AUTOIMMUNE INC.

2008

AUTOIMMUNE™ ANNUAL REPORT

To Our Shareholders:

This past year was a good one for AutoImmune Inc., highlighted by progress in several key programs, including BioMS Medical Corporation's ongoing Phase III trials.

Several years ago we licensed one application of our intellectual property to BioMS, which it uses in its dirucotide product (formerly called MBP8298). BioMS is conducting two pivotal trials on dirucotide for the treatment of secondary progressive multiple sclerosis and the FDA has granted the product fast track designation. Data from the first of these Phase III studies is expected during the last half of 2009. In December 2007, BioMS announced that it had signed a license and development agreement with Eli Lilly and Company granting them exclusive worldwide rights to dirucotide. AutoImmune's rights to payments and royalties and sales of dirucotide were unchanged by this new agreement. Lilly's commitment to commercializing this product is substantial, and if the product is successful in clinical trials, their regulatory, marketing and sales capabilities will be of great value in capitalizing on this opportunity and we should see increasing shareholder value.

The sales of dietary supplement products at Colloral LLC, our joint venture with Deseret Laboratories, Inc., were higher than in the prior year and are clearly trending up with end users. Bronson Laboratories still features Vital 3 in its catalogs and we continue marketing on television through The Shopping Channel in Canada. We remain optimistic that the efforts of Futurebiotics LLC to enter other channels and new markets with this product will be successful over the long term.

We also have a license agreement with Teva Pharmaceutical Industries, Ltd., relating to the development of an oral formulation of Copaxone® (glatiramer acetate), its injectable product for the treatment of relapsing-remitting multiple sclerosis. In 2006, Teva announced that it would not continue development of the enteric coated formulation that used our intellectual property, but was considering development of other non-parenteral formulations of the product. We do not know if they are pursuing such development, and, if they are, whether the new formulations will involve intellectual property licensed by us to Teva. Teva continues to make the payments necessary to maintain the license of our intellectual property.

By the end of 2008, the NIH had enrolled 115 of 350 anticipated patients in a multi-center Phase III clinical trial on whether treatment with our product, AI 401, can delay or prevent Type 1 diabetes. We hope this effort might lead to an additional licensing opportunity for the company.

It is clear that the success of our licensing efforts is dependent on expanding and defending AutoImmune's intellectual property. At year-end, we had 201 issued US and foreign patents, and have pending three foreign applications. 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, we believe we are well positioned for the future.

Your interest in AutoImmune is greatly appreciated.

Sincerely,

Robert C. Bishop
Chairman of the Board
April 14, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

OR

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

For the transition period from to

Commission File Number 0-20948

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:

None

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

Common Stock, $.01 par value

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2008 was approximately $19,693,838(1). There were 16,999,623 shares of the registrant's Common Stock, $0.01 par value per share, outstanding as of March 16, 2009.

(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 to be held on May 22, 2009, which the Company intends to file within 120 days after the end of the Company's fiscal year ended December 31, 2008 are incorporated by reference into Part III hereof.

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PART I

Item 1. Description of 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 products 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.

We believe we are a leading company for the development of products based upon the concepts of mucosal tolerance. 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. The status of each of our principal products is described in the section "Products" below.

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.

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 we might re-expand operations.

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 and 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 Pharmaceutical Industries, Ltd. relating to the development of an oral formulation of Copaxone (Teva's currently available, injectable drug for multiple sclerosis), our license agreement with BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp.) 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, The Collagen Solution and Vital 3 as dietary supplements.

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.

Products

Products on the Market. We have one product on the market as a dietary supplement. It is being sold by Colloral LLC, our joint venture with Deseret, under the brand names, Colloral®, The Collagen Solution and Vital 3. The chart set forth below describes the status of this product.

Product	Status
Colloral®	Market launched by Colloral LLC in February 2003.
The Collagen Solution	Market launched by Colloral LLC in October 2005.
Vital 3	Market launched by Futurebiotics LLC in December 2006.

Colloral®, The Collagen Solution and Vital 3. 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 dietary supplement for the relief of joint discomfort. In 2000, we completed a market analysis of Colloral as a dietary 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 by forming Colloral LLC to manufacture, market and sell Colloral as a dietary 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 committed to providing additional amounts. We have since made additional capital contributions of $1,032,000 to support sales and marketing initiatives. While we are not obligated to do so, we may make additional capital contributions to Colloral LLC in the future.

In consideration of our commitment to make capital contributions to support sales and marketing initiatives, the Colloral LLC operating agreement was amended in August 2005 to increase our share of fund distributions and allocations of profits and losses. As a result of the amendments to the operating agreement, we have consolidated Colloral LLC for financial reporting purposes, since the third quarter of 2005.

Colloral LLC began marketing the Colloral brand in February 2003. In 2006, Colloral LLC signed an agreement with Futurebiotics LLC granting it an option to undertake retail distribution of the product. Futurebiotics exercised its option and, in December 2006, began marketing the product under the trade name Vital 3. In 2007, Colloral LLC entered into another agreement with Futurebiotics and two of its affiliates, Bronson Laboratories, LLC and Jenasol LLC, under which it granted those companies rights to market the product under the Vital 3 name through direct response channels. Colloral LLC has also begun marketing the product under the Vital 3 brand through The Shopping Channel of Canada via on air segments and their website.

On February 18, 2005, we received a letter from the FDA stating that the FDA had 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. On April 15, 2005, we submitted a response to the FDA's letter and hope to have demonstrated that the product meets the statutory definition of a dietary supplement. It is possible that Colloral LLC and its licensed distributors will be unable to market the product as a dietary supplement, and that the product 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, The Collagen Solution and Vital 3 will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC. See "Part I, Item 1A, Risk Factors" 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. Many 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 and governmental agencies, 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.

Product	Disease/Condition	Development Status
MBP8298 (dirucotide)	Multiple sclerosis	Currently in Phase III trials for secondary progressive multiple sclerosis (conducted by the Company's licensee, BioMS Medical Corporation).
Oral Copaxone	Multiple sclerosis	Research (conducted by the Company's licensee, with Teva Pharmaceutical Industries, Ltd.).
AI 401	Type 1 diabetes	Currently in Phase III trials sponsored by the 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. in February 1999 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 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. In March 2006, Teva disclosed in a 20-F filing that it would not continue development of enteric coated oral formulation of Copaxone and was considering future development of non-parenteral formulations of the product. It is unclear whether these new formulations involve intellectual property licensed by us to Teva. If Teva develops a product using intellectual property licensed by us and receives product approval from the FDA, we will receive a $10 million milestone payment and escalating royalties on cumulative sales of such product. There can be no assurance, however, that Teva will develop a product using technology licensed to it by us or that, if it does so, such product will be approved by the FDA and brought to market. As of December 31, 2008, Teva's website makes no reference to any research program on Coral. Nonetheless, to date, Teva continues to maintain its license to our technology by paying a portion of our patent expenses.

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 II/III clinical trial (MAESTRO-01) of its MBP8298 treatment for secondary progressive multiple sclerosis. This study, which is being conducted at 47 sites across Canada and Europe, has completed

patient enrollment and recently received a ninth positive review by the Data Safety Monitoring Board. BioMS has announced that interim results on the first 200 patients enrolled in MAESTRO-01 will be available during the last half of 2009, when all participants have completed 24 months of treatment. Long-term follow-up data from multiple sclerosis patients enrolled in an earlier Phase II study and who continued to be treated with MBP8298 were published in the August 2006 issue of *European Journal of Neurology*. The data showed an impressive five-year delay in disease progression in an HLA (human leukocyte antigen)-defined subgroup of multiple sclerosis patients (up to 75% of multiple sclerosis patients) treated with the drug.

In November 2006, BioMS commenced enrollment in a Phase II clinical trial (MINDSET-01) of MBP8298 for treatment of relapsing remitting multiple sclerosis. This 15 month trial enrolled 218 patients at 24 sites in 6 countries. BioMS reported results from MINDSET-01 on January 30, 2009. In its press release, BioMS stated that MBP8298 did not meet the primary endpoint in the MINDSET-01 study of annualized relapse rate or associated secondary MRI endpoints. However, the study did meet certain secondary endpoints related to the progression of the disease, including mean change from baseline in the Expanded Disability Status Scale (EDSS) and the Multiple Sclerosis Functional Composite (MSFC) score.

In January 2007, BioMS announced it had received FDA approval to initiate a second pivotal trial in secondary progressive multiple sclerosis (MAESTRO-3), and in November 2008, BioMS announced that the trial is fully recruited with approximately 510 patients enrolled at 68 sites across the U.S. To date, the DSMB has conducted three reviews of the data from this trial and has recommended it continue.

In December 2007, BioMS signed a licensing and development agreement with Eli Lilly and Company granting Eli Lilly exclusive worldwide rights to MBP8298. If the trials are 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 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 that focused on younger patients 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

("NIH"). 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 were published in the May 2005 issue of *Diabetes Care*. In February 2007, the NIH initiated a multicenter Phase III clinical trial on AI 401 to delay or prevent Type 1 diabetes. As of January 1, 2009, 115 of the planned 300+ patients have been enrolled in this trial.

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, but do not have confirmation, that 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.

Other. 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 $0.7275 per share. Elan Plc's warrant to purchase 375,000 shares of our Common Stock at $3.13 per share expired effective September 16, 2006. The warrant to purchase 375,000 shares of our Common Stock at $0.7275 per share was due to expire on March 17, 2008. On February 27, 2008, we entered into an agreement to repurchase the warrant from Elan Plc for $125,000.

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, our development activities are presently focused on products for two of these diseases: multiple sclerosis and Type 1 diabetes. 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 1, 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 either 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 for other products, 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®, The Collagen Solution and Coral (the product that Teva was developing 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.

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 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. The Brigham and Women's Hospital has been performing sponsored research for us since 1988. Since June 30, 2004, we have not provided funding to The Brigham and Women's Hospital, but we continue to evaluate new methods that may facilitate the clinical development of products based upon mucosal tolerance and may at some point want to resume such funding.

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.

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 consolidated joint venture with Deseret) is producing Colloral, The Collagen Solution and Vital 3 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. Colloral LLC has contracted with Deseret for the manufacture of Colloral, The Collagen Solution and Vital 3 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, The Collagen Solution and Vital 3 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 other companies. Such arrangements may be exclusive or non-exclusive and may provide for marketing rights worldwide or in specific markets.

Colloral LLC (our consolidated joint venture with Deseret) 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. ("BDR") for the development of a consumer oriented marketing plan. Colloral LLC implemented this plan through a sales and marketing agreement with BDR, and in October 2005 re-launched the product under the brand name The Collagen Solution. While Colloral LLC has since terminated the sales and marketing agreement with BDR, sales of The Collagen Solution brand are continuing. In January 2007, Colloral LLC and Futurebiotics signed an agreement for domestic distribution of the product under a third brand name, Vital 3 Joint Solution, and in April 2007, a separate agreement was signed for international distribution of this private label product. Vital 3 is currently being sold by Futurebiotics through Bronson Laboratories and by Colloral LLC through The Shopping Channel of Canada.

Patents and Proprietary Rights

The establishment of a strong proprietary position is an important element of our strategy. As of December 31, 2008, we had pending three foreign patent applications. We have received or have exclusive rights to 201 U.S. and foreign patents and patent applications, including eight 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; two 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; three U.S. patents covering treatment of multiple sclerosis by oral administration of MBP or 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; one U.S. patent covering a method for preparing Type II collagen; and one U.S. patent covering suppression of vascular disorders by mucosal administration of heat shock protein. The U.S. Patent and Trademark 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 the 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 to us covering use of myelin basic protein in the treatment of multiple sclerosis. The European Patent Office has also granted one patent to us 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. Many of these have issued but (except for a relatively small number) only with substantially narrower claims. 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. Again, many have issued but often with substantially narrower claims.

There can be no assurance that patent applications owned by us, or licensed to us, will issue as patents or that 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, because we have been unable to obtain issuance of a patent with broad claims with respect to oral tolerance treatment of autoimmune diseases, 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 alleging patent infringement by us or our licensees or to have our patents declared invalid.

Competition

The pharmaceutical and dietary supplement industries are highly competitive, and research on the causes of and possible treatments for autoimmune and other cell-mediated inflammatory diseases is progressing 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 dietary supplement industries are better equipped than we are to develop and market products based on the application of new technologies. 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 had 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. On April 15, 2005, we submitted a response to the FDA's letter and hope to have demonstrated that the product meets the statutory definition of a dietary supplement. It is possible that Colloral LLC and its licensed distributors will be unable to market the product as a dietary supplement, and that the product 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, The Collagen Solution and Vital 3 will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC. See "Part I, Item 1A, Risk Factors" 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 20, 2009, we had no full-time employees. The President and the Director of Finance are currently working for us as employees on a part-time basis pursuant to agreements that we have entered into with them.

Item 1A. Risk Factors

Forward-Looking and Cautionary Statements.

Statements in this Annual Report that are not strictly historical are 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. These statements include statements about our future operating results, strategic relationships and product development. You can identify these forward-looking statements because they involve our expectations, beliefs, projections, anticipations or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ significantly from results discussed in the forward-looking statements. These factors 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 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.

We have limited staff, infrastructure and 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.

The pharmaceutical products being developed by our licensees are in or will undergo clinical trials and regulatory review, and there can be no assurance that the results from these trials will be favorable or that the products will be successfully marketed by our licensees.

We have not completed the development of any product except the dietary supplement marketed under the trade names Colloral®, The Collagen Solution and Vital 3. 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.

We have accumulated significant net losses, and there can be no assurance that we will be able achieve profitable operations in the future.

From our inception in 1988 through December 31, 2008, we have accumulated net losses of $110,102,000. We may continue to incur additional losses as we 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 and increase sales of our dietary supplement by Colloral LLC. There can be no assurance that we will achieve profitable operations at any time.

Most of our revenues to date have been earned in connection with collaborative and 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 in return for future payments based upon the achievement of certain milestones and royalties based on sales, if any, and we entered into our agreement with BioMS 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, and on March 20, 2006,

Teva disclosed in its 20-F filing that it will not continue development of the enteric coated oral version of its product Copaxone, it had been developing using our intellectual property. While the filing states Teva is considering future development of non-parenteral formulations of oral Copaxone, it is unclear whether any such future development would involve intellectual property licensed by us to Teva. 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 our joint venture with Deseret by forming Colloral LLC to manufacture, market and sell Colloral® as a dietary supplement. Our interest in Colloral LLC is greater than 50% and we actively participate in its management, but we do not have voting control of Colloral LLC. Therefore, the investment had historically been accounted for using the equity method. In August 2005, we amended the Colloral LLC operating agreement to increase our share of distributions and allocations of profits and losses in return for our commitment to fund 100% of the costs associated with the implementation of a marketing program for The Collagen Solution. In accordance with the amendment to the Colloral LLC operating agreement, we made additional capital contributions of $1,032,000 to Colloral LLC from 2003 through 2007. We satisfied our funding commitment in 2006 and have made no capital contributions during the year ended December 31, 2008. We may make additional contributions to Colloral LLC in the future. There can be no assurance that the sales and marketing initiatives for Colloral LLC that have been or, in the future, may be funded by our capital contributions will be successful. Accordingly, in the future we may again incur substantial losses.

We may be unable to market Colloral as a dietary supplement and may be subject to significant additional regulatory requirements if the FDA determines that Colloral is a drug under the Federal Food, Drug, and Cosmetic Act.

In 2000, we completed a market analysis of Colloral as a dietary 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 had 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. On April 15, 2005, we submitted a response to the FDA's letter and hope to have demonstrated that the product meets the statutory definition of a dietary supplement. It is possible that Colloral LLC and its distributors will be unable to market the product as a dietary supplement, and that the product 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, The Collagen Solution and Vital 3 will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC.

We may not be able to raise additional capital or access required financing to fund our long-term operations.

Since inception, we have raised net proceeds of approximately $116 million 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 2009, 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.

We are wholly dependent on collaborative agreements to develop and market our products and there can be no assurance that these agreements will be successful or that we will be able to enter into future agreements.

Currently, we are wholly dependent upon collaborative agreements or arrangements with others. We have granted Teva 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. On March 20, 2006, Teva disclosed in its 20-F filing that it will not continue development of the enteric coated oral version of its product Copaxone, it had been developing using our intellectual property, but is considering future development of non-parenteral formulations of oral Copaxone. It is unclear whether any such future development would involve intellectual property licensed by us to Teva. We also have granted BioMS exclusive worldwide rights to certain patents covering a product to treat multiple sclerosis. The agreement with BioMS provides for monthly diligence payments and royalties based on sales, if any. Obligations to make diligence payments will cease if BioMS terminates the agreement. BioMS sub-licensed these patents to Eli Lilly, but there is no assurance Eli Lilly will be successful in its efforts to commercialize this technology. We entered into a joint venture with Deseret by forming Colloral LLC to manufacture, market and sell Colloral as a dietary supplement. There can be no assurance that we will be able to negotiate other acceptable arrangements in the future or that any of our current or future collaborative agreements or 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 and we are not sponsoring a research program in any institution. If we were to re-initiate a research program, we expect to be dependent upon our ability to have 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.

Our patents and proprietary rights may not provide sufficient protection, and patents of other companies could prevent us from developing and marketing our products.

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 201 U.S. and foreign patents and patent applications. We are actively pursuing three foreign patent applications, 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 U.S. Patent and Trademark Office and the U.S. 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.

Many of our competitors have significantly greater experience and financial and technological resources than do we.

The biotechnology, pharmaceutical and dietary supplement industries are subject to rapid and significant technological change. Our competitors are numerous and include, among others, major pharmaceutical companies, biotechnology firms, dietary supplement 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 The Brigham and Women's Hospital under our agreement for sponsored research, however, we continue to evaluate new methods that may facilitate the clinical development of products based upon mucosal tolerance.

It may take many years and substantial expenditures of resources to obtain approval from the FDA and foreign regulatory agencies to market pharmaceutical products utilizing our technology.

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 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

We are currently operating with minimal employees and activities utilizing the personal office spaces of the President and the Director of Finance and, therefore, have no leases. Our consolidated joint venture, Colloral LLC, outsources all of its operations and also has no lease obligations. Our principal executive office is located at the President's personal office in Pasadena, California.

It is our policy not to invest in (a) real estate or interests in real estate; (b) real estate mortgages; or, (c) securities or interests in persons primarily engaged in real estate activities.

Item 3. Legal Proceedings.

We are not a party to any litigation or legal proceedings, or proceedings contemplated by a government authority of which we are aware.

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 2008.

Item 4A. Executive Officers of the Registrant

Robert C. Bishop, Ph.D., age 66, is AutoImmune's President, Chief Executive Officer and Chairman of the Board. Dr. Bishop was elected President and Chief Executive Officer and to the Board of Directors 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 President of Allergan Therapeutics Group 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, Chairman and a director of Caliper Life Sciences Corporation, a microfluidics company developing lab-on-a-chip instrument systems. Dr. Bishop is also a Manager/Trustee of MFS/Compass Funds Complex (a series of portfolios advised by MFS Investment Management) and serves on the Advisory Board for Waterstreet Capital, a leveraged buyout firm focused on opportunities in health care.

Diane M. McClintock, CPA, age 41, joined the Company in June 2005 and was appointed the Company's Treasurer and Director of Finance on August 18, 2005. From 1998 through 2005, Ms. McClintock was a Director in the Transaction Services practice at PricewaterhouseCoopers LLP where she provided financial advice and assistance to clients regarding potential transactions. From 1995 through 1998, Ms. McClintock was employed by Ernst & Young LLP where she was an Audit Manager. Ms. McClintock received her B.S. degree in Business Administration with a Concentration in Accounting from the University of New Hampshire.

PART II

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

Since May 26, 2004, our common stock has been listed on the OTC Bulletin Board and, for a period in 2008, the Pink Sheets under the symbol AIMM. The following table shows the quarterly high and low sales price on the OTC Bulletin Board and the Pink Sheets for a share of our common stock (based on intra-day trading) for the fiscal years ended December 31, 2007 and 2008. The high and low bid information was obtained from NASDAQ.com. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions.

	Price range of common stock	
	High	Low
Fiscal year ending December 31, 2007		
First quarter	$1.26	$1.14
Second quarter	$1.55	$1.22
Third quarter	$1.50	$1.31
Fourth quarter	$1.75	$1.34
Fiscal year ending December 31, 2008		
First quarter	$1.97	$1.58
Second quarter	$2.28	$1.70
Third quarter	$2.10	$1.31
Fourth quarter	$1.42	$0.80

As of March 23, 2009, there were 171 record holders and approximately 2,450 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.

Information with respect to shares of the Company's common stock that may be issued under its equity compensation plans is set forth in our Consolidated Financial Statements in a separate section of this Report commencing on Page F-1.

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, 2008, we have incurred ongoing losses from operations and have cumulative losses as of December 31, 2008 totaling $110,102,000. To date, our only revenue from the sale of products has been earned through our joint venture, Colloral LLC. The majority of revenues recorded from inception through December 31, 2008 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 our joint venture with Deseret by forming Colloral LLC to manufacture, market and sell Colloral® as a dietary supplement. Our interest in Colloral LLC is greater than 50% and we actively participate in its management, but we do not have voting control of Colloral LLC. Therefore, the investment had historically been accounted for using the equity method. In August 2005, we amended the Colloral LLC operating agreement to increase our share of distributions and allocations of profits and losses in return for our commitment to fund 100% of the costs associated with the implementation of a marketing program for The Collagen Solution. As a result of the amendments to the operating agreement, Colloral LLC is now considered a variable interest entity, of which we are the primary beneficiary. We have consolidated Colloral LLC in accordance with FIN 46R, effective since the third quarter of 2005.

In accordance with the amendment to the Colloral LLC operating agreement, we made additional capital contributions of $1,032,000 to Colloral LLC from 2003 through 2007. We satisfied our funding commitment in 2006 and have made no capital contributions during the year ended December 31, 2008. We may make additional contributions to Colloral LLC in the future. There can be no assurance that the sales and marketing initiatives that have been or, in the future, may be funded by our capital contributions will be successful. Accordingly, in the future we may again incur substantial losses.

The following table contains selected financial data for Colloral LLC. Shipping and handling costs have been classified as selling expenses. The balance sheet amounts as of December 31, 2007 and 2008 and Colloral LLC's operating results for the years then ended have been consolidated into our financial statements:

	For the year ended December 31, 2007	2008
Statement of Operations Data:		
Revenue	$114,000	$136,000
Cost of goods sold	21,000	45,000
Selling, general and administrative expense	109,000	57,000
Net income (loss)	$(16,000)	$ 34,000

	December 31, 2007	December 31, 2008
Balance Sheet Data:		
Current assets	$171,000	$219,000
Long term assets	—	—
Current liabilities	5,000	6,000
Long term liabilities	—	—

In 2000, we completed a market analysis of Colloral as a dietary 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. On April 15, 2005, we submitted a response to the FDA's letter and hope to have demonstrated that the product meets the statutory definition of a dietary supplement. We cannot predict whether or not the FDA will agree with our position and what the effect of the FDA's letter will be. It is possible that Colloral LLC and its licensed distributors will be unable to market the product as a dietary supplement and that the products 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, The Collagen Solution and Vital 3 will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC.

Years Ended December 31, 2007 and 2008

Revenue was $294,000 and $316,000 for the years ended December 31, 2007 and 2008, respectively. The revenue in 2007 and 2008 was comprised of monthly license payments from BioMS for their use of our patents pertaining to an injectable therapy for the treatment of multiple sclerosis and product revenues generated through our joint venture, Colloral LLC, whose results are consolidated with ours. From 2006 through January 2009, Colloral LLC executed a series of agreements with Futurebiotics, LLC and related companies whereby Futurebiotics began marketing Colloral's dietary supplement under the brand name, Vital 3, through several different channels, including the GNC chain of retail stores and both print and e-catalogs. Domestic retail store sales ceased in September 2007 and Futurebiotics is currently selling product through print and e-catalogs through its affiliate, Bronson Laboratories, while it works on both international and domestic selling opportunities. Option payments related to the execution of the Futurebiotics agreement are reflected as option fee revenue and are being amortized over the life of the agreement. Product shipped under these agreements generated revenue of $29,000 and $59,000 during the years ended December 31, 2007 and 2008, respectively. Colloral LLC also contracted with The Shopping Channel of Canada to market Vital 3 through televised segments and through their website. Product shipped under this agreement generated revenue of $18,000 and $31,000 during the years ended December 31, 2007 and 2008, respectively. The remaining product revenue is generated through direct sales of Colloral and the Collagen Solution to Colloral LLC's customers through its website

Cost of goods sold was $21,000 and $45,000 for the years ended December 31, 2007 and 2008, respectively. The increase is a result of the increase in product shipped in 2008 and the write-off of expired of inventory.

Research and development expenses were $144,000 and $174,000 for the years ended December 31, 2007 and 2008, respectively. The increase is due to the timing of patent related legal costs and an increase in patent annuities.

Selling, general and administrative expenses were $713,000 and $647,000 for the years ended December 31, 2007 and 2008, respectively. The decrease is a result of Colloral LLC's selling, general and administrative costs of $109,000 for the year ended December 31, 2007 compared to $57,000 for the year ended December 31, 2008, which have been consolidated into our operating results. The lower costs at Colloral LLC are a result of the termination of the Business Development Resources, Inc. relationship and Colloral LLC's fulfillment contract with SpeedFC, Inc. which reduced advertising and fulfillment costs by $50,000 in 2008. Also contributing to the decrease were a decline in our Directors and Officers liability insurance premiums of $18,000 and our reduction of legal costs of $23,000. The decrease is offset by an increase in noncash stock compensation from $91,000 for the year ended December 31, 2007 to $121,000 for the year ended December 31, 2008 due to the issuance of options in early 2008.

Interest income was $440,000 and $213,000 for the years ended December 31, 2007 and 2008, respectively. The decrease is primarily due to significant declines in market interest rates and returns on investment for U.S. Treasury obligations and other short term instruments.

Minority interest in joint venture was $1,000 and $(8,000) for the years ended December 31, 2007 and 2008, respectively. The minority interest in joint venture reflects Deseret's share of Colloral LLC's profits or losses calculated in accordance with the amended terms of the Colloral LLC operating agreement.

Other income was $25,000 for the year ended December 31, 2007. In February 2004, Enzo Biochem, Inc. acquired the assets of OraGen. In March 2007, we received the final distribution in respect of our ownership interest in OraGen in the amount of $25,000, which we have recorded as other income.

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.

We hold an interest in Colloral LLC, which is manufacturing, marketing and selling Colloral, The Collagen Solution and Vital 3 as dietary supplements, and manufacturing Vital 3 for sale by Futurebiotics LLC and related companies. While we are not contractually committed to make additional capital contributions to Colloral LLC, we may elect to do so. Despite any additional investment, there can be no assurance that these efforts will be successful. Accordingly, in the future we may again incur substantial losses.

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 2008, we utilized $214,000 of cash from operations. The most significant uses of cash for the year ended December 31, 2008 were legal and accounting expenses totaling $341,000 and the repurchase of warrants from Elan Plc for $125,000. The most significant sources of cash for the year ended December 31, 2008 were interest income of $213,000 and our license revenues $180,000. We expect to continue to use our current cash and cash equivalents on hand to fund our future

operations and development efforts. Based upon our budget for the calendar year 2009 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 generally invested in U.S. Treasury obligations and money market instruments. Our investment policy is designed to reduce credit and market risk. As of December 31, 2008, our cash and cash equivalents and marketable securities totaled $8,475,000. Current liabilities at December 31, 2008 were $147,000.

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. Effective for the third quarter of 2005, we are required to consolidate Colloral LLC, a joint venture for the development and marketing of dietary supplements.

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 Recognition

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, payments based upon achievement of certain milestones, or royalties on net product sales. We evaluate revenue from agreements entered that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21") "Revenue Arrangements with Multiple Deliverables." To account for multiple deliverables separately, 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.

Asset Impairments

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 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 registrant 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 to recovery. 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.

Variable Interest Entities

In January 2003, the FASB issued FIN 46, "Consolidation of Variable Interest Entities" and, in December 2003, the FASB issued FIN 46R. FIN 46R replaces FIN 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity 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 46R establishes standards for determining under what circumstances variable interest entities should be consolidated with their primary beneficiary. We adopted FIN 46R in the first quarter of 2004 for non-special purpose entities created prior to February 1, 2003, which included our interest in Colloral LLC. The adoption of FIN 46R did not have an initial material effect on our financial condition or results of operations. Our interest in Colloral LLC did not qualify as a variable interest entity and therefore, we continued to account for our investment in Colloral LLC under the equity method of accounting until August 2005.

In August 2005, we amended the Colloral LLC operating agreement to increase our share of fund distributions and allocations of profits and losses in return for our commitment to fund 100% of the costs associated with the implementation of a marketing program for The Collagen Solution undertaken by Colloral LLC. As a result of the amendments to the operating agreement, Colloral LLC is now considered a variable interest entity, of which we are the primary beneficiary. We are now required to consolidate Colloral LLC for financial reporting purposes, effective in the third quarter of 2005. In accordance with FIN 46R, we re-evaluate the provisions of FIN 46R when triggering events arise and to date, no events have transpired which would require deconsolidation. Certain events may arise in the future, including additional modifications to the operating agreements, which may require us to re-evaluate the joint venture under FIN 46R. Such re-evaluation may result in a conclusion that the joint venture is no longer a variable interest entity requiring consolidation.

Recent Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141R, "Business Combinations." SFAS No. 141R, among other aspects, requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction; establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; and requires the acquirer to disclose certain information to enable users to understand the nature and financial effect of the business combination. The statement requires that cash outflows such as transaction costs and post-acquisition restructuring be charged to expense instead of capitalized as a cost of the acquisition. Contingent purchase price will be recorded at its initial fair value and then re-measured as time passes through adjustments to net income. SFAS No. 141R is effective for us in 2009. We do not expect the adoption of SFAS No. 141R to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements." SFAS No. 160 will change the accounting for minority interests, which will be reclassified as noncontrolling interests and classified as a component of equity. SFAS No. 160 is effective for us in 2009. We do not expect the adoption of SFAS No. 160 to have a material impact on our consolidated financial statements.

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, "Accounting for Collaborative Arrangements." The EITF established the definition of a collaborative arrangement and determined that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the arrangements terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for us January 1, 2009 and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-1 to have a material impact on our consolidated financial statements.

In December 2008, the FASB issued Staff Position ("FSP") FAS No. 140-4 and FIN 46(R)-8, "Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities" ("FSP FAS 140-4"). The purpose of this FSP is to improve disclosures by public entities and enterprises until pending amendments to SFAS No. 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities" ("SFAS 140"), and FIN 46(R) are finalized and approved by the FASB. The FSP amends SFAS 140 to require public entities to provide additional disclosures about transferors' continuing involvements with transferred financial assets. It also amends FIN 46(R) to require public enterprises, to provide additional disclosures about their involvement with variable interest entities. FSP FAS 140-4 and FIN 46(R)-8 are effective for financial statements issued for fiscal years and interim periods ending after December 15, 2008. For periods after the initial adoption date, comparative disclosures are required. We adopted the FSP and FIN 46(R)-8 on December 31, 2008.

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

We have invested all of our cash in U.S. Government Agency debt securities and money market instruments. These investments are denominated in U.S. dollars. Our exposure to market interest rate risk relates to our cash, cash equivalents and marketable securities. As of December 31, 2008, our $8,475,000 of cash and cash equivalents consisted of Government agency and treasury money market instruments. Due to the conservative nature of these instruments, we do not believe that a change in market rates would have a material negative impact on the value of our cash and cash equivalents. Declines of interest rates over time will, however, reduce our interest income from our investments. Interest income was $213,000 for the year month ended December 31, 2008. A 1% change in interest rates could effect our annual interest income by approximately $85,000.

Item 8. Financial Statements.

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.

Not Applicable.

Item 9A(T). Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

The Company's management, consisting of our Chief Executive Officer and Director of Finance and Treasurer evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as

defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2008. Based upon this evaluation, our Chief Executive Officer and Director of Finance and Treasurer concluded that, as of December 31, 2008, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

Management's Annual Report on Internal Control Over Financial Reporting

Our Chief Executive Officer and Director of Finance and Treasurer are responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2008 based on criteria established in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, the Company's management concluded that, as of December 31, 2008, the Company's internal control over financial reporting was effective.

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Securities Exchange Act of 1934, as amended) during our last fiscal quarter and our year ended December 31, 2008 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report.

Item 9B. Other Information.

Not Applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information called for 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, 2008.

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, 2008.

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, 2008.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

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, 2008.

Item 14. Principal Accounting Fees and Services.

The 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, 2008.

Item 15. Exhibits.

(a)(1) Financial Statements

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

(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)
10.1	—Stock Option Plan for Nonemployee Directors(3)*
10.2	—1998 Stock Option Plan(4)*
10.3	—2008 Stock Option Plan(5)*
10.4	—Form of Stock Option Award under 2008 Stock Option Plan*
10.5	—Development and License Agreement dated as of December 4, 1998 between AutoImmune Inc. and Teva Pharmaceutical Industries Ltd.(6)+
10.6	—Consulting Agreement dated January 3, 2000 between AutoImmune Inc. and Robert C. Bishop, Ph.D.(7)*
10.7	—Consulting Agreement dated September 20, 1999 between AutoImmune Inc. and Fletcher Spaght, Inc.(7)
10.8	—Letter Agreement dated January 31, 2000 between AutoImmune Inc. and Fletcher Spaght, Inc.(8)+
10.9	—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(8)+
10.10	—Agreement dated August 1, 2000 between AutoImmune Inc. and Rycor Technology Instruments Corp. (now known as BioMS Medical Corporation)(9)+
10.11	—Limited Liability Company Operating Agreement of Colloral LLC, dated August 19, 2002(10)+
10.12	—License Agreement, dated August 19, 2002 between AutoImmune Inc. and Colloral LLC(10)
10.13	—Trademark License Agreement, dated August 19, 2002, between AutoImmune Inc. and Colloral LLC(10)
10.14	—Summary of Nonemployee Director Fees(11)*
10.15	—Letter Agreement, dated August 18, 2005, between AutoImmune Inc. and Diane M. McClintock(12)*
10.16	—First Amendment to Limited Liability Company Operating Agreement of Colloral LLC, dated August 29, 2005, by and between AutoImmune Inc. and Deseret Laboratories, Inc.(13)
10.17	—Supply and License Agreement dated effective as of January 10, 2007 between Colloral LLC and Futurebiotics, LLC(14)+
10.18	—Supply and License Agreement (International Territories) dated effective as of January 10, 2007 between Colloral LLC and Futurebiotics, LLC(14)+
10.19	—Supply and License Agreement dated effective August 20, 2007 between AutoImmune and Bronson Laboratories LLC, Futurebiotics LLC and Jenasol LLC(15)+
10.20	—Clarification and Amendment of BioMS License Agreement as of December 16, 2007 between AutoImmune and BioMS Technology Corp.(11)
10.21	—Second Amendment to the Supply and License Agreement dated effective January 15, 2009 between Colloral LLC and Futurebiotics LLC+
23.1	—Consent of Independent Registered Public Accounting Firm

Exhibit Number	Exhibit Description
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 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 Securities Exchange Act of 1934.

(4) 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).

(5) Incorporated by reference to Appendix A to AutoImmune's definitive Proxy Statement dated April 10, 2008 for the Annual Meeting of Shareholders held on May 15, 2008 filed pursuant to the Securities Exchange Act of 1934.

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

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

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

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

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

(11) Incorporated by reference to AutoImmune's Annual Report on Form 10-K for the year ended December 31, 2007.

(12) Incorporated by reference to AutoImmune's Current Report in Form 8-K filed with the Securities and Exchange Commission on August 24, 2005.

(13) Incorporated by reference to AutoImmune's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 31, 2005.

(14) Incorporated by Reference to AutoImmune's Quarterly Report on Form 10-QSB for the quarter ended March 31, 2007.

(15) Incorporated by Reference to AutoImmune's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2007.

\+ 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.

++ We have requested confidential treatment of the redacted portions of this exhibit pursuant to Rule 24b-2 under the Securities 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 this 25th day of March 2009.

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 25, 2009
/s/ DIANE M. MCCLINTOCK **Diane M. McClintock** **Principal Financial and Accounting Officer**	Director of Finance and Treasurer	March 25, 2009
/s/ HUGH A. D'ANDRADE **Hugh A. D'Andrade**	Director	March 25, 2009
/s/ ALLAN R. FERGUSON **Allan R. Ferguson**	Director	March 25, 2009
/s/ R. JOHN FLETCHER **R. John Fletcher**	Director	March 25, 2009

AutoImmune Inc.
(a development stage company)

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
AutoImmune Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the financial position of AutoImmune Inc. and its subsidiary (a development stage company) at December 31, 2008 and December 31, 2007, and the results of their operations and their cash flows for the years then ended and, cumulatively, for the period from September 9, 1988 (date of inception) to December 31, 2008 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 25, 2009

AutoImmune Inc.
(a development stage company)

Consolidated Balance Sheets

	December 31, 2007	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 7,994,000	$ 8,475,000
Marketable securities	810,000	—
Accounts receivable	12,000	37,000
Prepaid expenses, inventories and other current assets	155,000	158,000
Total current assets	8,971,000	8,670,000
Other assets	—	—
Total assets	$ 8,971,000	$ 8,670,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,000	$ 18,000
Accrued professional fees	99,000	110,000
Deferred revenue	20,000	19,000
Total current liabilities	128,000	147,000
Commitments and contingencies (Notes 5 and 11)		
Minority interest in joint venture	11,000	33,000
Stockholders' equity:		
Preferred stock, $0.01 par value: 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2007 and 2008	—	—
Common stock, $0.01 par value: 25,000,000 shares authorized; 16,979,623 shares issued and outstanding at December 31, 2007 and 16,999,623 shares issued and outstanding at December 31, 2008	170,000	170,000
Additional paid-in capital	118,420,000	118,426,000
Deficit accumulated during the development stage	(109,761,000)	(110,106,000)
Accumulated other comprehensive income	3,000	—
Total stockholders' equity	8,832,000	8,490,000
Total liabilities and stockholders' equity	$ 8,971,000	$ 8,670,000

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

AutoImmune Inc.
(a development stage company)

Consolidated Statements of Operations

	For the year ended December 31, 2007	2008	Period from September 9, 1988 (date of inception) to December 31, 2008
Revenue:			
License rights	$ 180,000	$ 180,000	$ 7,703,000
Option fees	10,000	4,000	2,214,000
Research and development revenue under collaborative agreements	—	—	955,000
Product revenue	104,000	132,000	476,000
Total revenue	294,000	316,000	11,348,000
Costs and expenses:			
Cost of product revenue	21,000	45,000	116,000
Research and development:			
Related party	12,000	12,000	20,007,000
All other	132,000	162,000	92,951,000
Selling, general and administrative	713,000	647,000	22,101,000
Total costs and expenses	878,000	866,000	135,175,000
Income (loss) from operations	(584,000)	(550,000)	(123,827,000)
Interest income	440,000	213,000	14,324,000
Interest expense	—	—	(303,000)
Minority interest in joint venture	1,000	(8,000)	4,000
Equity in net loss of unconsolidated affiliate	—	—	(250,000)
Other income (expense)	25,000	—	(50,000)
	466,000	205,000	13,725,000
Net income (loss)	$ (118,000)	$ (345,000)	$(110,102,000)
Net income (loss) per share—basic	$ (0.01)	$ (0.02)	
Net income (loss) per share—diluted	$ (0.01)	$ (0.02)	
Weighted average shares outstanding—basic	16,970,558	16,999,022	
Weighted average shares outstanding—diluted	16,970,558	16,999,022	

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

AutoImmune Inc.
(a development stage company)

Consolidated Statements of Changes In Stockholders' Equity
For the period from September 9, 1988 (date of inception) to December 31, 2008

	Common Stock Number of shares	Common Stock 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
Valuation of warrants issued during 2003			155,000				155,000
Stock-based compensation expense for the period from September 9, 1988 (date of inception) through December 31, 2006			40,000				40,000
Net loss for the period from September 9, 1988 (date of inception) through December 31, 2006				$(109,643,000)	(109,639,000)		(109,639,000)
Comprehensive loss				(109,643,000)			
Balance at December 31, 2006	16,919,623	169,000	118,297,000		(109,643,000)	$ —	8,823,000
Comprehensive loss:							
Issuance of common stock during 2007	60,000	1,000	32,000				33,000
Net loss				(118,000)	(118,000)		(118,000)
Other comprehensive income (loss):							
Net change in unrealized gain on marketable securities				3,000		3,000	3,000
Comprehensive loss				(115,000)			
Stock-based compensation expense			91,000				91,000
Balance at December 31, 2007	16,979,623	170,000	118,420,000		(109,761,000)	$ 3,000	8,832,000
Comprehensive loss:							
Issuance of common stock during 2008	20,000	—	10,000				10,000
Repurchase of outstanding warrants in 2008			(125,000)				(125,000)
Net loss				(345,000)	(345,000)		(345,000)
Other comprehensive income (loss):							
Net change in unrealized gain on marketable securities				(3,000)		(3,000)	(3,000)
Comprehensive loss				$ (348,000)			
Stock-based compensation expense			121,000				121,000
Balance at December 31, 2008	16,999,623	$170,000	$118,426,000		$(110,106,000)	$ —	$ 8,490,000

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

AutoImmune Inc.
(a development stage company)

Consolidated Statements 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:	2007	2008	2008
Net loss	$ (118,000)	$ (345,000)	$(110,102,000)
Adjustments to reconcile net loss to net cash used by operating activities:			
Interest expense related to demand notes converted into mandatorily redeemable convertible preferred stock	—	—	48,000
Patent costs paid with junior convertible preferred and common stock	—	—	3,000
Valuation of warrants issued in conjunction with license revenue	—	—	347,000
Noncash stock compensation	91,000	121,000	252,000
Noncash contributions to joint venture from minority interest	12,000	14,000	37,000
Minority interest in joint venture	(1,000)	8,000	(4,000)
Depreciation and amortization	—	—	4,464,000
Noncash interest income	—	(3,000)	(3,000)
Loss on sale/disposal of fixed assets	—	—	642,000
Decrease in patent costs	—	—	563,000
Impairment of investment in OraGen	—	—	100,000
Equity in net loss of unconsolidated affiliate	—	—	250,000
(Increase) decrease in accounts receivable	48,000	(25,000)	(37,000)
(Increase) decrease in prepaid expenses and other current assets	(12,000)	(3,000)	(158,000)
Increase (decrease) in accounts payable	(1,000)	9,000	18,000
Increase (decrease) in accrued expenses	11,000	11,000	90,000
Increase (decrease) in deferred revenue	(10,000)	(1,000)	19,000
Net cash (used by) provided by operating activities	20,000	(214,000)	(103,471,000)
Cash flows from investing activities:			
Purchase of available-for-sale marketable securities	(3,682,000)	—	(322,315,000)
Proceeds from sale/maturity of available-for-sale marketable securities	2,860,000	810,000	311,307,000
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	—	—	(230,000)
Purchases of fixed assets	—	—	(5,288,000)
Increase in patent costs	—	—	(563,000)
Increase in other assets	—	—	(125,000)
Net cash used by investing activities	(822,000)	810,000	(5,997,000)
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	33,000	10,000	105,557,000
Proceeds from issuance of convertible notes payable	—	—	2,200,000
Payments for repurchase of outstanding warrants	—	(125,000)	(125,000)
Net cash provided by financing activities	33,000	(115,000)	117,943,000
Net increase (decrease) in cash and cash equivalents	(769,000)	481,000	8,475000
Cash and cash equivalents at beginning of period	8,763,000	7,994,000	—
Cash and cash equivalents at end of period	$ 7,994,000	$8,475,000	$ 8,475,000

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

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

AutoImmune Inc.
(a development stage company)

Notes to the Consolidated 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 the dietary supplements Colloral®, The Collagen Solution and Vital 3. We contributed all of the equipment used to manufacture this product and certain Colloral-related intellectual property to Colloral LLC, a joint venture between us and Deseret Laboratories, Inc. formed in August 2002. Colloral LLC is currently the exclusive manufacturer of Colloral, The Collagen Solution and Vital 3. The product is marketed and sold by Colloral LLC and by Futurebiotics LLC through its affiliate Bronson Laboratories. Other products using our technology 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 dietary supplement and subsequently filed a "Notice of New Dietary Ingredient" with the Food and Drug Administration (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. On April 15, 2005, we submitted a response to the FDA's letter and hope to have demonstrated that the product 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 and its licensed distributors will be unable to market the product as a dietary supplement and that the product 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, The Collagen Solution and Vital 3 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, 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

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements include the accounts of AutoImmune, Inc and our joint venture with Deseret, Colloral LLC. Pursuant to Financial Accounting Standards Board ("FASB") Interpretation No. 46, "Consolidation of Variable Interest Entities" ("FIN 46"), as revised by FIN 46R we began to consolidate Colloral LLC in the third quarter of 2005 when it qualified as a variable interest entity of which we are the primary beneficiary. All significant intercompany accounts and transactions have been eliminated in consolidation. We discuss our investment in Colloral LLC in more detail in Note 5.

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 money market securities and U.S. Government debt securities of short maturity. Our investment policy is designed to reduce credit and market risk. The earnings on our investment portfolios may be adversely affected by changes in interest rates, credit ratings, collateral value, the overall strength of credit markets, and other factors that may result in other than temporary declines in the value of the securities. We specifically identify securities for purposes of determining gains and losses on the sale of cash equivalents and marketable securities. At December 31, 2007, 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. We did not hold any available-for-sale marketable securities at December 31, 2008.

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 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 to recovery. 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, 2008, our financial instruments primarily consisted of cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses. The carrying amounts of these instruments approximate their fair values.

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, payments based upon achievement of certain milestones, or royalties on net product sales. We evaluate revenue from agreements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21") "Revenue Arrangements with Multiple Deliverables." To account for multiple deliverables separately, 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.

License revenue generated in 2007 and 2008 was derived from an agreement with BioMS Medical Corporation (formerly known as Rycor Technology Investments Corp.) (See Note 13)

Product revenues generated in 2007 and 2008 were earned through our consolidated joint venture, Colloral LLC. We recognize revenue from product sales when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured.

Stock Compensation

On January 1, 2006, we adopted SFAS No. 123R "Accounting for Stock-Based Compensation" using the modified prospective method, which results in the provisions of SFAS No. 123R only being applied to the consolidated financial statements on a going-forward basis (that is, the prior period results have not been restated). Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the requisite service period using the graded vesting method. Stock-based employee compensation expense was $91,000 and $121,000 for the years ended December 31, 2007 and 2008, respectively. We recorded these noncash expenses to general and administrative expense. Previously, we had followed Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, which resulted in the accounting for employee share options at their intrinsic value in the consolidated financial statements.

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 2007 and 2008:

	December 31,	
	2007	**2008**
Risk free interest rate range	4.62% to 5.05%	2.67% to 3.1%
Expected range of life in years	3 years to 6 years	3 years to 6 years
Expected volatility	75%	75%
Expected dividends	—	—

Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

As of December 31, 2008, there remained approximately $247,000 of compensation costs related to non-vested stock options to be recognized as expense over a weighted-average period of approximately 1.78 years. The aggregate intrinsic value of all stock options outstanding at December 31, 2008 was $306,000. The aggregate intrinsic value of all vested stock options at December 31, 2008 was $301,000. During the year ended December 31, 2007, 60,000 options were exercised with an intrinsic value of $41,000 on the date of exercise. During the year ended December 31, 2008, 20,000 options were exercised with an intrinsic value of $24,000 on the date of exercise

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, 2007 and 2008, shares used to compute diluted earnings per share excluded 1,596,000 and 1,211,500 stock options and warrants, respectively, as their inclusion would have been anti-dilutive due to the net losses incurred in these years.

Advertising Costs
All advertising costs are expensed as incurred and are included in selling and administrative expenses in the consolidated statements of operations. Advertising expenses for 2007 and 2008 were $47,000 and $16,000, respectively.

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.

Reclassifications
Certain amounts in 2007 have been reclassified in the accompanying financial statements in order to be consistent with the current year's classifications, including reclassifications between marketable securities and prepaid expenses and between option fee revenue and license rights. The reclassifications have no effect on stockholders' equity or net loss.

Recent Accounting Pronouncements
In December 2007, the FASB issued SFAS No. 141R, "Business Combinations." SFAS No. 141R, among other aspects, requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction; establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; and requires the acquirer to disclose certain information to enable users to understand the nature and financial effect of the business combination. The statement requires that cash outflows such as transaction costs and post-acquisition restructuring be charged to expense instead of capitalized as a cost of the acquisition. Contingent purchase price will be recorded at its initial fair value and then re-measured as time passes through adjustments to net income. SFAS No. 141R is effective for us in 2009. We do not expect the adoption of SFAS 141R to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements." SFAS No. 160 will change the accounting for minority interests, which will be reclassified as noncontrolling interests and classified as a component of equity. SFAS No. 160 is effective for us in 2009. We do not expect the adoption of SFAS 160 to have a material impact on our consolidated financial statements.

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, "Accounting for Collaborative Arrangements." The EITF established the definition of a collaborative arrangement and determined that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the arrangements terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial- statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for us January 1, 2009 and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-1 to have a material impact on our consolidated financial statements.

In December 2008, the FASB issued Staff Position ("FSP") FAS No. 140-4 and FIN 46(R)-8, "Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities" ("FSP FAS 140-4"). The purpose of this FSP is to improve disclosures by public entities and enterprises until pending amendments to SFAS No. 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities" ("SFAS 140"), and FIN 46(R) are finalized and approved by the FASB. The FSP amends SFAS 140 to require public entities to provide additional disclosures about transferors' continuing involvements with transferred financial assets. It also amends FIN 46(R) to require public enterprises, to provide additional disclosures about their involvement with variable interest entities. FSP FAS 140-4 and FIN 46(R)-8 is effective for financial statements issued for fiscal years and interim periods ending after December 15, 2008. For periods after the initial adoption date, comparative disclosures are required. We adopted the FSP and FIN 46(R)-8 on December 31, 2008.

Disclosure of Non-Cash Investing and Financing Activities
During the years ended December 31, 2007 and 2008, Deseret contributed services in kind of $12,000 and $14,000 to our consolidated joint venture, Colloral LLC, which were recorded as a capital contribution.

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 2007 and 2008, 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. Fair Value Measurements

Effective January 1, 2008, we implemented Statement of Financial Accounting Standard No. 157, "Fair Value Measurement", or SFAS 157, for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. In accordance with the provisions of FSP No. FAS 157-2, "Effective Date of FASB Statement No. 157", we have elected to defer implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. The adoption of SFAS 157 to our financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have an impact on our financial results.

The following table presents information about our assets that are measured at fair value on a recurring basis as of December 31, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and included situations where there is little, if any, market activity for the asset:

	December 31, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$8,206,000	$8,206,000	$—	$—
Total	$8,206,000	$8,206,000	$—	$—

The fair values of cash equivalents are determined through market, observable and corroborated sources.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, other current assets, accounts payable and accrued expenses and other approximate fair value due to their short-term maturities.

4. Cash Equivalents and Marketable Securities

Cash equivalents are carried at amortized cost, which approximated fair value at December 31, 2007 and December 31, 2008. As of December 31, 2007 we were primarily invested in money market accounts and U.S. Government Agency debt securities. As of December 31, 2008, we were primarily invested in money market accounts classified as cash equivalents.

The following is a summary of available-for-sale marketable securities held by us at December 31, 2007 which are carried at fair market value. We did not hold any available-for-sale marketable securities at December 31, 2008.

	Maturity term	Fair Value	Unrealized gains	Unrealized losses	Amortized cost
December 31, 2007:					
U.S. Government Agency debt securities	Within 1 year	$810,000	$3,000	$—	$807,000
		$810,000	$3,000	$—	$807,000

Gross realized gains and losses on sales of marketable securities for the year ended December 31, 2008 were not significant.

Marketable securities that were purchased and sold in periods prior to adoption of SFAS No. 115 "Accounting for Certain Investments in Debt and Equity Securities," 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.

5. Other Assets

In January 2003, the FASB issued FIN 46 and, in December 2003, the FASB issued FIN 46R. FIN 46R replaces FIN 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity 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 46R establishes standards for determining under what circumstances variable interest entities should be consolidated with their primary beneficiary. We adopted FIN 46R in the first quarter of 2004 for non-special purpose entities created prior to February 1, 2003. The adoption of FIN 46R did not have an initial material effect on our financial condition or results of operations. We now evaluate all transactions and relationships with potential variable interest entities (VIEs) in accordance with FIN 46R.

Our overall methodology for evaluating transactions and relationships under FIN 46R includes the following:

- determining whether the entity is a VIE, and, if so,
- determining whether we are the primary beneficiary of the VIE.

In performing the first step, the significant factors and judgments that we consider include:

- the design of the entity, including the nature of its risks and the purpose for which the entity was created, to determine the variability that the entity was designed to create and distribute to its interest holders,

- the nature of our involvement with the entity,
- whether control of the entity results through arrangements that do not involve voting equity,
- whether there is sufficient equity investment at risk to finance the activities of the entity, and
- whether parties other than the equity holders have the obligation to absorb expected losses or the right to receive expected residual returns.

For each VIE identified, we evaluate whether we are the primary beneficiary of the VIE by considering:

- whether our variable interest absorbs the majority of the VIE's expected losses,
- whether our variable interest receives the majority of the VIE's expected residual returns, and
- whether we have the ability to make decisions that significantly affect the VIE's results and activities.

Based on our evaluation of the above factors and judgments, as of December 31, 2008, we consolidate one VIE, Colloral LLC, of which we are the primary beneficiary.

In August 2002, we entered into our joint venture with Deseret by forming Colloral LLC to manufacture, market and sell Colloral® as a dietary supplement. Our interest in Colloral LLC is greater than 50% and we actively participate in its management, but we do not have voting control of Colloral LLC. Therefore, the investment had historically been accounted for using the equity method. Upon adoption of FIN 46R our interest in Colloral LLC did not qualify as a variable interest entity and therefore we continued to account for our investment in Colloral LLC under the equity method of accounting until August 2005. In August 2005, we amended the Colloral LLC operating agreement to increase our share of distributions and allocations of profits and losses in return for our commitment to fund 100% of the costs associated with the implementation of a marketing program for The Collagen Solution. As a result of the amendments to the operating agreement, Colloral LLC is considered a variable interest entity, of which we are the primary beneficiary. We are required to consolidate Colloral LLC for financial reporting purposes in accordance with FIN 46R, effective in the third quarter of 2005. In accordance with FIN 46R, we re-evaluate the provisions of FIN 46R when triggering events arise and, to date, no events have transpired which would require deconsolidation. Certain events may arise in the future, including additional modifications to the operating agreements, which may require us to re-evaluate the joint venture under FIN 46R. Such re-evaluation may result in a conclusion that the joint venture is no longer a variable interest entity requiring consolidation.

In accordance with the amendment to the Colloral LLC operating agreement, we made additional capital contributions of $1,032,000 to Colloral LLC from 2003 through 2007. We satisfied our funding commitment in 2006 and have made no capital contributions during the year ended December 31, 2008. We may make additional contributions to Colloral LLC in the future. There can be no assurance that the sales and marketing initiatives that have been or, in the future, may be funded by our capital contributions will be successful. Accordingly, in the future we may again incur substantial losses.

At December 31, 2007 and 2008, the excess of Deseret's capital contributions over their portion of the accumulated losses is recorded as a minority interest liability in our consolidated balance sheet. To the extent Deseret's share of accumulated losses exceeds its capital contributions in the future, we would be required to recognize 100% of Colloral LLC's losses and if future earnings materialized, we would recognize 100% of Colloral LLC's net income to the extent of the Deseret losses we previously recognized.

The following table contains selected financial data for Colloral LLC. Shipping and handling costs have been classified as selling expenses. The balance sheet amounts as of December 31, 2007 and 2008 and Colloral LLC's operating results for the years then ended have been consolidated into our financial statements:

	For the year ended December 31, 2007	2008
Statement of Operations Data:		
Revenue	$114,000	$136,000
Cost of goods sold	21,000	45,000
Selling, general and administrative expense	109,000	57,000
Net income (loss)	$(16,000)	$ 34,000

	December 31, 2007	December 31, 2008
Balance Sheet Data:		
Current assets	$171,000	$219,000
Long term assets	—	—
Current liabilities	5,000	6,000
Long term liabilities	—	—

In 2000, we completed a market analysis of Colloral as a dietary 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. On April 15, 2005, we submitted a response to the FDA's letter and hope to have demonstrated that the product 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 and its licensed distributors will be unable to market the product as a dietary supplement and that the products 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, The Collagen Solution and Vital 3 will be withdrawn from the market, which would eliminate the possibility of future distributions to us from Colloral LLC.

6. 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, we entered into related technology transfer and research and development agreements with The Brigham and Women's Hospital. The technology transfer agreement provides us with all rights and interests in certain The Brigham and Women's Hospital patented technology in exchange for the issuance of the aforementioned stock and the payment of royalties under certain conditions. The research and development agreement provided for the performance of certain research activities by The Brigham and Women's Hospital on our behalf. Our agreement with The Brigham and Women's Hospital expired on June 30, 2006. Since June 30, 2004, there has been no funding provided to The Brigham and Women's Hospital under this agreement. However, we continue to evaluate new methods that may facilitate the clinical development of products based upon mucosal tolerance.

A portion of our consolidated joint venture's (Colloral LLC) manufacturing and operating expenses, including internal operating costs, are incurred by the joint venture partners on behalf of the joint venture and are then charged back to Colloral LLC. The determination of the amount of internal operating costs incurred by each joint venture partner on behalf of Colloral LLC requires judgment. As a result, the financial results of Colloral LLC may not be indicative of the results that would have occurred had the joint venture obtained all of its manufacturing and commercialization from third parties. During the years ended December 31, 2007 and 2008, the joint venture incurred costs of $24,000 and $38,000, respectively for the purchase of inventory from Deseret and costs of $11,000 and $12,000, respectively for labor and overhead incurred by Deseret on behalf of the joint venture. Revenues from a single customer, Futurebiotics, represented 13% and 20% of total revenues for the year ended December 31, 2007 and 2008, respectively.

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 its joint-venture with Deseret to manufacture, market and sell Colloral as a nutritional product. As of December 31, 2008, Fletcher Spaght had received no payment under its agreements with AutoImmune, other than $50,000 of retainer fees.

7. 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, 2007	2008
Income tax benefit (expense):		
Federal	$ 153,000	$ 228,000
State	(10,000)	(4,000)
	143,000	224,000
Increase (decrease) in deferred tax asset valuation allowance	(143,000)	(224,000)
	$ —	$ —

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 2007 and 2008 to pre-tax loss is as follows:

	Year ended December 31, 2007	2008
(Provision) benefit at statutory rate	$ 41,000	$ 121,000
Permanent items	44,000	77,000
Expiration of federal and state research and development, orphan drug and investment tax credits and federal and state net operating loss carryforwards	(234,000)	(439,000)
State tax benefit (provision), net of federal tax liability	6,000	29,000
Other items	—	(12,000)
	(143,000)	(224,000)
(Increase) decrease in valuation allowance	143,000	224,000
	$ —	$ —

Deferred tax assets are comprised of the following:

	December 31, 2007	2008
Research costs capitalized for tax purposes	$ 25,662,000	$ 25,731,000
Research and development, orphan drug and investment tax credits	10,526,000	10,103,000
Loss carryforwards	13,327,000	13,471,000
Other temporary differences	112,000	97,000
Gross deferred tax assets	49,627,000	49,402,000
Deferred tax asset valuation allowance	(49,627,000)	(49,402,000)
	$ —	$ —

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. If we achieve profitability, these deferred tax assets, portions of which are subject to annual limitations, may be available to offset future income tax liabilities and expenses. Of the $49,402,000 valuation allowance at December 31, 2008, $965,000 relating to deductions for stock option compensation will be credited to additional paid-in capital upon realization.

At December 31, 2008, AutoImmune has federal and state net operating loss carryforwards of $38,221,000 and $1,884,000 respectively, which began to expire in 2003. AutoImmune also has federal and state credit carryforwards of $9,380,000 and $1,113,000 respectively, which began to expire in 2003.

At January 1, 2007, we had net operating loss, or NOL, carryforwards and Research and Development, or R&D, credit carryforwards. Utilization of the NOL and R&D credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), as well as similar state and foreign provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and

R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since our formation, we have raised capital through the issuance of capital stock which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in an ownership change or could result in an ownership change in the future upon subsequent disposition. We have not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since our formation, due to the significant complexity and cost associated with such study. There also could be additional ownership changes in the future. If we have experienced an ownership change at any time since our formation, utilization of our NOL or R&D credit carryforwards will be subject to an annual limitation under Section 382, which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

We have elected to recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2008, we have not accrued any interest or penalties related to uncertain tax positions.

We conduct business in the United States. We are subject to examination in the normal course of business by taxing authorities in this jurisdiction. As of December 31, 2008, no examinations related to income taxes have occurred. The tax years 2004-2007 remain open to examination by the taxing jurisdictions to which we are subject.

8. 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, 2008, 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.

9. 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, 2008, we have reserved 1,580,000 shares of common stock for use in our stock option plan. Our employee stock purchase plan was terminated in May 2008.

10. Stock Option and Employee Stock Purchase Plans

1988 Stock Option Plan

Our 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. At December 31, 2007, options to purchase 34,000 shares of common stock were outstanding. At December 31, 2008, all options to purchase shares of common stock under the 1988 Stock Option Plan had expired.

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

1998 Stock Option Plan

Our 1998 Stock Option Plan, adopted by our shareholders on May 28, 1998, provided 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 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 our common stock reserved for issuance in accordance with the terms of the 1998 Stock Option Plan was 1,300,000. At December 31, 2008, options to purchase 953,000 shares of common stock were outstanding.

The 1998 Stock Option Plan expired on February 3, 2008. No options were issued under the plan in 2008.

2008 Stock Option Plan

Our 2008 Stock Option Plan, adopted by our shareholders on May 15, 2008, provides 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 is responsible for the administration of the 2008 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 2008 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 2008 Stock Option Plan is 327,000, of which 281,500 were available for grant at December 31, 2008. At December 31, 2008, options to purchase 45,500 shares of common stock were outstanding.

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. As of December 31, 2008, options to purchase 377,000 shares of common stock have been granted under the Director Option Plan. Options to purchase 164,000 shares of common stock have been cancelled. At December 31, 2008, options to purchase 213,000 shares of common stock were 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.

The following table summarizes information about stock options outstanding at December 31, 2007 and 2008. All stock options as of December 31, 2008 or are expected to vest.

	Year Ended			
	December 31, 2007		December 31, 2008	
	Shares	Weighted average exercise price	Shares	Weighted average exercise price
Outstanding at beginning of period	1,273,500	$1.17	1,221,000	$1.11
Granted	264,750	$1.38	65,000	$1.80
Exercised	(60,000)	$0.53	(20,000)	$0.53
Cancelled	(257,250)	$1.82	(54,500)	$2.84
Outstanding at end of period	1,221,000	$1.11	1,211,500	$1.06
Options exercisable at end of period	863,188	$1.01	900,688	$0.93
Weighted average grant date fair value of options granted		$0.84		$1.07

At December 31, 2008, stock options were outstanding and exercisable as follows:

	Outstanding			Exercisable	
Range of Exercise Price	**Number**	**Weighted average remaining contractual life**	**Weighted average exercise price**	**Number**	**Weighted average exercise price**
$0.52	500,000	3.5 years	$0.52	500,000	$0.52
$0.79—$1.80	612,500	7.2 years	$1.25	301,688	$1.08
$2.03—$ 2.50	76,500	0.1 years	$2.30	76,500	$2.30
$3.06—$3.60	22,500	2.4 years	$3.53	22,500	$3.53
	1,211,500	5.12 years		900,688	

Weighted average remaining contractual life of exercisable options 4.0 years.

Employee Stock Purchase Plan
On July 20, 1994, our Board of Directors approved the 1994 Employee Stock Purchase Plan (the "Purchase Plan"). This plan enabled eligible employees to purchase our common stock at 85% of the fair market value of the stock. During 2007 and 2008, no shares were purchased under the Purchase Plan. On May 15, 2008, our Board of Directors voted to terminate the Purchase Plan.

11. Warrant redemption

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. In connection with the agreement, Elan Plc received a warrant to purchase 375,000 shares of our common stock at $3.13 per share in September 2001 and a warrant to purchase 375,000 shares of our common stock at $0.7275 per share in March 2003. The warrant to purchase 375,000 shares of our common stock at $3.13 per share expired effective September 16, 2006. On February 27, 2008, we entered into a securities redemption agreement to repurchase the warrant to purchase 375,000 shares of our common stock at $0.7275 from Elan Plc for $125,000 which was recorded as a reduction of additional paid in capital.

12. Accumulated Other Comprehensive Loss

The components of comprehensive loss consisted of the following:

	For the year ended December 31,	
	2007	**2008**
Net income (loss)	$(118,000)	$(345,000)
Change in unrealized gain (loss) on investments	3,000	(3,000)
Comprehensive income (loss)	$(115,000)	$(348,000)

13. Commitments and Contingencies

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. On March 20, 2006, Teva disclosed in a 20-F filing that it would not continue development of the enteric coated oral formulation of Copaxone and was considering future development of non-parenteral formulations of the product. As of December 31, 2008, Teva's website disclosed that new and potentially improved formulations of an oral version of Copaxone® are in preclinical development. It is unclear whether these new formulations involve intellectual property licensed by us to Teva. If Teva were to develop a product using intellectual property licensed by us and the product were approved for sale, we would receive a milestone payment 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 our common stock at $3.13 per share in September 2001 and a warrant to purchase 375,000 shares of our 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. The warrant to purchase 375,000 shares of our Common Stock at $3.13 per share expired effective September 16, 2006. The warrant to purchase 375,000 shares of our common stock at $0.7275 per share was due to expire on March 17, 2008. On February 27, 2008, we entered into an agreement to repurchase the warrant from Elan Plc for $125,000. Furthermore, under the terms of this agreement, we 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, we are 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 increased by $30,000 each year until they reached 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 December 2007, BioMS signed a licensing and development agreement with Eli Lilly & Company granting Eli Lilly exclusive worldwide rights to MBP8298. If the trials are 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.

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 dietary supplement and a non-exclusive license in certain of our information, data and knowledge needed to manufacture and sell Colloral as a dietary supplement. 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. In August 2005, we amended the Colloral LLC operating agreement to increase our share of distributions and allocations of profits and losses in return for our commitment to fund 100% of the costs associated with the implementation of a marketing program. Commencing in the third quarter of 2005, we began consolidating Colloral LLC under FIN 46.

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 de minimus.

Leases
We have limited operations utilizing the personal office spaces of the President and the Director of Finance, and our consolidated joint venture, Colloral LLC, outsources all of its operations. As a result, at December 31, 2008, we had no lease obligations and no future minimum lease commitments.

14. Quarterly Results (Unaudited)

The following table sets forth unaudited selected financial information for the periods indicated. This information has been derived from unaudited financial statements, which, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of such information. 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
2007				
Total revenue	$ 97,000	$ 63,000	$ 59,000	$ 75,000
Total expenses	224,000	244,000	179,000	231,000
Net income (loss)	8,000	(62,000)	(8,000)	(56,000)
Income (loss) per share—basic and diluted	$ 0.00	$ (0.00)	$ (0.00)	$ (0.00)
2008				
Total revenue	$ 67,000	$101,000	$ 57,000	$ 91,000
Total expenses	259,000	245,000	129,000	233,000
Net income (loss)	(107,000)	(86,000)	(23,000)	(129,000)
Income (loss) per share—basic and diluted	$ (0.01)	$ (0.01)	$ (0.00)	$ (0.01)

Price Range of Common Stock and Dividend Policy

Since May 26, 2004, our common stock has been listed on the OTC Bulletin Board and, for a period in 2008, the Pink Sheets under the symbol AIMM. The following table shows the quarterly high and low sales price on the OTC Bulletin Board and the Pink Sheets for a share of our common stock (based on intra-day trading) for the fiscal years ended December 31, 2007 and 2008. The high and low bid information was obtained from NASDAQ.com. The market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not represent actual transactions.

	Price range of Common Stock	
	High	Low
Fiscal year ending December 31, 2007		
First quarter	$1.26	$1.14
Second quarter	1.55	1.22
Third quarter	1.50	1.31
Fourth quarter	1.75	1.34
Fiscal year ending December 31, 2008		
First quarter	$1.97	$0.58
Second quarter	2.28	1.70
Third quarter	2.10	1.31
Fourth quarter	1.42	0.50

As of March 23, 2009, there were 171 record holders and approximately 2,450 total shareholders of the AutoImmune's common stock.

AutoImmune has never declared or paid any cash dividends on its capital stock. AutoImmune 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, Colorado 80401

Independent Accountants

PricewaterhouseCoopers LLP
Boston, Massachusetts

General Counsel

Nutter, McClennen & Fish, LLP
Boston, Massachusetts

Stock Exchange

OTC Bulletin Board
Symbol: AIMM

Investor Information

Additional copies of the 2008 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, California 91103

Annual Meeting

The Annual Meeting of Shareholders will be held on Friday, May 22, 2009, at 11:00 a.m. EDT, at the offices of Nutter, McClennen & Fish, 155 Seaport Blvd. in Boston, Massachusetts.

Corporate Directory

Corporate Mailing Address

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

Executive Officers

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

Diane M. McClintock
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
Retired

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

Secretary

Michelle Basil, Esq.
Partner
Nutter, McClennen & Fish, LLP

This Annual Report contains forward-looking statements which involve risks and uncertainties. AutoImmunes'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 trial results and product development, AutoImmunes's dependence on third parties for licensing and other revenue, AutoImmunes's dependence on determinations of regulatory authorities and the risks of technological change and competition. These factors are more fully discussed in AutoImmunes's most recent Annual Report on Form 10-K included herein.

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