related to arrangements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Revenue from service contracts is earned as the related services are performed.

Revenue generated in 2001 and 2002 was derived from agreements with a subsidiary of Elan Plc and BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp.) (see Note 13).

Stock Compensation

The Company accounts for stock-based compensation using the intrinsic based method prescribed in Accounting Principles Board Opinion ("APB") No. 25. *Accounting for Stock Issued to Employees.* The Company applies the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation.* Accordingly, no compensation cost has been recognized for options granted to employees with exercise prices equal to or greater than the fair market value at the grant date. Had compensation cost been determined based on the fair value at the grant dates for awards in 2000, 2001 and 2002 consistent with the provisions of SFAS No. 123, the Company's net income (loss) and net income (loss) per share would have been changed to the pro forma amounts indicated below:

	Year ended December 31, 2000	2001	2002
Net income (loss):			
As reported	$3,148,000	$848,000	$(889,000)
Deduct: total stock-based employee compensation expense determined under the fair-value-based method for all awards	(43,000)	(58,000)	(82,000)
Pro forma	$3,105,000	$790,000	$(971,000)
Net income (loss) per share—basic			
As reported	$ 0.19	$ 0.05	$ (0.05)
Pro forma	0.19	0.05	(0.06)
Net income (loss) per share—diluted			
As reported	$ 0.18	$ 0.05	$ (0.05)
Pro forma	0.18	0.05	(0.06)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2000, 2001 and 2002: no dividend yield for all years; expected volatility of 70% for all years; risk free interest rates ranging from 2.1% to 7.4% and a weighted average expected option term ranging from 3 to 6.5 years for options granted during all years. Because additional option grants are expected to be made each year, the pro forma impact on the three years ended December 31, 2002 is not representative of the pro forma effects which may be expected in future years.

Net Income (Loss) Per Share—Basic and Diluted

Basic earnings (loss) per share is calculated based on the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated based on the weighted average number of common shares and dilutive common equivalent shares assumed outstanding during the period. For the year ended December 31, 2002, shares used to compute diluted earnings per share in loss years excluded 128,544 common share equivalents, as their inclusion would have been anti-dilutive. For the years

ended December 31, 2000 and 2001, the difference between weighted average shares outstanding basic and diluted is due to the effect of stock options.

Use of Estimates

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

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51." FIN 46 requires certain variable interest entities ("VIE"), to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all VIE created or acquired after January 31, 2003. For VIE created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company believes Colloral LLC would be considered a VIE and has included transitional disclosures required by FIN 46. The Company is currently assessing the impact that the adoption of FIN 46 will have on its financial position and results of operation.

On December 31, 2002, the FASB issued FASB Statement No. 148 (FAS 148), *Accounting for Stock-Based Compensation—Transition and Disclosure*, which amends FAS 123, *Accounting for Stock-Based Compensation*. FAS 148 provides specific guidance for companies choosing to transition from employee stock option accounting under the provisions of APB 25 to employee stock option accounting under FAS 123. The Company currently accounts for employee stock option grants under APB 25 and will continue to do so during fiscal 2003.

In addition, the provisions of FAS 148 require that, in all annual and interim financial statements, companies disclose for each period for which an income statement is presented an accounting policy footnote that includes: the method of accounting for stock options; total stock compensation cost that is recognized in the income statement and would have been recognized had FAS 123 been adopted for recognition purposes as of its effective date; and pro forma net income and earnings per share that would have been reported had FAS 123 been adopted for recognition purposes as of its effective date. The Company currently provides these disclosures in the annual financial statements but, commencing in Q1 2003, will be required to disclose this information in the interim financial statements.

In November 2002, the FASB issued FIN No. 45 "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others an interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34." The Interpretation requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken by issuing the guarantee. The Interpretation also requires additional disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees it has issued. The accounting requirements for the initial recognition of guarantees are applicable on a prospective basis for guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for all

guarantees outstanding, regardless of when they were issued or modified, during the first quarter of fiscal 2003. The adoption of FIN No. 45 did not have a material effect on the Company's financial statements.

Statement of Cash Flows

Disclosure of Non-Cash Investing and Financing Activities

In 1988, 168,750 shares of common stock and 168,750 shares of junior convertible preferred stock were issued to the Brigham and Women's Hospital in exchange for patent rights and technology contributed or licensed in connection with the formation of the Company.

Notes payable to stockholders totaling $2,200,000 and related interest of $48,000 were converted into Series A mandatorily redeemable convertible preferred stock in 1991.

Bridge notes of $300,000 were converted into Series C mandatorily redeemable convertible preferred stock in 1991.

In 1991, 168,750 shares of junior convertible preferred stock were converted into 506,250 shares of common stock.

In 1993, 2,117,856 shares of mandatorily redeemable convertible preferred stock were converted into 6,353,568 shares of common stock in connection with the Company's initial public offering of common stock.

Supplemental Disclosure of Cash Flow Information

The Company paid interest of $255,000 since inception. In 2000, 2001 and 2002, there was no paid interest. The Company paid income taxes of $11,000 in 1996, which are the only income taxes paid by the Company.

3. Cash Equivalents and Marketable Securities

The following is a summary of cash equivalents held by the Company. Cash equivalents are carried at fair market value, which approximated amortized cost at December 31, 2001 and 2002.

	December 31, 2001	2002
Money market	$3,894,000	$5,024,000
U.S. Government debt securities	—	—
	$3,894,000	$5,024,000

The following is a summary of available-for-sale marketable securities held by the Company at December 31, 2001 and 2002 which are carried at fair market value:

	Maturity term	Fair Value	Unrealized gains	Unrealized losses	Amortized cost
December 31, 2001:					
U.S. Government debt securities	within 1 year	$6,863,000	$ —	$ —	$6,863,000
December 31, 2002:					
U.S. Government debt securities	within 1 year	$4,985,000	$ 4,000	$ —	$4,981,000

All of the Company's marketable securities were classified as current on December 31, 2001 and 2002 as these funds are highly liquid and are available to meet working capital needs and to fund current operations. Gross realized gains and losses on sales of marketable securities for the years ended December 31, 2001 and 2002 were not significant.

Marketable securities which were purchased and sold in periods prior to adoption of SFAS No. 115 on January 1, 1994, other than held-to-maturity marketable securities, are included in the category available-for-sale marketable securities in the "period from inception" column of the statement of cash flows.

4. Fixed Assets

Fixed assets consist of the following:

	Estimated useful life (years)	December 31, 2001	December 31, 2002
Laboratory equipment	2-5	$ 160,000	$ —
Less—accumulated depreciation and amortization		(160,000)	—
		$ —	$ —

There was no depreciation for the years ended December 31, 2001 and 2002. There were no assets held under capital leases on December 31, 2001 or 2002. In 2002, fixed assets with a total cost of $160,000 and a net book value of $0 were contributed to Colloral LLC (see Note 5). As of December 31, 2002, the Company has no fixed assets.

5. Other Assets

Other assets are comprised of two investments, one in Oragen Corporation and one in Colloral LLC.

Oragen Corporation is a private company in which AutoImmune's interest is less than 20%. Prior to the fourth quarter of 2002, the investment in Oragen Corporation was carried at cost. In the fourth quarter of 2002, the Company determined that the entire value of its investment in Oragen should be reduced to zero to reflect Oragen's continued difficulty in obtaining funding for its operations. As a result, a loss of $100,000 has been recorded in other expense in the fourth quarter of 2002.

Colloral LLC is a joint venture created in August 2002 between AutoImmune and Deseret Laboratories Inc. (a private company headquartered in St. George, Utah) to manufacture, market and sell Colloral®, a product for nutritional support of patients with rheumatoid arthritis. AutoImmune's interest in Colloral LLC is greater than 50%, but AutoImmune does not have control of Colloral LLC. Therefore, the investment is accounted for using the equity method. AutoImmune contributed the equipment used to manufacture bulk product and a license to certain Colloral-related intellectual property to Colloral LLC. These assets had a net book value of $0. Deseret contributed cash and is committed to providing additional amounts, which additional amounts are refundable if the board of directors of Colloral LLC determines that the money is no longer needed. AutoImmune has no obligation to make additional capital contributions.

The investment was initially recorded by AutoImmune at a cost of $0. Profits and losses will be allocated in accordance with the joint venture agreement. Under equity accounting, AutoImmune will not recognize a

gain on this investment until AutoImmune's share of the profits of Colloral LLC exceeds its share of the cumulative losses. As of December 31, 2002, Colloral has not generated any profit; therefore, the investment is carried at $0.

6. Related Party Transactions

In connection with the formation of the Company and the issuance of 168,750 shares of common stock and 168,750 shares of junior convertible preferred stock to The Brigham and Women's Hospital ("BWH"), the Company entered into related technology transfer and research and development agreements with BWH. The technology transfer agreement provides the Company with all rights and interests in certain BWH patented technology in exchange for the issuance of the aforementioned stock and the payment of royalties under certain conditions. The research and development agreement provides that certain research activities are performed by BWH on behalf of the Company.

The current research and development agreement with BWH extends until June 30, 2003, and is renewable for additional one year periods by mutual consent. The Company has agreed to pay BWH $48,000 for the one-year period ending June 30, 2003 of which $24,000 remains to be paid in 2003. There is no guaranteed minimum payment for the one-year period ending June 30, 2004. The agreement also provides for payments to BWH for royalties on sales of related patented products by the Company, as well as for payments to BWH for a portion, as defined in the agreement, of any proceeds received by the Company in connection with the licensing of patented technology to, and royalty or milestone payments received from, third parties. During the years ended December 31, 2000 and 2001, the Company paid to BWH $200,000 and $75,000, respectively, which amounts represent a portion of the cash payment received from a subsidiary of Elan Plc. Royalty payments to BWH begin upon the commercialization of the related products and will continue for the life of the underlying patent. For a period not to exceed three years after the first commercial sale of any product of the Company, the Company is required to make payments to BWH in each quarter only to the extent that the Company has a positive cash flow in such quarter with the balance deferred to the succeeding quarter.

Deferred payments will be subject to interest. If the Company defaults in the payment of any amount due to BWH, BWH will have an option to purchase all technology developed under the research program at a purchase price equal to the sum of all amounts previously paid by the Company to BWH. In addition, certain expenses were paid by the Company for research conducted at BWH.

During the year ended December 31, 2000, the Company paid $50,000 for consulting services to an entity whose founder is a director of the Company.

7. Income Taxes

The components of deferred income tax benefit (expense) are as follows:

	Year ended December 31,		
	2000	2001	2002
Income tax benefit (expense):			
Federal	$ (865,000)	$(171,000)	$274,000
State	(269,000)	(52,000)	85,000
	(1,134,000)	(223,000)	359,000
Deferred tax asset valuation allowance	1,134,000	223,000	(359,000)
	$ —	$ —	$ —

No significant federal or state taxes were payable in any years as a result of losses incurred and utilization of net operating losses and credits.

A reconciliation between the amounts of reported income tax (expense) benefit and the amount determined by applying the U.S. federal statutory rate of 35% for 2000, 2001 and 2002 to pre-tax loss is as follows:

	Year ended December 31,		
	2000	2001	2002
(Income) loss at statutory rate	$(1,102,000)	$(297,000)	$311,000
Permanent items	89,000	91,000	(2,000)
Federal and state research and development, orphan drug, and investment tax credits	18,000	9,000	4,000
State tax benefit (liability), net of federal tax liability	(139,000)	(26,000)	46,000
	(1,134,000)	(223,000)	359,000
(Increase) decrease in valuation allowance	1,134,000	223,000	(359,000)
	$ —	$ —	$ —

Deferred tax assets are comprised of the following:

	December 31,	
	2001	2002
Research costs capitalized for tax purposes	$ 25,044,000	$ 25,198,000
Research and development, orphan drug and investment tax credits	11,327,000	11,331,000
Loss carryforwards	14,745,000	14,841,000
Other temporary differences	—	40,000
Gross deferred tax assets	51,116,000	51,410,000
Deferred tax asset valuation allowance	(51,116,000)	(51,410,000)
	$ —	$ —

The Company has provided a full valuation allowance for net deferred tax assets since the realization of these future benefits is not sufficiently assured as of the end of each related year. The increase in the valuation allowance for deferred tax assets in 2002 relates to the accumulation of additional net operating loss carryforwards. As the Company achieves profitability, these deferred tax assets will be available to offset future income tax liabilities and expenses. Of the $51,410,000 valuation allowance at December 31, 2002, $965,000 relating to deductions for stock option compensation will be credited to additional paid-in capital upon realization.

At December 31, 2002, the Company had the following net operating loss, research and development, orphan drug and investment tax credit carryforwards available to reduce future tax liabilities, which expire as follows:

Year of expiration	Net operating loss carryforward	Research and development, orphan drug and investment tax credit carryforwards
2003		$ 19,000
2004		91,000
2005		121,000
2006		162,000
2007		234,000
2008		420,000
2009		960,000
2010		728,000
2011		3,895,000
2012	$34,325,000	3,670,000
2018	553,000	889,000
2019	1,825,000	583,000
2020	—	26,000
2021	—	13,000
2022	400,000	6,000
	$37,103,000	$11,817,000

Ownership changes, as defined in the Internal Revenue Code, resulting from the Company's initial public offering of stock in January 1993 and subsequent follow-on offerings in 1995, had no impact on the amount of net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income or tax liabilities. Subsequent significant ownership changes could, however, limit the utilization of these carryforwards in future years.

8. Preferred Stock

Upon the closing of the Company's initial public offering on January 27, 1993 each share of Series A, Series B and Series C convertible preferred stock automatically converted into three shares of common stock (Note 9). No dividends had been paid to the preferred stockholders.

At December 31, 2002, the Company had 5,000,000 authorized shares of $.01 par value preferred stock. Preferred stock may be issued at the discretion of the Board of Directors of the Company (without stockholder approval) with such designations, rights and preferences as the Board of Directors may determine from time to time. The preferred stock may have dividend, liquidation, redemption, conversion, voting or other rights which may be more expansive than the rights accorded to the common stock.

On May 17, 1995, the Company's Board of Directors adopted a shareholder rights plan. The Board declared a distribution of one right for each share of common stock outstanding on June 1, 1994. Stock issued after that date will be issued with an attached right. Each right will entitle the holder, upon the occurrence of certain events, to purchase 1/100th of a share of preferred stock at an exercise price of $73. The Board may, at any time, redeem the rights until their expiration on June 1, 2005, and may amend the rights under certain circumstances until they become exercisable.

9. Stockholders' Equity and Common Stock

In December 1992, the Company effected a three-for-one stock split of the Company's common stock in the form of a stock dividend. All common shares and per share amounts have been adjusted to give retroactive effect to the common stock split for all years presented.

In January 1993, the Company completed its initial public offering of 3,000,000 shares of common stock. Proceeds to the Company, net of issuance costs, amounted to $35,690,000.

In January 1995, the Company completed a private placement of 2,039,547 shares of common stock. Proceeds to the Company, net of issuance costs, amounted to $9,136,000.

In August and September 1995, the Company completed its second public offering of 3,925,000 shares of common stock. Proceeds to the Company, net of issuance costs, amounted to $58,878,000.

As of December 31, 2002, the Company has reserved 2,089,196 shares of common stock for use in the Company's stock option plans and employee stock purchase plan (Note 10).

10. Stock Option and Employee Stock Purchase Plans

1988 Stock Option Plan

The Company's 1988 Stock Option Plan (the "1988 Stock Option Plan"), as amended effective May 15, 1996, provided for the granting of incentive stock options and non-qualified stock options to employees and other individuals performing services on behalf of the Company. The Compensation Committee, appointed by the Board of Directors, is responsible for the administration of the 1988 Stock Option Plan. The Compensation Committee determined the term of each option, option price, number of shares for which each option was granted, whether restrictions were imposed on the shares subject to options and the rate at which each option becomes exercisable. The maximum number of shares of common stock of the Company reserved for issuance in accordance with the terms of the 1988 Stock Option Plan was 3,700,000.

The 1988 Stock Option Plan expired on September 19, 1998.

1998 Stock Option Plan

The Company's 1998 Stock Option Plan (the "1998 Stock Option Plan"), adopted by the shareholders on May 28, 1998, provides for the granting of incentive stock options and non-qualified stock options to employees, directors and other individuals performing services on behalf of the Company. The Compensation Committee is responsible for the administration of the 1998 Stock Option Plan. The Compensation Committee determines the term of each option, option price, number of shares for which each option is granted, whether restrictions will be imposed on the shares subject to options and the rate at which each option is exercisable. The exercise price for stock options granted may not be less than 100% of the fair market value per share of the underlying common stock on the date granted (110% for options granted to holders of more than 10% of the voting stock of the Company). The term of options granted under the 1998 Stock Option Plan cannot exceed ten years (five years for options granted to holders of more than 10% of the voting stock of the Company). The maximum number of shares of common stock of the Company reserved for issuance in accordance with the terms of the 1998 Stock Option Plan is 1,300,000.

Director Stock Option Plan

In 1993, the Company's Board of Directors approved a stock option plan for non-employee directors (the "Director Option Plan"). This plan was approved by the Company's shareholders in 1994 and an amendment to the plan was approved by the shareholders on May 15, 1996. Under the original Director Option Plan, each director who was eligible to participate in the plan on May 19, 1993 received, at fair market value on the date of grant, options to purchase 4,000 shares of common stock. Under the amended Director Option Plan, upon the first election of a non-employee to the Board of Directors, the director receives an option to purchase 25,000 shares of common stock. In each year thereafter, if the individual is still a member of the Board of Directors, the director receives options to purchase an additional 6,500 shares of common stock. In addition, an option to purchase 1,000 shares of common stock was granted to each director who was a member of a standing committee of the Board of Directors on May 19, 1993, and the amended Director Option Plan provides that an option for 1,000 shares will be granted automatically to each member of a standing committee following his first election to each such committee, and options to purchase 1,000 additional shares will automatically be granted every four years thereafter for each standing committee of which the individual remains a member. Options to purchase 246,000 shares of common stock have been granted under the Director Option Plan. Options to purchase 30,000 shares of common stock have been cancelled. At December 31, 2002, options to purchase 216,000 shares of common stock are outstanding. A maximum of 300,000 shares of common stock of the Company is reserved for issuance in accordance with the terms of the amended Director Option Plan.

A summary of option activity under the Stock Option Plans and the Director Option Plan for the years ended December 31, 2000, 2001 and 2002 is as follows:

	Shares	Weighted average exercise price
Outstanding at December 31, 1999	1,643,381	$1.74
Granted (weighted average fair value $0.79)	26,000	1.31
Exercised	(101,751)	1.90
Cancelled	(139,344)	1.77
Outstanding at December 31, 2000	1,428,286	1.72
Granted (weighted average fair value $0.79)	31,000	3.43
Exercised	(160,000)	0.03
Cancelled	(122,250)	0.83
Outstanding at December 31, 2001	1,177,036	2.08
Granted (weighted average fair value $0.34)	576,500	0.58
Exercised	—	
Cancelled	(510,000)	1.33
Outstanding at December 31, 2002	1,243,536	1.70
Options exercisable at year end	618,286	2.67

As of December 31, 2000 and 2001, 1,261,536 and 1,046,786 options were exercisable, respectively, under the 1988 and 1998 Stock Option Plans and Director Option Plan.

The following table summarizes information about stock options outstanding at December 31, 2002:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable	Weighted average exercise price
$ 0.52	500,000	9.5 years	$ 0.52	—	$ —
$ 0.53—$1.81	372,500	6.3 years	1.32	286,250	1.45
$ 2.00—$ 3.00	261,600	5.1 years	2.39	245,100	2.39
$ 3.06—$ 8.75	83,436	3.9 years	5.57	60,936	6.32
$10.25	26,000	3.4 years	10.25	26,000	10.25
	1,243,536			618,286	

Employee Stock Purchase Plan

On July 20, 1994, the Board of Directors approved the 1994 Employee Stock Purchase Plan (the "Purchase Plan"). This plan enables eligible employees to purchase the Company's common stock at 85% of the fair market value of the stock on the date an offering commences or on the date an offering terminates, whichever is lower. The Purchase Plan is available to substantially all employees, subject to certain limitations. An eligible employee may elect to have up to 12% of his or her base pay withheld and applied toward the purchase of shares in such an offering (not to exceed $25,000 in any year). At December 31, 2002, 158,160 shares of common stock were reserved for purchases under the Purchase Plan. During 2000, 2001 and 2002, no shares were purchased under the Purchase Plan.

11. Accumulated Other Comprehensive Income

In the first quarter of 1998, the Company adopted SFAS No. 130, Reporting Comprehensive Income. This statement requires disclosure of comprehensive income and its components in interim and annual reports. Comprehensive income includes all changes in stockholders' equity during a period except those resulting from investments by stockholders and distributions to stockholders. Accordingly, the components of comprehensive income include net income and unrealized gains and losses on available-for-sale securities.

Net unrealized gains on marketable securities are comprised of the following:

	2000	2001	2002
Unrealized holding gain (loss) arising during the period	$ —	$ —	$4,000
Reclassification adjustment for (gain) loss included in net income	—	—	—
Net unrealized gain (loss) on marketable securities	$ —	$ —	$4,000

12. Commitments and Contingencies

Clinical Research Agreement

The Company entered into an agreement with CATO Research, effective June 1993, to have a clinical investigational study performed on the Company's multiple sclerosis product. The agreement allowed for termination by either the Company or CATO, upon prior written notice. In 1997, the Company terminated the agreement. Additionally, CATO was granted a warrant to purchase 30,000 shares of common stock of

the Company at $10.50 per share which expires in June 2003. In 1998, the warrant to purchase 10,000 shares became exercisable upon the achievement of a specific milestone. The value ascribed to these shares was not significant. Given the uncertainty surrounding the achievement of the final milestone, the estimated fair value of the remaining contingent stock purchase warrants to purchase 20,000 shares of common stock of the Company cannot be reasonably determined at December 31, 2002.

License Agreements

In December 1994, the Company entered into a license agreement with Eli Lilly and Company. Under the agreement, Eli Lilly provided support for clinical testing of the Company's autoimmune mediated (Type 1) diabetes product in exchange for certain worldwide license rights for the manufacture, distribution and sale of the related products. This agreement was terminated in the first quarter of 1999 as a result of Eli Lilly's failure to make a required milestone payment. Eli Lilly is obligated to complete the trials now underway and to provide the Company with full access to the data therefrom, including the right to use the data for any purpose. The Company has regained all rights to the product. Eli Lilly is completing the trials under a non-exclusive license for research purposes only.

In November 1999, the Company entered an agreement with Teva Pharmaceutical Industries Ltd. The agreement covers the development by Teva of an oral formulation of Copaxone® (glatiramer acetate), Teva's currently available injectable drug for multiple sclerosis. AutoImmune will receive a milestone payment if the product is approved for sale and an escalating royalty based on cumulative sales of products covered by the agreement.

In March 2000, the Company entered an agreement under which a subsidiary of Elan Plc has purchased all of AutoImmune's rights to certain patent applications involving the treatment of Alzheimer's Disease. Under the terms of the agreement, AutoImmune received a $4 million cash payment in March 2000, a $1.5 million cash payment in September 2001 and a $1.5 million cash payment in March 2003. In addition, Elan Plc received a warrant to purchase 375,000 shares of AutoImmune common stock at $3.13 per share in September 2001 and a warrant to purchase 375,000 shares of AutoImmune common stock at $0.7275 per share in March 2003. The valuation of the warrant issued in September 2001, as determined by the Black -Scholes method, of $192,000 was recorded as an offset to revenue. Furthermore, under the terms of this agreement, AutoImmune and The Brigham and Women's Hospital have indemnified the subsidiary of Elan Plc against any claim, demand or action, arising from any misrepresentation made to the subsidiary of Elan Plc about patent rights and warranties, up to the amount of monies received by AutoImmune under the agreement.

In August 2000, the Company entered an agreement with BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp). Under the terms of the agreement, AutoImmune granted BioMS an exclusive license to certain of the Company's patents to develop an injectable therapy for multiple sclerosis. So long as the agreement remains in effect and until BioMS markets such therapy, BioMS shall make monthly diligence payments to AutoImmune. These payments total $30,000 in the first year of the agreement and increase by $30,000 each year until they reach a maximum of $180,000 per year. In addition, AutoImmune is entitled to receive an escalating royalty based on cumulative sales of product covered by the agreement.

In August 2002, the Company entered into a License Agreement with Colloral LLC. Under the agreement, AutoImmune granted Colloral LLC an exclusive, worldwide license in certain patents related to the production of Colloral as a nutraceutical and a non-exclusive license in certain of AutoImmune's information, data and knowledge needed to manufacture and sell Colloral as a nutraceutical. In return for these license grants, Colloral LLC agreed to use diligent efforts to market and obtain maximum sales of

Colloral. Pursuant to the operating agreement of Colloral LLC, AutoImmune is entitled to a percentage of the distributions of Colloral LLC on a quarterly basis.

Indemnification

The Company enters into standard indemnification agreements in its ordinary course of business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally its business partners, in connection with any U.S. patent, or any copyright or other intellectual property infringement claim by any third party with respect to its products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments that could be required under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal.

Leases

The Company is currently operating in a virtual mode utilizing the personal office spaces of the President and the Director of Finance and therefore no leases are required. As a result, at December 31, 2002 the Company has no lease obligations and there were no future minimum lease commitments.

13. Subsequent Event

In March 2003, the Company received a $1.5 million cash payment from Elan Plc (see Note 12). In addition, Elan Plc received a warrant to purchase 375,000 shares of AutoImmune common stock at $0.7275 per share.

14. Quarterly Results (Unaudited)

The following table sets forth unaudited selected financial information for the periods indicated. This information has been derived from unaudited financial statements, which, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of such information. This information has not been audited or reviewed by the Company's independent accountants in accordance with standards established for such reviews. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2001				
Total revenue	$ 7,000	$ 8,000	$1,318,000	$ 15,000
Total expenses	294,000	197,000	274,000	196,000
Net income (loss)	(122,000)	(70,000)	1,141,000	(101,000)
Income (loss) per share—basic and diluted	$ (0.01)	$ (0.01)	$ 0.07	$ (0.01)
2002				
Total revenue	$ 15,000	$ 15,000	$ 18,000	$ 22,000
Total expenses	282,000	242,000	311,000	214,000
Net income (loss)	(216,000)	(177,000)	(245,000)	(251,000)
Income (loss) per share—basic and diluted	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.01)

Price Range of Common Stock and Dividend Policy

The Company's Common Stock is traded on the Nasdaq SmallCap Market under the symbol AIMM. The following table shows the quarterly high and low closing price on Nasdaq for a share of the Company's Common Stock for the two years ended 2002.

	Price range of Common Stock	
	High	Low
Fiscal year ending December 31, 2001		
First quarter	$2.65	$1.47
Second quarter	4.00	2.04
Third quarter	3.80	0.62
Fourth quarter	1.39	0.84
Fiscal year ending December 31, 2002		
First quarter	$1.35	$1.03
Second quarter	1.09	0.60
Third quarter	1.09	0.49
Fourth quarter	0.93	0.63

As of March 20, 2003, there were 203 record holders and approximately 5,000 total shareholders of the Company's Common Stock.

AutoImmune has never declared or paid any cash dividends on its capital stock. The Company currently intends to retain its earnings, if any, and therefore does not anticipate paying any cash dividends on its capital stock in the foreseeable future.

Stockholder Information

Transfer Agent

Computershare Trust Company, Inc.
350 Indiana Street, Suite 800
Golden, CO 80401

Independent Accountants

PricewaterhouseCoopers LLP
Boston, Massachusetts

General Counsel

Nutter, McClennen & Fish, LLP
Boston, Massachusetts

Stock Exchange

Nasdaq SmallCap Market
Symbol: AIMM

Investor Information

A copy of the 2002 Annual Report as filed with the Securities and Exchange Commission on Form 10-K may be obtained free of charge by writing to:

AutoImmune Inc.
1199 Madia Street
Pasadena, CA 91103

Annual Meeting

The Annual Meeting of Shareholders will be held on Thursday, May 22, 2003 at 11:00 o'clock in the morning, Eastern Time, at the offices of Nutter, McClennen & Fish, LLP, World Trade Center West, 155 Seaport Boulevard, Boston, Massachusetts.

Corporate Directory

Corporate Mailing Address

AutoImmune Inc.
1199 Madia Street
Pasadena, California
91103
Tel. 626-792-1235
Fax 626-792-1236

Executive Officers

Robert C. Bishop, Ph.D.
Chairman, President and
Chief Executive Officer

Heather A. Ellerkamp
Director of Finance
and Treasurer

Board of Directors

Robert C. Bishop, Ph.D.
Chairman of the Board,
President and
Chief Executive Officer
AutoImmune Inc.

Hugh A. D'Andrade
Retired

Allan R. Ferguson
Managing Director
3i Ventures Corporation

R. John Fletcher
Chief Executive Officer
Fletcher Spaght, Inc.

Henri A. Termeer
President,
Chief Executive Officer
And Chairman of the Board
Genzyme Corporation

Constantine Alexander, Esq.
Secretary

This Annual Report contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from results discussed in the forward-looking statements due to a number of factors, including, but not limited to, the Company's extremely limited operations, the uncertainties of clinical trials results, the Company's dependence on third parties for licensing and other revenue, and the risks of technological change and competition. These factors are more fully discussed in the Company's most recent Annual Report on Form 10-K included herein.

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