AUTOIMMUNE INC.

2004

ANNUAL REPORT

AUTOIMMUNE™

To Our Shareholders:

AutoImmune Inc. had a turbulent year in 2004, with both positive and negative events impacting the company. Although it was transparent to many of you, NASDAQ made a determination that from their perspective we were not sufficiently an operating company to maintain a SmallCap market listing and thus had to transfer stock trading to the OTC Bulletin Board.

Despite all efforts to date, we have not yet been successful in building substantial sales volume for the dietary supplement produced by our joint venture with Deseret Laboratories, Inc. The issues here are believed related both to product positioning and the choice of sales channels. Business Development Resources, Inc., a prominent consumer marketing firm, has been retained to create a plan that addresses these deficiencies. We remain optimistic this product can produce considerable value for our company, but need to resolve a current challenge to its regulatory status before making a final decision on significant promotional investments.

As long term shareholders well know, AutoImmune has licensed two applications of its intellectual property to capable partners in deals that could generate substantial value for the Company if 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. During the last half of 2004, Teva began a Phase II human clinical trial looking at two different doses of the oral product. We expect the first data from this trial will be available sometime next year. The second license is with BioMS Medical Corporation, which in December 2004 began a Phase III trial of its MBP8298 product for the treatment of chronic progressive multiple sclerosis. Recruitment for this trial is expected to take at least twelve months. We are pleased with the progress of our licensees this past year and look forward to the results of their clinical studies.

Final data from the oral insulin arm of the NIH sponsored diabetes prevention trial (DPT1), which tested a therapeutic method covered by AutoImmune's patents, is soon to be published and shows a statistically significant benefit for patients enrolled under the original entry criteria. We are told that NIH is currently planning a confirmatory study that could start later this year and hope this might lead 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 174 issued US and foreign patents, plus two 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 in the future.

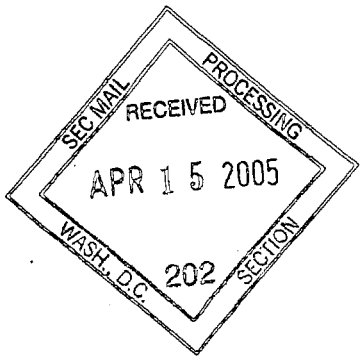
With adequate financial reserves to wait for results from clinical trials of products based on our intellectual property and the prospect of positive cash flows in the future, we believe we are well positioned for success and remain optimistic that our technology will be proven of significant therapeutic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

Your interest in AutoImmune is greatly appreciated.

Sincerely,

Robert C. Bishop

Robert C. Bishop
Chairman of the Board
March 30, 2005



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, 2004.

Commission File Number 0-20948

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 30, 2004, the aggregate market value of the common stock held by non-affiliates of the registrant was $10,567,373[1]. As of March 17, 2005, 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 10% 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, 2004 are incorporated by reference into Part III hereof.

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PART I

Item 1. Business.

Overview

We are a healthcare company that owns or has rights to technology that we believe could lead to the development of a new class of therapeutics for the treatment of autoimmune and other cell-mediated inflammatory diseases and conditions. We believe, based on preclinical and clinical data, that our 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 our 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.

We believe AutoImmune is the leading company for the development of therapeutics based upon the concepts of mucosal tolerance. The status of each of our principal products is as follows:

Colloral®—Between 1991 and 1999, we 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 showed 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, we began exploring the possibility of repositioning Colloral as a nutraceutical. In 2000, we completed a market analysis of Colloral as a nutritional supplement and subsequently 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, we entered into a joint venture with Deseret Laboratories, Inc. (a private company headquartered in St. George, Utah) by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutritional supplement. The joint venture began marketing Colloral in February 2003. In September 2003 and November 2004, we made additional capital contributions of $25,000 and $100,000, respectively, to Colloral LLC to support sales and marketing initiatives.

On February 18, 2005, we received a letter from the FDA stating that the FDA reconsidered the information contained in our Notice of New Dietary Ingredient and concluded that Colloral is not a dietary supplement but appears to be a drug under the Federal Food, Drug, and Cosmetic Act, and thus subject to the regulatory requirements for drugs. We are currently working with outside counsel to respond to this letter and hope to demonstrate that Colloral meets the statutory definition of a dietary supplement. See the section "Factors To Be Considered" below.

Products for Multiple Sclerosis—In February 1999, we 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, called Coral®, uses our proprietary technology for oral tolerance. After an unsuccessful efficacy trial, Teva conducted additional immunologic and pharmacological studies on oral formulations. During the second half of 2004, Teva re-initiated human clinical trials on Coral® with a Phase II study in Europe.

In August 2000, we entered into an agreement with BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp.), under which we granted BioMS an exclusive license to our patents pertaining to

an injectable therapy for the treatment of multiple sclerosis. During December 2004, BioMS began enrolling patients in a Phase III clinical trial on its MBP8298 treatment for chronic progressive multiple sclerosis.

Diabetes—Under a license and collaborative agreement signed in 1994, Eli Lilly and Company initiated three different Phase II clinical trials in an effort to demonstrate human proof of principle for oral administration of our product AI 401 in patients newly diagnosed with Type 1 diabetes. This agreement was restructured in 1999 to a non-exclusive license for research purposes only under which Eli Lilly completed the trials then underway. Two of the Eli Lilly studies, both of which looked at younger patients, reported negative results. The final study found that, in patients greater than 20 years of age, there was a statistically significant benefit from treatment with AI-401. Eli Lilly also provided AI 401 for the Diabetes Prevention Trial ("DPT-1") conducted by the National Institutes of Health ("NIH"). The oral arm of this trial was designed to determine whether AI 401 can delay or prevent the clinical onset of Type 1 diabetes. Final analysis of the DPT-1 data showed that for patients enrolled under the original entry criteria, there was a statistically significant benefit from treatment with AI 401. These results have been accepted for publication and should appear during the first half of 2005. The NIH is expected to initiate a confirmatory study on AI 401 during 2005.

Our intellectual property also is being used in the Diabetes Prediction and Prevention project, which is a Phase II clinical trial in Finland on the use of intranasal insulin to delay or prevent the clinical onset of Type I diabetes.

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

We were incorporated in Delaware in September 1988 as AutoImmune Technologies, Inc. We changed our name to AutoImmune Inc. in July 1991. Our principal executive address is 1199 Madia Street, Pasadena, CA 91103, our telephone number is (626) 792-1235, and our web site address is www.autoimmuneinc.com. We include our web site address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our web site.

Strategy

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

Leveraging Our Technology Platform. We believe our technology is applicable to a variety of autoimmune and other cell-mediated diseases and conditions. We have entered into, and plan to continue to seek opportunities for, licensing arrangements, joint ventures or other collaborative arrangements to assist in financing the development and commercialization of our products. This strategy has resulted in our collaboration with Eli Lilly and Company for clinical testing of our product to treat autoimmune-mediated diabetes, our agreement with Teva relating to the development of an oral formulation of Copaxone, our license agreement with BioMS relating to our patents pertaining to an injectable therapy for the treatment of multiple sclerosis, and our joint venture with Deseret Laboratories, Inc. to manufacture, market and sell Colloral as a nutritional supplement.

Our strategy also resulted in an agreement with OraGen Corporation, under which we 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 conditions resulting from infectious diseases. In February 2004, Enzo Biochem, Inc. acquired the assets of OraGen, including its technology related to mucosal tolerance.

We have developed 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 was designed to further our understanding of the mechanisms of mucosal tolerance with the goal of increasing the effectiveness of our products and exploring new therapeutic applications for this technology. We currently have no internal research and development activities or capabilities.

In March 2000, we entered into an agreement under which a subsidiary of Elan Plc purchased all of our rights to certain patent applications involving the treatment of Alzheimer's Disease. Under the terms of the agreement, we received $7.0 million in cash paid in three installments the last of which was received in March 2003, and Elan Plc received warrants to purchase 375,000 shares of our Common Stock at $3.13 per share and 375,000 shares of our Common Stock at $.7275 per share.

Protecting Our Proprietary Technology. From our inception, we have sought to establish a strong proprietary position. As of December 31, 2004, we had pending two original and continuation-in-part United States patent applications and numerous foreign counterparts. We have received or have exclusive rights to 174 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; five 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 issued a patent covering bystander suppression of Type 1 diabetes by oral administration of glucagon. The European and Japanese Patent Offices have each granted a patent to us covering the use of compositions containing autoantigens to treat a group of human autoimmune diseases. The European Patent Office and the Japanese Patent Office have each granted one patent covering use of myelin basic protein in the treatment of multiple sclerosis. The European Patent Office has also granted one patent covering bystander suppression of autoimmune disease.

Minimizing Costly Infrastructure and Capital Investment. From our inception, we have sought to conserve our financial capital. We have historically made extensive use of external resources, such as clinical research organizations and consultants. Currently, we anticipate minimizing investments in infrastructure and personnel until positive cash flow from the distributions from our joint venture Colloral LLC and/or royalties from our licensing agreements, if any, creates a solid base from which to re-expand operations.

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. 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 often have serious toxicity and side effect problems with long-term use.

While there are numerous cell-mediated autoimmune diseases, we are presently focused on products for three of these diseases: rheumatoid arthritis, multiple sclerosis and Type 1 diabetes. 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. 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 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.

We have directed our 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 our mucosal tolerance approach. No completely satisfactory treatment currently exists for any of these conditions.

Our Technology

Most of our 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 our 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 our products and patent claims. See the section "Patents and Proprietary Rights" below.

Our technology 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.

We have completed a wide range of human, animal and in vitro tests relating to the mucosal administration of our products in a variety of disease indications. We believe 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.

Our 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. We refer to this phenomenon as "bystander suppression," and have filed patent applications and have patents to protect our 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, our 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 our products, we believe 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. We believe our approach of inducing the activation of regulatory T cells in order to suppress disease distinguishes us from most others currently conducting autoimmune disease research.

Our approach offers a number of important clinical and commercial advantages:

Adverse Reactions Unlikely. We believe that, because the therapeutic substances used in the products under development employing our technology are protein-based products taken in small quantities and stimulate natural functions, they are unlikely to cause adverse reactions. Our human studies to date have shown a lack of both toxicity and significant side effects, which we believe may expedite the regulatory process.

Tissue-Specific Immunosuppression. Our 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. Colloral® and Coral (Teva's product under development using our licensed technology) are administered orally, the preferred method of treating chronic diseases. Other forms of immunotherapy that are being marketed sometimes require, and those that we know are in development by competitors for the most part require, chronic intravenous, sub-cutaneous or intra-muscular administration.

Broad Application. We believe that, in addition to the diseases and conditions on which we have been working to date, our 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

Products on the Market. We have one product on the market as a dietary supplement. The chart set forth below describes the status of that product.

PRODUCTS ON THE MARKET

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

Colloral®. Between 1991 and 1999, we 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 showed 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, we began exploring the possibility of repositioning Colloral as a nutraceutical. In 2000, we completed a market analysis of Colloral as a nutritional supplement and subsequently 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, we entered into a joint venture with Deseret Laboratories, Inc. (a private company headquartered in St. George, Utah) by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutritional supplement. We contributed equipment used to manufacture bulk product and a license to certain Colloral-related intellectual property to the joint venture. 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. The joint venture began marketing Colloral in February 2003. In September 2003 and November 2004, we made additional capital contributions of $25,000 and $100,000, respectively, to Colloral LLC to support sales and marketing initiatives. To date, sales of Colloral by the joint venture have not been significant. We have no obligation to make additional capital contributions to Colloral LLC.

On February 18, 2005, we received a letter from the FDA stating that the FDA reconsidered the information contained in our Notice of New Dietary Ingredient and concluded that Colloral is not a dietary supplement but appears to be a drug under the Federal Food, Drug, and Cosmetic Act, and thus subject to the regulatory requirements for drugs. We are currently working with outside counsel to respond to this letter and hope to demonstrate that Colloral meets the statutory definition of a dietary supplement. See the section "Factors To Be Considered" below.

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, but have other side effect issues. 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 nutritional support products.

Principal Products in Development. We have products in development, through our licensees, for the treatment of multiple sclerosis and Type 1 diabetes. The chart set forth below describes the stage of development of each of the principal products being developed.

PRINCIPAL PRODUCTS IN DEVELOPMENT

Product	Disease/Condition	Development Status
Coral®	Multiple sclerosis	Currently in Phase II trials (conducted by Teva).
MBP8298	Multiple sclerosis	Currently in Phase III trials (conducted by BioMS).
AI 401	Type 1 diabetes	Additional studies in the US are in the planning stage at the National Institutes of Health (NIH).

Multiple Sclerosis. In the second quarter of 1997, we 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, we 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 our proprietary technology for oral tolerance. After an unsuccessful efficacy trial, Teva conducted additional immunologic and pharmacologic studies on oral formulations. During the second half of 2004, Teva re-initiated human clinical trials on Coral® with a Phase II study in Europe. If Teva receives product approval from the FDA, we will receive a $10 million milestone payment and escalating royalties on cumulative sales of all products covered by the Teva agreement.

In August 2000, we entered into an agreement with BioMS Medical Corporation under which we granted BioMS an exclusive license to our patents pertaining to an injectable therapy for the treatment of multiple sclerosis. During December 2004, BioMS began enrolling patients in a Phase III clinical trial 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, we 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, several products have been approved by the FDA for the treatment of relapsing/remitting multiple sclerosis. All four 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, which include injection site reactions, flu-like symptoms and shortness of breath.

Type 1 Diabetes. In December 1994, we entered into a license and collaborative agreement with Eli Lilly and Company under which Eli Lilly initiated support for clinical testing of our orally administered autoimmune-mediated (Type 1) diabetes product, AI 401. This agreement was restructured in the first quarter of 1999 into a non-exclusive license for research purposes only as a result of Eli Lilly's failure to make a required milestone payment. Eli Lilly completed the trials then underway and remains obligated to provide us with full access to the data therefrom, including the right to use such data for any purpose. Investigators sponsored by Eli Lilly completed three different Phase II clinical trials in an effort 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. Published results of that study showed AI 401 to benefit adult patients who were diagnosed with Type 1 diabetes at age 20 and older. 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) conducted by the National Institutes of Health. The oral arm of this trial, which began in September 1996, was designed to determine whether AI 401 can delay or prevent the clinical onset of Type 1 diabetes. Final analysis of the DPT-1 data showed that for patients enrolled under the original entry criteria, there was a statistically significant benefit from treatment with AI 401. These results have been accepted for publication and should appear during the first half of 2005. The NIH is expected to initiate a confirmatory study on AI 401 during 2005. Currently in Finland, a clinical trial of intranasal insulin to delay or prevent the clinical onset of Type I diabetes, called the Diabetes Prediction and Prevention Project, is being conducted. We believe this clinical trial is using our intellectual property.

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. We believe that the preferred therapeutic approach would be an oral treatment, 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. We expect 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 our diabetes product.

Collaborative Research Agreements

During the early stages of our development, we chose to operate through a variety of agreements with medical research institutions. Our 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 us to conduct pilot human studies and demonstrate the potential utility of its technique in a number of diseases at a early stage of our development.

The Brigham and Women's Hospital. BWH, a teaching hospital affiliated with Harvard Medical School, has been performing sponsored research for us since 1988. Our agreement with BWH extends until June 30, 2005 and is renewable for additional one-year periods by mutual consent. Since June 30, 2004 there has been no funding provided to BWH under this agreement. It is currently anticipated that research funding will be reinitiated June 30, 2005. We 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. If successful, we will pay to BWH (i) a royalty on all products sold by us that are subject to a patent covering an invention developed under the research program or as to which rights were acquired by us from BWH, and (ii) a percentage of any upfront payments and/or royalties received by us with respect to sales of such products by others. BWH also may receive a percentage of any milestone payments we receive from licensees or other transferees of such patent after the first commercial sale of a product covered by a patent. If we default 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 us to BWH.

The following are the amounts spent during the last three fiscal years on our company-sponsored research program with BWH:

For the Year Ended		
December 31, 2004	**December 31, 2003**	**December 31, 2002**
$24,000	$123,000(1)	$48,000

(1) Includes $75,000 paid to BWH from payment received from Elan Plc pursuant to an agreement entered into between Elan Plc. and AutoImmune effective January 29, 2000.

The research at BWH constitutes our only sponsored research activity involving our technology. Other medical research institutions and firms are conducting research in this area and the question of whether they may require a license from us to commercialize their efforts cannot be determined at this time.

BWH is a shareholder of AutoImmune, and both of the scientists who made the discoveries which led to the founding of AutoImmune are affiliated with BWH.

Manufacturing and Raw Materials

Currently, we are not producing any products for clinical or commercial use on our own and have no plans to manufacture products.

Colloral LLC (our joint venture with Deseret Laboratories, Inc.) is producing Colloral for use by consumers. As part of our capital contribution to Colloral LLC we contributed all of the equipment and procedures previously used by us 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. All of the raw materials used in the manufacture of Colloral are, at the present time, widely available in the marketplace.

Marketing and Sales

In order to market any of our products directly, we would need to develop a marketing and sales organization. We have no plans to develop our own marketing and sales organization, but rather plan to market and sell our 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.

Colloral LLC (our joint venture with Deseret Laboratories, Inc.) began marketing Colloral in February 2003 through direct mail solicitation of individuals who had previously expressed interest in obtaining the product. In the third quarter of 2003, Colloral LLC began market testing several approaches to increase the sales of Colloral in geographically limited areas, and in the fourth quarter of 2004, Colloral LLC contracted with Business Development Resources, Inc. for the development of a consumer oriented marketing plan.

Patents and Proprietary Rights

The establishment of a strong proprietary position is an important element of our strategy. As of December 31, 2004, we had pending two original and continuation-in-part United States patent applications and numerous foreign counterparts. We have received or have exclusive rights to 174 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; five 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 issued a patent covering bystander suppression of Type 1 diabetes by oral administration of glucagon.

The European and Japanese Patent Offices have each granted a patent to us 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, we eventually prevailed, and the Japanese patent has been reinstated with narrower claims. We prevailed in the opposition to its European patent and that patent remains in force essentially as issued. The European Patent Office and the

Japanese Patent Office have each granted one patent covering use of myelin basic protein in the treatment of multiple sclerosis. The European Patent Office has also granted one patent covering bystander suppression of autoimmune disease.

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

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

Lastly, there can be no assurance that third-parties will not bring suit against us for patent infringement by us or a licensee of ours or to have our 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. We compete with a number of pharmaceutical and biotechnology companies that have financial, technical and marketing resources significantly greater than ours. Companies with established positions in the pharmaceutical and nutraceutical industries are better equipped than we are 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 more actively seeking patent protection and licensing arrangements to collect royalties for use of technologies they have developed. These institutions also may market competitive commercial products on their own or through joint ventures.

Our competitors may succeed in developing products that are just as safe and more effective than our products. Rapid technological change or developments by others may result in our products and potential products becoming obsolete or non-competitive.

For additional information concerning products developed and under development by our competitors to treat rheumatoid arthritis, see the section "Products" above.

Government Regulation

The manufacturing and marketing of our products and certain areas of our 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 our products. There can be no assurance that we or our licensees will ever obtain the government approvals necessary to make commercial sales of any products.

We believe that some of the pharmaceutical products under development by us or our licensees 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 biologic products require several steps in order to receive regulatory approval, including (i) preclinical laboratory and animal tests; (ii) submission to the FDA of an application for an Investigational New Drug Application ("IND"), or submission to an Institutional Review Board of a research institution 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 and that 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 evaluations, 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. Any clinical trials we conduct 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 also may 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.

In November 2000, we notified the FDA that we would begin marketing Colloral as a dietary supplement. Dietary supplements are subject to regulation under the Dietary Supplement Health and Education Act of 1994. On February 18, 2005, we received a letter from the FDA stating that the FDA reconsidered the information contained in our notice and concluded that Colloral is not a dietary supplement but appears to be a drug under the Federal Food, Drug, and Cosmetic Act, and thus subject to the regulatory requirements for drugs. We are working currently with outside counsel to respond to this letter and hope to demonstrate that Colloral meets the statutory definition of a dietary supplement. See the section "Factors To Be Considered" below.

If and when we begin producing a product for sale ourselves, we 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 our 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 us to maintain price levels sufficient for realization of an appropriate return on its investment in product development.

Employees

As of March 17, 2005, we have no full-time employees. The President and the Director of Finance are currently working for AutoImmune as employees on a part-time basis pursuant to agreements that we have entered into with them.

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. Our 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 our extremely limited operations, the uncertainties of clinical trial results and product development, our dependence on third parties for licensing and other revenue, our dependence on determinations of regulatory authorities, and the risks of technological change and competition. Set forth below is a discussion of certain factors that could cause our actual results to differ materially from the results projected in such forward looking statements.

Limited Operations. Since January 2000, we have operated with minimal staff and infrastructure. We have no full-time employees and our activities, conducted through our part-time President and Director of Finance, are primarily directed toward managing our investment in the Colloral LLC joint venture, supporting our current licensees and exploring additional opportunities to license our technology to additional companies that desire to develop, manufacture and sell products based upon our technology.

Developmental Stage of AutoImmune's and its Licensees' Products. We have not completed the development of any product except Colloral®. The pharmaceutical products being developed by us and our licensees 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 either we or our licensees will successfully develop additional products or that our 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 our inception in 1988 through December 31, 2004, we have accumulated net losses of $108,492,000. We expect to incur additional losses as we continue to sponsor research and to pursue opportunities to license and otherwise exploit our technology. Our ability to achieve profitable operations depends in part on successful completion of the development by us and others of products utilizing our technology, the ability to obtain any required regulatory approvals and the ability to manufacture and market these products. There can be no assurance that we will achieve profitable operations at any time.

Our revenues to date have been earned in connection with collaborative/licensing agreements and the granting of short term rights (see "Dependence on Collaborative Agreements" below). Payments to us 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, we 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 we 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 we will derive any additional revenues from these agreements.

In August 2002, we entered into a joint venture with Deseret Laboratories, Inc. (a private company headquartered in St. George, Utah) by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutraceutical. Our interest in Colloral LLC is greater than 50%, but we do 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, we will record income for our proportionate share. During February 2003, Colloral LLC began marketing Colloral through direct mail solicitation of individuals who had previously expressed interest in obtaining the product. In the third quarter of 2003, Colloral LLC began market testing in geographically limited areas several approaches to increase the sales of Colloral, and in the fourth quarter of 2004, Colloral LLC contracted with Business Development Resources, Inc. for development of a consumer oriented marketing plan. If a decision is made to implement this plan, substantial additional contributions to the joint venture will be required, and there can be no assurance that we will derive income from these investments.

Colloral May Be Classified as a Drug Rather Than a Nutritional Supplement. In 2000, we completed a market analysis of Colloral as a nutritional supplement and subsequently filed a "Notice of New Dietary Ingredient" with the FDA that was accepted without comment. On February 18, 2005, we received a letter from the FDA stating that the FDA reconsidered the information contained in our Notice of New Dietary Ingredient and concluded that Colloral is not a dietary supplement but appears to be a drug under the Federal Food, Drug, and Cosmetic Act, and thus subject to the regulatory requirements for drugs. We are currently working with outside counsel to respond to this letter and hope to demonstrate that Colloral meets the statutory definition of a dietary supplement. We cannot predict what the effect of the FDA's letter will be. It is possible that Colloral LLC will be unable to market Colloral as a nutraceutical and that Colloral will be subject to the regulatory

requirements for drugs. If the FDA makes a final determination that requires us to comply with the regulatory requirements for drugs, Colloral will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC.

Additional Financing Requirements and Access to Capital. Since inception, we have raised net proceeds of $116,000,000 from the sale of equity securities in private placements and public stock offerings. We do not believe we currently have the ability to raise significant additional funds. Based upon our budget for calendar year 2005, we believe that current cash and marketable securities and the interest earned from the investment thereof will be sufficient to meet our operating expenses and capital requirements for at least five years. Thereafter, or if our operations change substantially, we will need to raise substantial additional capital to fund our operations, including clinical trials and commercialization efforts. There can be no assurance that such capital will be available on acceptable terms, if at all.

Dependence on Collaborative Agreements. Currently, we are wholly dependent upon collaborative agreements or arrangements with others. We have granted Teva Pharmaceutical Industries, Ltd. exclusive worldwide rights to certain of our patents covering the multiple sclerosis and myasthenia gravis applications of our technology. These rights were granted in return for payments based upon the achievement of certain milestones and royalties based on sales, if any. We also have 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, we 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 we will be able to negotiate other acceptable arrangements in the future or that such arrangements will be successful.

The majority of our basic research to date has been done through agreements with The Brigham and Women's Hospital and other medical research institutions. Between 1993 and 1999, we conducted some of our research and most of our development activities internally. Currently, we have no employees engaged in research and product development. Therefore, we expect to continue to be dependent upon research performed under contract with The Brigham and Women's Hospital. If we are unable to maintain this relationship, we would be adversely affected and our ability to commercialize future products may be delayed or eliminated.

Patents and Proprietary Rights. Our success will depend, in part, on our 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 our rights. We have received or have exclusive rights to 174 U.S. and foreign patents. We have filed and are actively pursuing numerous applications for additional U.S. and foreign patents, and are 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 us will provide us with any competitive advantages or will not be challenged by any third parties, that the patents of others will not impede our ability to do business or that third parties will not be able to circumvent our patents, that our licensees will not terminate their licenses or that they will be successful in producing and marketing products that trigger the payment of royalties to us, or that any of our 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 our products, or those of our licensees, or, if patents are issued to us, design around the patented products developed by us.

Both we and our 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 our 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 us or to our licensees. If we or our

licensees do not obtain such licenses, we or our 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, we could incur substantial costs in defending our self in suits for patent infringement brought against us or a licensee of ours or in filing suits against others to have their patents declared invalid.

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

Technological Change and Competition. The biotechnology, pharmaceutical and nutraceutical industries are subject to rapid and significant technological change. Our 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 our competitors will not develop technologies and products that would render our technology and products obsolete or noncompetitive. Most of our competitors have substantially greater financial and technical resources and production and marketing capabilities than we have. In addition, most of our competitors have significantly greater experience than we do 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, our competitors may obtain FDA approval for products more rapidly than we do.

We currently have no internal research and development activities or capabilities. We rely upon sponsored research with The Brigham and Women's Hospital for our research and development activities. Since June 30, 2004 there has been no funding provided to BWH under our agreement for sponsored research. It is currently anticipated that research funding will be reinitiated June 30, 2005.

Government Regulation. Prior to marketing, any pharmaceutical product utilizing our 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 our products and our 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.

Item 2. Properties.

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

Item 3. Legal Proceedings.

We are 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 AutoImmune's shareholders during the fourth quarter of fiscal year 2004.

Item 4A. Executive Officers of the Registrant.

The executive officers of AutoImmune are as follows:

Robert C. Bishop, Ph.D., age 62, is AutoImmune'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 AutoImmune 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 AutoImmune, 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 Millipore Corporation, a purification technologies/systems company serving the biopharmaceutical and analytical laboratories markets, a director of Caliper Life Sciences 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 Manager/Trustee of MFS/Compass Funds Complex (36 portfolios advised by MFS Investment Management).

Heather A. Ellerkamp, CPA, age 40, joined AutoImmune in February 1994. Ms. Ellerkamp has been Director of Finance and Treasurer of AutoImmune since June 1997, and from February 1994 to June 1997, she held various financial positions with AutoImmune, 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.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on the OTC Bulletin Board under the symbol AIMM. We received a letter dated February 24, 2004 from the Nasdaq Listing Qualifications Staff notifying us that, based upon the Staff's review of us and under its discretionary authority granted by the Nasdaq Marketplace Rules, our securities would be delisted on March 4, 2004 unless we appealed the Staff's decision. We appealed the Staff's decision and a hearing was held on April 1, 2004 before the Nasdaq Listing Qualifications Panel to review the Staff's decision. On May 24, 2004, the Company received notice from Nasdaq that the Listing Qualifications Panel rejected the Company's appeal and determined to delist the Company's securities from the Nasdaq SmallCap Market effective May 26, 2004.

The following table shows the quarterly high and low sales price on the Nasdaq SmallCap Market (before May 26, 2004) and the OTC Bulletin Board (beginning May 26, 2004) for a share of our common stock (based on intra-day trading) for the fiscal years ended December 31, 2003 and 2004.

	Price range of common stock	
	High	Low
Fiscal year ending December 31, 2003		
First quarter	$0.85	$0.62
Second quarter	$2.25	$0.47
Third quarter	$2.05	$1.12
Fourth quarter	$2.04	$1.25
Fiscal year ending December 31, 2004		
First quarter	$1.90	$1.15
Second quarter	$1.32	$0.65
Third quarter	$0.95	$0.75
Fourth quarter	$0.95	$0.78

As of March 17, 2005, there were 214 record holders and approximately 3,400 total shareholders of our common stock.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain our earnings, if any, and therefore, do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

Item 6. Selected Financial Data.

The selected financial data set forth below have been derived from our audited financial statements. The balance sheets at December 31, 2003 and December 31, 2004 and the related statements of operations and of cash flows for the three years ended December 31, 2002, December 31, 2003 and December 31, 2004 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 AutoImmune's financial statements and related notes included elsewhere in this Form 10-K.

	For the year ended December 31,				
	2000	2001	2002	2003	2004
Statement of Operations Data:					
Revenue:					
License rights	$ 4,010,000	$ 1,348,000	$ 70,000	$ 1,445,000	$ 130,000
Total revenue	4,010,000	1,348,000	70,000	1,445,000	130,000
Costs and expenses:					
Research and development:					
Related party	260,000	135,000	61,000	135,000	36,000
All other	522,000	237,000	327,000	179,000	290,000
General and administrative	679,000	589,000	661,000	605,000	608,000
Total costs and expenses	1,461,000	961,000	1,049,000	919,000	934,000
Income (loss) from operations	2,549,000	387,000	(979,000)	526,000	(804,000)
Interest income	599,000	461,000	190,000	127,000	138,000
Equity in net loss of unconsolidated affiliate	—	—	—	(25,000)	(95,000)
Other expense	—	—	(100,000)	—	—
Net income (loss)	$ 3,148,000	$ 848,000	$ (889,000)	$ 628,000	$ (761,000)
Net income (loss) per share—basic	$ 0.19	$ 0.05	$ (0.05)	$ 0.04	$ (0.04)
Net income (loss) per share—diluted	$ 0.18	$ 0.05	$ (0.05)	$ 0.04	$ (0.04)
Weighted average common shares outstanding—basic	16,743,349	16,909,541	16,919,623	16,919,623	16,919,623
Weighted average common shares outstanding—diluted	17,288,172	17,253,299	16,919,623	17,398,633	16,919,623

	December 31,				
	2000	2001	2002	2003	2004
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 9,883,000	$ 10,792,000	$ 10,018,000	$ 10,744,000	$ 9,996,000
Working capital	9,753,000	10,697,000	9,912,000	10,695,000	9,925,000
Total assets	9,955,000	10,934,000	10,099,000	10,779,000	10,038,000
Deficit accumulated during development stage	(108,322,000)	(107,474,000)	(108,363,000)	(107,735,000)	(108,496,000)
Total stockholders' equity	9,753,000	10,797,000	9,912,000	10,695,000	9,930,000

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. Our 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 our extremely limited operations, the uncertainties of clinical trial results and product development, our dependence on third parties for licensing and other revenue, our dependence on determinations of regulatory authorities, and the risks of technological change and competition.

From our inception through December 31, 2004, we have incurred ongoing losses from operations and have cumulative losses as of December 31, 2004 totaling $108,492,000. To date, we have not recorded any revenue from the sale of products. Revenues recorded through December 31, 2004 were earned in connection with license rights, contract research and the granting of certain short-term rights. As a result, inflation has not materially affected our revenues and income from continuing operations.

In August 2002, we entered into a joint venture with Deseret Laboratories, Inc. by forming an entity called Colloral LLC to manufacture, market and sell Colloral as a nutritional supplement. Our interest in Colloral LLC is greater than 50% and we actively participate in its management, but we do 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, we 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. In September 2003 and November 2004, AutoImmune made additional capital contributions of $25,000 and $100,000, respectively, to support sales and marketing initiatives. In the fourth quarter of 2004, Colloral LLC contracted with Business Development Resources, Inc. for the development of a consumer oriented marketing plan. If a decision is made to implement this plan, substantial additional contributions to the joint venture will be required, and there can be no assurance that these efforts will be successful. Accordingly, we may continue to incur substantial losses.

On February 18, 2005, we received a letter from the FDA stating that the FDA has concluded that Colloral is not a dietary supplement but appears to be a drug under the Federal Food, Drug, and Cosmetic Act, and thus subject to the regulatory requirements for drugs. We are currently working with outside counsel to respond to this letter and hope to demonstrate that Colloral meets the statutory definition of a dietary supplement. It is possible that Colloral LLC will be unable to market Colloral as a nutraceutical, and that Colloral will be subject to the regulatory requirements for drugs. If the FDA makes a final determination that requires us to comply with the regulatory requirements for drugs, Colloral will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC.

Years Ended December 31, 2003 and 2004

Revenue was $1,445,000 and $130,000 for the years ended December 31, 2003 and 2004, respectively. In the first quarter of 2003, revenue was comprised of (i) a $1,500,000 payment by a subsidiary of Elan Plc for the purchase of certain patent rights related to Alzheimer's disease net of warrants valued at $155,000 granted to Elan Plc at the time of the payment and (ii) monthly license payments from BioMS Medical Corporation. The revenue in 2004 and the remainder of 2003 was comprised solely of monthly license payments from BioMS. The payment from Elan Plc was the third and final payment pursuant to the agreement entered into between Elan Plc and us dated effective January 29, 2000. Under the terms of that agreement, AutoImmune and The Brigham and Women's Hospital have indemnified Elan Plc against any claim, demand or action arising from any misrepresentation made to Elan Plc about patent rights and breach of warranties.

Research and development expenses were $314,000 and $326,000 for the years ended December 31, 2003 and 2004, respectively. The increase is due to a $112,000 increase in patent-related legal costs, which was partially offset by the decrease in the amount we paid to The Brigham and Women's Hospital under a research and development agreement. In the first quarter of 2003, we paid The Brigham and Women's Hospital $75,000 of the payment we received from Elan Plc during the same quarter. Effective for the current fiscal year contract, the research and development agreement with the Brigham and Women's Hospital was extended but unfunded, and therefore, the quarterly payments were terminated effective the third quarter of 2004. We currently expect to renew the agreement and renew funding under the agreement effective June 30, 2005 which may result in additional research and development expense for the year ended December 31, 2005.

General and administrative expenses were $605,000 and $608,000 for the years ended December 31, 2003 and 2004, respectively. The increase is due to higher corporate legal costs and other costs associated with the delisting of our securities from Nasdaq SmallCap in the second quarter of 2004, which was partially offset by a decrease in insurance expenses and other general costs.

Interest income was $127,000 and $138,000 for the years ended December 31, 2003 and 2004, respectively. The increase is primarily due to improvements in market interest rates and returns on investment for U.S. Treasury obligations and other short term instruments.

Other expense in 2003 was $25,000, which reflects our September 2003 capital contribution to Colloral LLC to support a sales and marketing initiative. Our previously unrecorded equity in prior accumulated net losses of Colloral LLC was greater than $25,000; therefore, the additional investment has been reduced by the full $25,000. Other expense in 2004 was $95,000, which reflects our November 2004 capital contribution of $100,000 to Colloral LLC to support further sales and marketing initiatives. Our equity in prior accumulated net losses of Colloral LLC was $95,000. The additional investment, therefore, was reduced by the $95,000 and was recognized as equity in net loss of unconsolidated affiliate.

The following table contains selected financial data for Colloral LLC:

	For the year ended December 31,		
	2002	**2003**	**2004**
Statement of Operations Data:			
Revenue	$ —	$ 19,000	$ 24,000
Net loss	(22,000)	(53,000)	(165,000)

	As of December 31,	
	2003	**2004**
Balance Sheet Data:		
Current assets	$21,000	$6,000
Long term assets	—	—
Current liabilities	6,000	1,000
Long term liabilities	—	—

Years Ended December 31, 2002 and 2003

Revenue was $70,000 and $1,445,000 for the years ended December 31, 2002 and 2003, respectively. In the first quarter of 2003, revenue was comprised of (i) a $1,500,000 payment by a subsidiary of Elan Plc for the purchase of certain patent rights related to Alzheimer's disease net of warrants valued at $155,000 granted to Elan Plc at the time of the payment and (ii) monthly license payments from BioMS Medical Corporation. The revenue in 2002 and the remainder of 2003 was comprised solely of monthly license payments from BioMS. The payment from Elan Plc was the third and final payment pursuant to the agreement entered into between Elan Plc and us dated effective January 29, 2000. Under the terms of that agreement, AutoImmune and The Brigham and

Women's Hospital have indemnified Elan Plc against any claim, demand or action arising from any misrepresentation made to Elan Plc about patent rights and breach of warranties.

Research and development expenses were $388,000 and $314,000 for the years ended December 31, 2002 and 2003, respectively. The decrease is due to a $139,000 decrease in patent-related legal costs, which was partially offset by the amount we paid to The Brigham and Women's Hospital under a research and development agreement, including $75,000 of the payment we received from Elan Plc in the first quarter of 2003.

General and administrative expenses were $661,000 and $605,000 for the years ended December 31, 2002 and 2003, respectively. The decrease is primarily due to a decrease in corporate costs.

Interest income was $190,000 and $127,000 for the years ended December 31, 2002 and 2003, respectively. The decrease is primarily due to reductions in market interest rates and returns on investment for U.S. 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 our investment in OraGen Corporation. In the fourth quarter of 2002, we determined that the entire value of our investment in OraGen should be reduced to zero to reflect OraGen's continued difficulty in obtaining funding for its operations. In February 2004, Enzo Biochem, Inc. acquired the assets of Oragen. As of December 31, 2004, the total amount and timing of distributions we expect to receive is unknown. We will recognize a gain on this investment if and when distributions from this sale are paid to us. Other expense in 2003 was $25,000, which expense reflects our September 2003 capital contribution of $25,000 to Colloral LLC to support a sales and marketing initiative. Our previously unrecorded equity in prior accumulated net losses of Colloral LLC was greater than $25,000, therefore, the additional investment was reduced by the full $25,000.

Liquidity and Capital Resources

Our needs for funds have historically fluctuated from period to period as we have increased or decreased the scope of our research and development activities. Since inception, we have funded these needs almost entirely through sales of our equity securities. Our current needs have been significantly reduced as a result of the termination of our direct research and development activities, all full-time employees and other operating expenses in 1999.

As of December 31, 2004, we hold an interest in a joint venture called Colloral LLC, which is manufacturing, marketing and selling Colloral as a nutraceutical. We have no obligation to make additional capital contributions to Colloral LLC or current plans to do so, but we may do so in the future. To the extent that Colloral LLC generates income in excess of cumulative losses, we may receive cash distributions from the joint venture.

Our working capital and capital requirements will depend on numerous factors, including the strategic direction that we and our shareholders choose, the level of resources that we devote to the development of our patented products, the extent to which we proceed by means of collaborative relationships with pharmaceutical or nutraceutical companies and our competitive environment. During 2004, we used $644,000 of cash for operations. We expect to continue to use our current cash and marketable investments on hand to fund our future operations and development efforts. Based upon our budget for the calendar year 2005 and current expectations for future years, we believe that current cash and marketable securities and the interest earned from the investment thereof will be sufficient to meet our operating expenses and capital requirements for at least five years. At the appropriate time, we 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, we will have to reduce or not pursue certain activities, which could include areas of research, product development, marketing activity, or otherwise modify our business strategy. Such a reduction would have a material adverse effect on us.

In order to preserve principal and maintain liquidity, our funds are invested in U.S. Treasury obligations, high-grade corporate obligations and money market instruments. As of December 31, 2004, our cash and cash equivalents and marketable securities totaled $9,996,000. Current liabilities at December 31, 2004 were $108,000.

Contractual Obligations

	Payment due by period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt Obligations	—	—	—	—	—
Capital Lease Obligations	—	—	—	—	—
Operating Lease Obligations	—	—	—	—	—
Purchase Obligations					
• Contractual payments payable to Howard L. Weiner(1)	$12,000	$12,000	—	—	—
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet Under GAAP	—	—	—	—	—
Total	$12,000	$12,000	—	—	—

(1) Payments made on a quarterly basis pursuant to the Amended Consulting Agreement, dated July 1992, which amends the Amended and Restated Consulting Agreement, dated November 1998, between AutoImmune Inc. and Howard L. Weiner. This agreement will continue until terminated by either party in writing, effective on the following June 30th.

Off-Balance Sheet Arrangements

We have not created, and are not party to, any special-purpose or off-balance sheet entities for the purpose of raising capital, incurring debt or operating parts of our business that are not consolidated into our financial statements other than our interest in Colloral LLC, a joint venture for the development and marketing of Colloral. In September 2003, we made a capital contribution of $25,000 to Colloral LLC to support a sales and marketing initiative. In November 2004, we made another capital contribution of $100,000 to further support sales and marketing initiatives. We are not obligated to make additional capital contributions. We account for our investment in Colloral LLC using the equity method. We will not recognize equity income from this investment until our share of future profits of Colloral LLC exceeds our share of the LLC's cumulative losses. As of December 31, 2004, Colloral LLC has not generated any profit.

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.

We believe the following critical accounting policies affect certain judgments and estimates used in the preparation of our financial statements:

Revenue is recognized in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104 "Revenue Recognition". 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 our 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. We evaluate revenue from agreements entered into or modified after June 15, 2003 that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21 "Revenue Arrangements with Multiple Deliverables." EITF 00-21 requires that the delivered items have value to the customer on a standalone basis, there is objective and reliable evidence of fair value of the undelivered items, and delivery or performance of the undelivered item is probable and within our control. If the components of the arrangement qualify as separate units of accounting under EITF 00-21, we defer the greater of the fair value of any undelivered elements of the contract or the portion of the contract which is not payable until the undelivered elements are delivered.

Where we have continuing performance obligations under the terms of a collaborative arrangement or associated with non-refundable license fees, revenue is recognized over the period we complete our performance obligations. Under the terms of our agreement with a subsidiary of Elan Plc, AutoImmune and The Brigham & Women's Hospital have indemnified the subsidiary against any claim, demand or action arising from any misrepresentation made by us to the subsidiary of Elan Plc about patent rights and breach of warranties, up to the amounts previously received by us under the agreement. We do not consider this a performance obligation that would preclude or defer revenue recognition.

Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which we have 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 we complete our performance obligations.

Revenue from service contracts is recognized 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. In evaluating whether a decline in fair value below cost basis is other than temporary, we employ a methodology that considers available evidence regarding our marketable securities. In the event that the cost basis of a security exceeds its fair value, we evaluate, 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 our 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.

In January 2003, the FASB issued FIN No. 46, "Consolidation of Variable Interest Entities" and, in December 2003, the FASB issued FIN No. 46R. FIN No. 46R replaces FIN No. 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity ("VIE") is an entity that does not have sufficient equity investment to permit it to finance its activities without additional financial support from a third party, or whose equity investors lack the characteristics of a controlling financial interest. FIN No. 46R establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary. We adopted FIN No. 46R in the first quarter of 2004 for non-special

purpose entities created prior to February 1, 2003, which includes our interest in Colloral LLC. The adoption of FIN No. 46R did not have a material effect on our financial condition or results of operations and we continue to account for our investment in Colloral LLC under the equity method of accounting. We have no commitment to provide additional funding to Colloral LLC and have no current plans to do so. We record our portion of the joint venture's losses until the carrying value of our investment in the joint venture is reduced to zero because we are not obligated to make additional contributions to the joint venture.

Recent Accounting Pronouncements

SFAS No. 123R (revised 2004) "Share-Based Payment" was issued in December 2004. This standard requires companies to measure and recognize the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the equity award. The effective date is the first interim reporting period beginning after June 15, 2005. We are currently evaluating the transition provisions of this standard and will begin expensing stock options in the third quarter of 2005.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We have invested all of our cash in U.S. Treasury obligations, high-grade corporate obligations and money market instruments. These investments are denominated in U.S. dollars. Due to the conservative nature of these instruments, we do not have material exposure to interest rate or market risk.

Item 8. Financial Statements and Supplementary Data.

Information with respect to our financial statements and financial statement schedules filed with this report is set forth in a separate section of this Report commencing on Page F-1.

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

None.

Item 9A. Controls and Procedures.

Our Chief Executive Officer and Director of Finance and Treasurer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2004. Based upon that evaluation, our Chief Executive Officer and Director of Finance and Treasurer have concluded that, as of December 31, 2004, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The information called for by this Item and not provided above in Item 4A is incorporated by reference to our proxy statement which we intend to file with the Securities and Exchange Commission and mail to shareholders within 120 days of our fiscal year ended December 31, 2004.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to our proxy statement which we intend to file with the Securities and Exchange Commission and mail to shareholders within 120 days of our fiscal year ended December 31, 2004.

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 our proxy statement which we intend to file with the Securities and Exchange Commission and mail to shareholders within 120 days of our fiscal year ended December 31, 2004.

Item 13. Certain Relationships and Related Transactions.

The information required by this Item is incorporated by reference to our proxy statement which we intend to file with the Securities and Exchange Commission and mail to shareholders within 120 days of our fiscal year ended December 31, 2004.

Item 14. Principal Accounting Fees and Services.

This information required by this item is incorporated by reference to our proxy statement which we intend to file with the Security and Exchange Commission and mail to shareholders within 120 days of our fiscal year ended December 31, 2004.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements

Our financial statements and notes to our financial statements filed with this report are set forth as follows:

(a)(2) Financial Statement Schedules

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

(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	—Amended and Restated Research and Development Agreement, dated July 1, 1992, between AutoImmune Inc. and The Brigham and Women's Hospital, Inc.(2)
10.4	—Research Agreement, dated October 21, 1992, and Royalty Agreement, dated 1992, between AutoImmune Inc. and Joslin Diabetes Center(2)
10.5	—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)
10.6	—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)
10.7	—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)
10.8	—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)

Exhibit Number	Exhibit Description
10.9	—Consulting Agreement, dated February 1, 1989, between AutoImmune Inc. and James P. Tam, Ph.D.(2)
10.10	—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)
10.11	—Scientific Advisory Board Agreement, dated August 11, 1992, between AutoImmune Inc. and Herman N. Eisen, M.D.(2)
10.12	—Scientific Consultant Agreement, dated July 16, 1992, between AutoImmune Inc. and Henry Oettinger, Ph.D.(2)
10.13	—Stock Option Plan for Nonemployee Directors (4)*
10.14	—1998 Stock Option Plan(9)*
10.15	—Development and License Agreement dated as of December 4, 1998 between AutoImmune Inc. and Teva Pharmaceutical Industries Ltd.(10)+
10.16	—Consulting Agreement dated January 3, 2000 between AutoImmune Inc. and Robert C. Bishop, Ph.D.(11)
10.17	—Consulting Agreement dated November 20, 1999 between AutoImmune Inc. and Heather A. Ellerkamp(11)
10.20	—Consulting Agreement dated September 20, 1999 between AutoImmune Inc. and Fletcher Spaght, Inc.(11)
10.21	—Letter Agreement dated January 31, 2000 between AutoImmune Inc. and Fletcher Spaght, Inc.(12)+
10.22	—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)+
10.23	—Letter Agreement dated March 16, 2000 between AutoImmune Inc. and Brigham and Women's Hospital Inc.(12)+
10.24	—Agreement dated August 1, 2000 between AutoImmune Inc. and Rycor Technology Instruments Corp. (now known as BioMS Medical Corporation)(13)+
10.25	—Limited Liability Company Operating Agreement of Colloral LLC, dated August 19, 2002 (14)+
10.26	—License Agreement, dated August 19, 2002 between AutoImmune Inc. and Colloral LLC (14)
10.27	—Trademark License Agreement, dated August 19, 2002, between AutoImmune Inc. and Colloral LLC (14)
10.28	—Amendment to Research and Development Agreement, dated effective July 1, 2003, between The Brigham and Women's Hospital and AutoImmune Inc.(15)
10.29	—Summary of Nonemployee Director Fees*
23.1	—Consent of Independent Registered Public Accounting Firm
31.1	—Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a)/15d-14(a)
31.2	—Certification of Director of Finance pursuant to Exchange Act Rules 13a-14(a)/15d-14(a)
32.1	—Certification of the Chief Executive Officer and Director of Finance pursuant to 18 U.S.C. Section 1350

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

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

(3) Incorporated by reference to AutoImmune'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 AutoImmune'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 AutoImmune'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 AutoImmune's Annual Report on Form 10-K for the year ended December 31, 1994, as amended.

(7) Incorporated by reference to AutoImmune's Annual Report on Form 10-K for the year ended December 31, 1995.

(8) Incorporated by reference to AutoImmune's Annual Report on Form 10-K for the year ended December 31, 1997.

(9) Incorporated by reference to AutoImmune'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 AutoImmune's Annual Report on Form 10-K for the year ended December 31, 1998.

(11) Incorporated by reference to AutoImmune's Annual Report on Form 10-K for the year ended December 31, 1999.

(12) Incorporated by reference to AutoImmune's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.

(13) Incorporated by reference into AutoImmune's Annual Report on Form 10-K for the year ended December 31, 2000, as amended.

(14) Incorporated by reference to AutoImmune's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

(15) Incorporated by reference to AutoImmune's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.

+ We have 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 have separately filed a complete copy of this exhibit with the Securities and Exchange Commission.

* Management contract or compensatory plan or arrangement.

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 30th day of March, 2004.

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 30, 2004
/s/ HEATHER A. ELLERKAMP **Heather A. Ellerkamp** **Principal Financial and Accounting Officer**	Director of Finance and Treasurer	March 30, 2004
/s/ HUGH A. D'ANDRADE **Hugh A. D'Andrade**	Director	March 30, 2004
/s/ ALLAN R. FERGUSON **Allan R. Ferguson**	Director	March 30, 2004
/s/ R. JOHN FLETCHER **R. John Fletcher**	Director	March 30, 2004

AutoImmune Inc.
(a development stage company)

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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, 2003 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 and cumulatively, for the period from September 9, 1988 (date of inception) to December 31, 2004, 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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

Boston, Massachusetts
March 30, 2005

AutoImmune Inc.
(a development stage company)

Balance Sheet

	December 31, 2003	2004
Assets		
Current assets:		
Cash and cash equivalents	$ 2,280,000	$ 9,996,000
Marketable securities	8,464,000	—
Prepaid expenses and other current assets	35,000	37,000
Total current assets	10,779,000	10,033,000
Other assets	—	5,000
Total assets	$ 10,779,000	$ 10,038,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,000	$ 10,000
Accrued professional fees	73,000	85,000
Deferred revenue	—	13,000
Total current liabilities	84,000	108,000
Commitments and contingencies (Notes 5 and 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value: 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2003 and 2004	—	—
Common stock, $0.01 par value: 25,000,000 shares authorized; 16,919,623 shares issued and outstanding at December 31, 2003 and 2004	169,000	169,000
Additional paid-in capital	118,257,000	118,257,000
Deficit accumulated during the development stage	(107,735,000)	(108,496,000)
Accumulated other comprehensive income	4,000	—
Total stockholders' equity	10,695,000	9,930,000
Total liabilities and stockholders' equity	$ 10,779,000	$ 10,038,000

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, 2002	2003	2004	Period from September 9, 1988 (date of inception) to December 31, 2004
Revenue:				
License rights	$ 70,000	$ 1,445,000	$ 130,000	$ 7,003,000
Option fees	—	—	—	2,200,000
Research and development revenue under collaborative agreements	—	—	—	955,000
Total revenue	70,000	1,445,000	130,000	10,158,000
Costs and expenses:				
Research and development:				
Related party	61,000	135,000	36,000	19,959,000
All other	327,000	179,000	290,000	92,310,000
General and administrative	661,000	605,000	608,000	18,797,000
Total costs and expenses	1,049,000	919,000	934,000	131,066,000
Income (loss) from operations	(979,000)	526,000	(804,000)	(120,908,000)
Interest income	190,000	127,000	138,000	12,939,000
Interest expense	—	—	—	(303,000)
Equity in net loss of unconsolidated affiliate	—	(25,000)	(95,000)	(120,000)
Other expense	(100,000)	—	—	(100,000)
	90,000	102,000	43,000	12,416,000
Net income (loss)	$ (889,000)	$ 628,000	$ (761,000)	$(108,492,000)
Net income (loss) per share—basic	$ (0.05)	$ 0.04	$ (0.04)	
Net income (loss) per share—diluted	$ (0.05)	$ 0.04	$ (0.04)	
Weighted average shares outstanding—basic	16,919,623	16,919,623	16,919,623	
Weighted average shares outstanding—diluted	16,919,623	17,398,633	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 September 9, 1988 (date of inception) to December 31, 2004

	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
Issuance of common stock during 2000	101,751	1,000	193,000				194,000
Issuance of common stock during 2001	160,000	1,000	3,000				4,000
Valuation of warrants issued during 2001			192,000				192,000
Net loss for the period from September 9, 1988 (date of inception) through December 31, 2001				$(107,470,000)	(107,470,000)		(107,470,000)
Other comprehensive income (loss)				—		—	—
Comprehensive loss				$(107,470,000)			
Balance at December 31, 2001	16,919,623	169,000	118,102,000		(107,470,000)	—	10,797,000
Comprehensive loss:							
Net loss				$ (889,000)	(889,000)		(889,000)
Other comprehensive income (loss):							
Net change in unrealized gain on marketable securities (Note 3)				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
Comprehensive income:							
Net income				$ 628,000	628,000		628,000
Other comprehensive income (loss)				—		—	—
Comprehensive income				$ 628,000			
Valuation of warrants issued			155,000				155,000
Balance at December 31, 2003	16,919,623	169,000	118,257,000		(107,735,000)	4,000	10,695,000
Comprehensive loss:							
Net loss				$ (761,000)	(761,000)		(761,000)
Other comprehensive income (loss):							
Net change in unrealized gain on marketable securities (Note 3)				(4,000)		(4,000)	(4,000)
Comprehensive loss				$ (765,000)			
Balance at December 31, 2004	16,919,623	$169,000	$118,257,000		$(108,496,000)	$ —	$9,930,000

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

AutoImmune Inc.
(a development stage company)

Statement of Cash Flows

	For the year ended December 31,			Period from September 9, 1988 (date of inception) to December 31,
Cash flows from operating activities:	**2002**	**2003**	**2004**	**2004**
Net income (loss)	$ (889,000)	$ 628,000	$ (761,000)	$(108,492,000)
Adjustments to reconcile net income (loss) to net cash provided by (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	—	155,000	—	347,000
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
Equity in net loss of unconsolidated affiliate	—	25,000	95,000	120,000
(Increase) decrease in prepaid expenses and other current assets	(39,000)	46,000	(2,000)	(37,000)
Increase (decrease) in accounts payable	(5,000)	(31,000)	(1,000)	10,000
Increase (decrease) in accrued expenses	55,000	(72,000)	12,000	85,000
Increase in deferred revenue	—	—	13,000	13,000
Net cash provided (used) by operating activities	(778,000)	751,000	(644,000)	(102,134,000)
Cash flows from investing activities:				
Purchase of available-for-sale marketable securities	(11,887,000)	(11,426,000)	(1,974,000)	(318,648,000)
Proceeds from sale/maturity of available-for-sale marketable securities	13,769,000	7,947,000	10,434,000	307,637,000
Proceeds from maturity of held-to-maturity marketable securities	—	—	—	11,011,000
Proceeds from sale of equipment	—	—	—	306,000
Investment in OraGen	—	—	—	(100,000)
Investment in Colloral LLC	—	(25,000)	(100,000)	(125,000)
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	(1,882,000)	(3,504,000)	8,360,000	(5,895,000)
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	—	—	—	105,514,000
Proceeds from issuance of convertible notes payable	—	—	—	2,200,000
Net cash provided by financing activities	—	—	—	118,025,000
Net increase (decrease) in cash and cash equivalents	1,104,000	(2,753,000)	7,716,000	9,996,000
Cash and cash equivalents at beginning of period	3,929,000	5,033,000	2,280,000	—
Cash and cash equivalents at end of period	$ 5,033,000	$ 2,280,000	$ 9,996,000	$ 9,996,000

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

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

AutoImmune Inc.
(a development stage company)

Notes to the Financial Statements

1. Formation and Operations of AutoImmune

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

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

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

In 2000, we completed a market analysis of Colloral as a nutritional supplement and subsequently filed a "Notice of New Dietary Ingredient" with the FDA that was accepted without comment. On February 18, 2005, we received a letter from the FDA stating that the FDA reconsidered the information contained in our Notice of New Dietary Ingredient and concluded that Colloral is not a dietary supplement but appears to be a drug under the Federal Food, Drug, and Cosmetic Act, and thus subject to the regulatory requirements for drugs. We are currently working with outside counsel to respond to this letter and hope to demonstrate that Colloral meets the statutory definition of a dietary supplement. We cannot predict what the effect of the FDA's letter will be. It is possible that Colloral LLC will be unable to market Colloral as a nutraceutical and that Colloral will be subject to the regulatory requirements for drugs. If the FDA makes a final determination that requires us to comply with the regulatory requirements for drugs, Colloral will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC.

Since January 2000, we have operated with minimal staff and infrastructure. We have no full-time employees and our activities are primarily directed toward managing our investment in Colloral LLC, our joint venture with Deseret Laboratories, Inc., supporting our current licensees and finding additional companies that will license our technology to develop, manufacture and sell products based upon our technology. We anticipate continuing our minimal investments in infrastructure and personnel until positive cash flow from the distributions from our joint venture Colloral LLC and/or royalties from our licensing agreements, if any, create a solid base from which to re-expand our operations.

2. Summary of Significant Accounting Policies

Cash Equivalents and Marketable Securities

We consider all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. We invest primarily in U.S. Government debt securities and money market securities of short maturity. These investments are subject to minimal credit and market risks. We specifically identify

securities for purposes of determining gains and losses on the sale of cash equivalents and marketable securities. At December 31, 2003, we had classified all of our 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.

Marketable securities are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. In evaluating whether a decline in fair value below cost basis is other than temporary, we employ a methodology that considers available evidence regarding our marketable securities. In the event that the cost basis of a security exceeds its fair value, we evaluate, 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 our 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 our portfolio, if, among other things, relevant information related to the marketable securities was not publicly available or if other factors not considered would have been relevant to the determination of impairment.

Fair Value of Financial Instruments
At December 31, 2004, our financial instruments primarily consisted of cash equivalents, accounts payable and accrued expenses. The carrying amounts of these instruments approximate their fair values. In the fourth quarter of 2002, an impairment expense of $100,000 was recorded in other expense because we determined that the entire value of our investment in OraGen should be reduced to zero to reflect OraGen's continued difficulty in obtaining funding for its operations.

Stock Purchase Warrants
The value of contingent stock purchase warrants issued by us in connection with clinical research agreements is determined on the date that we estimate that it is probable that such contingencies will be met. The fair value of the warrants on the measurement date is recorded as an offset to revenue.

Revenue Recognition
Revenue is recognized in accordance with Securities and Exchange Commission's Staff Accounting Bulletin No. 104 "Revenue Recognition". 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 our product candidates and products using our technology. 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. We evaluate revenue from agreements entered into on or after June 15, 2003 that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force ("EITF") Issue No. 00-21 "Revenue Arrangements with Multiple Deliverables." EITF 00-21 requires that the delivered items have value to the customer on a standalone basis, there is objective and reliable evidence of fair value of the undelivered items, and delivery or performance of the undelivered item is probable and within our control. If the

components of the arrangement qualify as separate units of accounting under EITF 00-21, we defer the greater of the fair value of any undelivered elements of the contract or the portion of the contract which is not payable until the undelivered elements are delivered.

Where we have continuing performance obligations under the terms of a collaborative arrangement or associated with non-refundable license fees, revenue is recognized over the period we complete our performance obligations. Under the terms of one agreement, AutoImmune and The Brigham and Women's Hospital have indemnified a subsidiary of Elan Plc against any claim, demand or action arising from any misrepresentation made to the subsidiary of Elan about patent rights and breach of warranties, up to the amounts previously received by us under the agreement. We do not consider this a performance obligation that would preclude or defer revenue recognition.

Revenues from milestone payments related to arrangements under which we have no continuing performance obligations are recognized upon achievement of the related milestone. Revenues from milestone payments related to arrangements under which we have 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 we complete our performance obligations.

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

Revenue generated in 2003 and 2004 was derived from agreements with a subsidiary of Elan Plc and BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp.) (see Note 10).

Stock Compensation

We account for employee and qualified director stock-based compensation using the intrinsic based method prescribed in Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees*. We apply 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 a fixed number of shares and fixed 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 all awards consistent with the provisions of SFAS No. 123, our net income (loss) and net income (loss) per share would have been changed to the pro forma amounts indicated below:

	Year ended December 31,		
	2002	**2003**	**2004**
Net income (loss):			
As reported	$(889,000)	$628,000	$(761,000)
Deduct: total stock-based employee compensation expense determined under the fair-value-based method for all awards	(82,000)	(89,000)	(44,000)
Pro forma	$(971,000)	$539,000	$(805,000)
Net income (loss) per share—basic			
As reported	$ (0.05)	$ 0.04	$ (0.04)
Pro forma	(0.06)	0.03	(0.05)
Net income (loss) per share—diluted			
As reported	$ (0.05)	$ 0.04	$ (0.04)
Pro forma	(0.06)	0.03	(0.05)

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 2002, 2003 and 2004: no dividend yield for all years; expected volatility of 70% for 2002 and 75% for 2003 and 2004; risk free interest rates ranging from 1.6% to 5.3% and a weighted average expected option term ranging from 2 to 6 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, 2004 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 years ended December 31, 2002 and 2004, shares used to compute diluted earnings per share excluded 1,618,536 and 1,930,100 stock options and warrants, respectively, as their inclusion would have been anti-dilutive due to the net losses incurred in these years. For the year ended December 31, 2003, the difference between weighted average shares outstanding basic and diluted is due to the effect of stock options with exercise prices less than the average market value of the common stock. For the year ended December 31, 2003, stock options and warrants to purchase 942,462 weighted shares of common stock were outstanding with exercise prices greater than the fair value of the common stock and, accordingly, were excluded from the calculation of diluted net income per share.

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.

Accounting For Our Interest in Colloral LLC

In January 2003, the FASB issued FIN No. 46, "Consolidation of Variable Interest Entities" and, in December 2003, the FASB issued FIN No. 46R. FIN No. 46R replaces FIN No. 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity ("VIE") is an entity that does not have sufficient equity investment to permit it to finance its activities without additional financial support from a third party, or whose equity investors lack the characteristics of a controlling financial interest. FIN No. 46R establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary. We adopted FIN No. 46R in the first quarter of 2004 for non-special purpose entities created prior to February 1, 2003, which includes our interest in Colloral LLC. The adoption of FIN No. 46R did not have a material effect on our financial condition or results of operations and we continue to account for our investment in Colloral LLC under the equity method of accounting. We have no commitment to provide additional funding to Colloral LLC. We record our portion of the joint venture's losses until the carrying value of our investment in the joint venture is reduced to zero because we are not obligated to make additional contributions to the joint venture and have no current plans to do so.

Recent Accounting Pronouncements

SFAS No. 123R (revised 2004) "Share-Based Payment" was issued in December 2004. This standard requires companies to measure and recognize the cost of employee services received in exchange for an

award of equity instruments based on the grant-date fair value of the equity award. The effective date is the first interim reporting period beginning after June 25, 2005. we are currently evaluating the transition provisions of this standard and will begin expensing stock options in the third quarter of 2005. The pro forma presentation included above under "Stock Compensation" approximates what the impact of SFAS No. 123R would have had on the periods presented.

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 AutoImmune.

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 AutoImmune's initial public offering of common stock.

Supplemental Disclosure of Cash Flow Information
We have paid interest of $255,000 since inception. In 2002, 2003 and 2004, we did not pay any interest. We paid income taxes of $11,000 in 1996, which are the only income taxes we have paid.

3. Cash Equivalents and Marketable Securities

Cash equivalents are carried at fair market value, which approximated amortized cost at December 31, 2004. As of December 31, 2004, all investments have original maturities of 90 days or less and, therefore, are classified as cash equivalents.

The following is a summary of available-for-sale marketable securities held by us at December 31, 2003 which are carried at fair market value:

	Maturity term	Fair Value	Unrealized gains	Unrealized losses	Amortized cost
December 31, 2003:					
U.S. Government debt securities	Within 1 year	$5,028,000	$4,000	$ —	$5,024,000
Corporate debt securities	Within 1 year	3,436,000	—	—	3,436,000
		$8,464,000	$4,000	$ —	$8,460,000

All of our marketable securities were classified as current at December 31, 2003 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, 2003 and 2004 were not significant.

Marketable securities that 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. Other Assets

At December 31, 2003 and 2004, we had two investments, one in OraGen Corporation and one in Colloral LLC.

OraGen Corporation is a private company in which our interest was less than 20% and is accounted for under the cost method. Prior to the fourth quarter of 2002, the investment in OraGen Corporation was carried at cost. In the fourth quarter of 2002, we 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 was recorded in other expense in the fourth quarter of 2002 and the carrying value is zero at December 31, 2004. In February 2004, Enzo Biochem, Inc. acquired the assets of Oragen. As of December 31, 2004, the total amount and timing of distributions we expect to receive is unknown. We will recognize a gain on this investment if and when distributions from this sale are paid to us.

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® as a dietary supplement. Our interest in Colloral LLC is greater than 50%, but we do not have control of Colloral LLC, therefore, the investment is accounted for using the equity method. In 2002, we 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. In September 2003, AutoImmune made an additional capital contribution of $25,000 to Colloral LLC to support a sales and marketing initiative. In November 2004, AutoImmune made another capital contribution of $100,000 to further support sales and marketing initiatives. We are not obligated to make additional capital contributions.

We initially recorded the investment in Colloral LLC at a cost of $0 and increased it to reflect the cash contributions paid in September 2003 and November 2004. Profits and losses will be allocated in accordance with the joint venture agreement. As of September 30, 2003, our equity in prior accumulated net losses was greater than $25,000, therefore, the $25,000 investment was reduced by the full $25,000. As of December 31, 2004, our previously unrecorded equity in additional prior accumulated net losses was $95,000. Therefore, the $100,000 investment was reduced by $95,000 which was recognized as equity in net loss of unconsolidated affiliate. Under equity accounting, we will not recognize equity income from this investment until our share of future profits of Colloral LLC exceeds our share of Colloral LLC's cumulative losses.

The following table contains selected financial data for Colloral LLC:

	For the year ended December 31,		
	2002	**2003**	**2004**
Statement of Operations Data:			
Revenue	$ —	$ 19,000	$ 24,000
Net loss	(22,000)	(53,000)	(165,000)

	As of December 31,	
	2003	**2004**
Balance Sheet Data:		
Current assets	$21,000	$6,000
Long term assets	—	—
Current liabilities	6,000	1,000
Long term liabilities	—	—

5. Related Party Transactions

In connection with the formation of AutoImmune 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"), we entered into related technology transfer and research and development agreements with BWH. The technology transfer agreement provides us 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 for the performance of certain research activities by BWH on our behalf.

The current research and development agreement with BWH extends until June 30, 2005, and is renewable for additional one year periods by mutual consent. We have agreed to make no payments to the BWH for the one-year period ending June 30, 2005. There is no guaranteed minimum payment for the one-year period ending June 30, 2006. The agreement also provides for payments to BWH for royalties on sales of related patented products by us as well as for payments to BWH for a portion, as defined in the agreement, of any proceeds received by us in connection with the licensing of patented technology to, and royalty or milestone payments received from, third parties. During 2003, we paid BWH $75,000, which represents a portion of the cash payment we 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 of our products, we are required to make payments to BWH in each quarter only to the extent that we have a positive cash flow in such quarter with the balance deferred to the succeeding quarter.

Deferred payments will be subject to interest. If we default 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 us to BWH. In addition, we paid certain expenses related to research conducted at BWH.

Mr. Fletcher, a director of AutoImmune, is the founder and Chief Executive Officer of Fletcher Spaght, Inc., a management consulting firm. In January 2000, AutoImmune entered into an agreement with Fletcher Spaght under which Fletcher Spaght agreed to assist AutoImmune with the potential launch of Colloral as a dietary supplement. Under the agreement, as amended, Fletcher Spaght is entitled to receive a payment of (i) 2.5% of the amount, if any, that AutoImmune receives for any U.S. rights to Colloral as a nutritional

product in a transaction consummated on or before December 31, 2002 less (ii) $50,000 of retainer fees received by Fletcher Spaght under the agreement. In August 2002 AutoImmune entered into a joint-venture with Deseret Laboratories, Inc. to manufacture, market and sell Colloral as a nutritional product. As of December 31, 2004, Fletcher Spaght had received no payment under its agreements with AutoImmune, other than $50,000 of retainer fees.

6. Income Taxes

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.

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

	Year ended December 31,		
	2002	**2003**	**2004**
Income tax benefit (expense):			
Federal	$ 274,000	$ (238,000)	$ 379,000
State	85,000	(1,917,000)	50,000
	359,000	(2,155,000)	429,000
(Increase) decrease in deferred tax asset valuation allowance	(359,000)	2,155,000	(429,000)
	$ —	$ —	$ —

The 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 2002, 2003 and 2004 to pre-tax loss is as follows:

	Year ended December 31,		
	2002	**2003**	**2004**
(Provision) benefit at statutory rate	$ 311,000	$ (220,000)	$ 271,000
Permanent items	(2,000)	(9,000)	116,000
Federal and state research and development, orphan drug and investment tax credits	4,000	(180,000)	3,000
State tax benefit (provision), net of federal tax liability	46,000	(1,746,000)	39,000
	359,000	(2,155,000)	429,000
(Increase) decrease in valuation allowance	(359,000)	2,155,000	(429,000)
	$ —	$ —	$ —

Deferred tax assets are comprised of the following:

	December 31,	
	2003	**2004**
Research costs capitalized for tax purposes	$ 25,320,000	$ 25,455,000
Research and development, orphan drug and investment tax credits	11,152,000	11,140,000
Loss carryforwards	12,733,000	12,869,000
Other temporary differences	50,000	220,000
Gross deferred tax assets	49,255,000	49,684,000
Deferred tax asset valuation allowance	(49,255,000)	(49,684,000)
	$ —	$ —

We have 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 decrease in the valuation allowance for deferred tax assets in 2003 relates to the expiration and utilization of net operating loss carryforwards. As we achieve profitability, these deferred tax assets, portions of which are subject to annual limitations, will be available to offset future income tax liabilities and expenses. Of the $49,684,000 valuation allowance at December 31, 2004, $965,000 relating to deductions for stock option compensation will be credited to additional paid-in capital upon realization.

At December 31, 2004, AutoImmune has federal and state net operating loss carryforwards of $36,464,000 and $2,134,000 respectively, which began to expire in 2003. AutoImmune also has federal and state credit carryforwards of $10,409,000 and $1,124,000 respectively, which began to expire in 2003.

Ownership changes, as defined in the Internal Revenue Code, resulting from our 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.

7. Preferred Stock

Upon the closing of our 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. No dividends had been paid to the preferred stockholders.

At December 31, 2004, we had 5,000,000 authorized shares of $.01 par value preferred stock. Preferred stock may be issued at the discretion of our Board of Directors (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, our 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 and before the expiration or termination of the plan 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.

8. Stockholders' Equity and Common Stock

In December 1992, we effected a three-for-one stock split of our 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, we completed an initial public offering of 3,000,000 shares of common stock. Proceeds to AutoImmune, net of issuance costs, amounted to $35,690,000.

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

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

As of December 31, 2004, we have reserved 2,043,260 shares of common stock for use in our stock option plans and employee stock purchase plan.

9. Stock Option and Employee Stock Purchase Plans

1988 Stock Option Plan

Our 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 our behalf. 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 AutoImmune 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

Our 1998 Stock Option Plan (the "1998 Stock Option Plan"), adopted by our 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 our behalf. 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 AutoImmune). 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 AutoImmune). The maximum number of shares of our common stock reserved for issuance in accordance with the terms of the 1998 Stock Option Plan is 1,300,000.

Director Stock Option Plan

In 1993, our Board of Directors approved a stock option plan for non-employee directors (the "Director Option Plan"). This plan was approved by our 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 290,000 shares of common stock have been granted under the Director Option Plan. Options to purchase 97,500 shares of common stock have been cancelled. At December 31, 2004, options to purchase 192,500 shares of common stock are outstanding. A maximum of 300,000 shares of our common stock 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, 2002, 2003 and 2004 is as follows:

	Shares	Weighted average exercise price
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
Granted (weighted average fair value $0.34)	35,500	1.08
Exercised	—	
Cancelled	(78,375)	3.15
Outstanding at December 31, 2003	1,200,661	1.58
Granted (weighted average fair value $0.56)	50,000	0.94
Exercised	—	
Cancelled	(70,561)	4.63
Outstanding at December 31, 2004	1,180,100	$1.37
Options exercisable at year end	887,600	$1.59

As of December 31, 2002 and 2003, 618,286 and 933,661 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, 2004:

	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	7.5 years	$0.52	300,000	$0.52
$ 0.53—$1.81	418,500	5.0 years	1.28	331,625	1.37
$ 2.00—$ 2.87	196,100	3.3 years	2.32	196,100	2.32
$ 3.00—$ 3.60	42,000	5.0 years	3.28	36,375	3.24
$ 7.50—$ 10.25	23,500	1.2 years	9.78	23,500	9.78
	1,180,100			887,600	

Employee Stock Purchase Plan

On July 20, 1994, our Board of Directors approved the 1994 Employee Stock Purchase Plan (the "Purchase Plan"). This plan enables eligible employees to purchase our 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, 2004, 158,160 shares of common stock were reserved for purchases under the Purchase Plan. During 2002, 2003 and 2004, no shares were purchased under the Purchase Plan.

10. Commitments and Contingencies

Clinical Research Agreement

We entered into an agreement with CATO Research, effective June 1993, to have a clinical investigational study performed on our multiple sclerosis product. The agreement allowed for termination by either party, upon prior written notice. In 1997, we terminated the agreement. Additionally, CATO was granted a warrant to purchase 30,000 shares of our common stock at $10.50 per share which expired in June 2003.

License Agreements

In December 1994, we entered into a license and collaborative agreement with Eli Lilly and Company. Under the agreement, Eli Lilly provided support for clinical testing of our 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 restructured 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 provide us with full access to the data from the clinical trials it supported, including the right to use the data for any purpose. We have regained all rights to the product.

In November 1999, we 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. Under the agreement, we are responsible for filing, prosecuting and maintaining the intellectual property rights licensed to Teva in our name. We will receive a milestone payment if the product is approved for sale and an escalating royalty based on cumulative sales of all products covered by the Teva agreement.

In March 2000, we entered an agreement under which a subsidiary of Elan Plc purchased all of our rights to certain patent applications involving the treatment of Alzheimer's Disease. Under the terms of the agreement, we 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 warrants issued in September 2001 and March 2003, as determined by using a Black-Scholes model, of $192,000 and $155,000, respectively, 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 breach of warranties, up to the amount of monies received by us under the agreement.

In August 2000, we entered an agreement with BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp). Under the terms of the agreement, we granted BioMS an exclusive license to certain of our patents to develop an injectable therapy for multiple sclerosis. Under the agreement, AutoImmune is responsible for filing, prosecuting and maintaining the patent rights licensed to BioMS thereunder. So long as the agreement remains in effect and until BioMS markets such therapy, BioMS is required to make monthly diligence payments to us. These payments totaled $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, we are entitled to receive an escalating royalty based on cumulative sales of all products covered by the BioMS agreement.

In August 2002, we entered into a License Agreement with Colloral LLC. Under the agreement, we 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 our 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, we are entitled to a percentage of the distributions of Colloral LLC on a quarterly basis.

Indemnification

We enter into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, we indemnify, hold harmless, and agree to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally our 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 our products. The term of these indemnification agreements is generally perpetual. The maximum potential amount of future payments that could be required under these indemnification agreements is unlimited. We have 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

We have limited operations 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, 2004 we had no lease obligations and no future minimum lease commitments.

11. 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. 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
2003				
Total revenue	$1,367,000	$ 23,000	$ 25,000	$ 30,000
Total expenses	368,000	197,000	184,000	170,000
Net income (loss)	1,033,000	(142,000)	(155,000)	(108,000)
Income (loss) per share—basic and diluted	$ 0.06	$ (0.01)	$ (0.01)	$ (0.01)
2004				
Total revenue	$ 30,000	$ 30,000	$ 33,000	$ 37,000
Total expenses	229,000	360,000	164,000	181,000
Net income (loss)	(168,000)	(300,000)	(96,000)	(197,000)
Income (loss) per share—basic and diluted	$ (0.01)	$ (0.02)	$ (0.01)	$ (0.01)

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Price Range of Common Stock and Dividend Policy

The Company's Common Stock is traded on the OTC Bulletin Board under the symbol AIMM. The following table shows the quarterly high and low sales price on the Nasdaq SmallCap market (before May 26, 2004) and the OTC Bulletin Board (beginning May 26, 2004) for a share of the Company's Common Stock (based on intra-day trading) for the two years ended 2004.

	Price range of Common Stock	
	High	Low
Fiscal year ending December 31, 2003		
First quarter	$0.85	$0.62
Second quarter	2.25	0.47
Third quarter	2.05	1.12
Fourth quarter	2.04	1.25
Fiscal year ending December 31, 2004		
First quarter	$1.90	$1.15
Second quarter	1.32	0.65
Third quarter	0.95	0.75
Fourth quarter	0.95	0.78

As of March 17, 2005, there were 214 record holders and approximately 3,400 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

Trading Market

OTC Bulletin Board
Symbol: AIMM

Investor Information

A copy of the 2004 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 19, 2005 at 11:00 a.m. at the Louis D. Brandeis Conference Center, 5th Floor, Nutter, McClennen & Fish, LLP, World Trade Center West, 155 Seaport Boulevard, Boston, Massachusetts.

Corporate Directory

Corporate Mailing Address

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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.

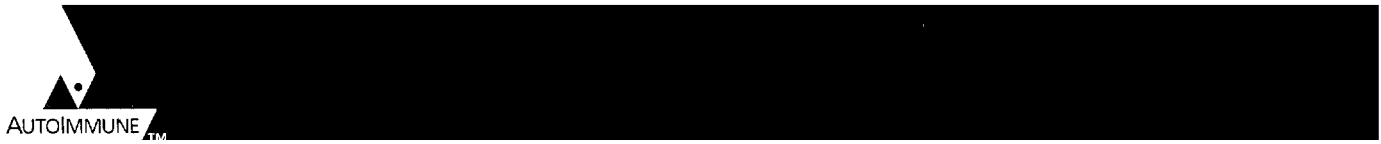
Hugh A. D'Andrade
Retired

Allan R. Ferguson
Managing Director
3i Ventures Corporation

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

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 and product development, the Company's dependence on third parties for licensing and other revenue, the Company's dependence on determinations of regulatory authorities, 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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