



# FORM 10-K

## IMMUNE RESPONSE CORP – IMNR

**Filed: March 28, 2006 (period: December 31, 2005)**

Annual report which provides a comprehensive overview of the company for the past year

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

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

For the year ended December 31, 2005

OR

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

Commission file number 0-18006

**THE IMMUNE RESPONSE CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

33-0255679

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

5931 Darwin Court  
Carlsbad, California

(Address of principal executive offices)

92008

(Zip Code)

Registrant's telephone number, including area code: (760) 431-7080

Securities registered pursuant to Section 12(b) of the Exchange Act: None

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

Common Stock  
Class B Warrants

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 Exchange 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 or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

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 common stock held by non-affiliates of the registrant, based on the closing sale price as reported by the Nasdaq Stock Market as of June 30, 2005, was approximately \$26,831,000.

As of March 9, 2006 there were 155,705,156 shares of our common stock outstanding.



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## PART I

### **Item 1. BUSINESS**

*This report contains forward-looking statements. Such forward-looking statements can be identified by use of forward-looking terminology such as “believes,” “expects,” “may,” “intends,” “will,” “should” or “anticipates,” or the negative thereof or other variations thereon or comparable terminology, or by discussions of plans or strategy. Although we believe these statements are based upon reasonable assumptions, no assurance can be given that the future results covered by the forward-looking statements will be achieved. Forward-looking statements are subject to risks, uncertainties and other factors that are or may be outside of our control or that are not presently known to us and that could cause actual results to differ materially from future results expressed or implied by the forward-looking statements. Some key risks, uncertainties and other factors are discussed under the heading “Risk Factors”. Further, any forward-looking statement speaks only as of the date it was made; and, subject to applicable law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, could cause actual results to differ materially from those contained in any forward-looking statement.*

### **GENERAL**

The Immune Response Corporation (OTCBB: IMNR.OB) is an immuno-pharmaceutical company focused on developing products to treat autoimmune and infectious diseases. Our lead immune-based therapeutic product candidates are NeuroVax™ for the treatment of multiple sclerosis (MS) and IR103 for the treatment of Human Immunodeficiency Virus (HIV). Both of these therapies are in Phase II clinical development and are designed to stimulate pathogen-specific immune responses aimed at slowing or halting the rate of disease progression.

NeuroVax™, which is based on our patented T-cell receptor (TCR) peptide technology, has shown potential clinical value in the treatment of relapsing forms of MS. NeuroVax™ has been shown to stimulate strong disease specific cell mediated immunity in nearly all patients treated by enhancing levels of FOXP3+ T Regulatory (Treg) cells that are able to down regulate the activity of pathogenic T-cells that cause MS. Increasing scientific findings have associated diminished levels of FOXP3+ Treg cell responses with the pathogenesis and progression of MS and other autoimmune diseases such as rheumatoid arthritis (RA), psoriasis and Crohn’s disease. In addition to MS, we have open Investigational New Drug Applications (IND) with the U.S. Food and Drug Administration (FDA) for clinical evaluation of TCR peptide-based immune-based therapies for RA and psoriasis.

IR103 is based on our patented whole-inactivated virus technology, co-invented by Dr. Jonas Salk and indicated to be safe and immunogenic in extensive clinical studies of, our first-generation HIV product candidate. IR103 is a more potent formulation that combines its whole-inactivated antigen with a synthetic Toll-like receptor (TLR-9) agonist to create enhanced HIV-specific immune responses. We are currently testing IR103 in two Phase II clinical studies as a first-line treatment for drug-naïve HIV-infected individuals not yet eligible for antiretroviral therapy according to current medical guidelines.

In early 2006 we made a strategic decision to accelerate the development of IR103, rather than pursue a Phase III trial with Remune®. All of our products are still in the development stage. We have never had revenues from the sale of products. We were founded in 1986.

### **MULTIPLE SCLEROSIS**

#### *Overview*

MS is an autoimmune disease in which the immune system, the body’s principal defense against foreign substances such as bacteria, mistakenly attacks normal tissues of the central nervous system (CNS). It afflicts approximately 400,000 people in the United States and more than 2.5 million worldwide. Specifically, the disease in its early stages of relapsing-remitting disease (RRMS) is characterized by patients experiencing sudden onset of exacerbations (relapses) that remit within a few weeks only to occur again at unpredicted times in the future. This phase of the disease often lasts for many years, after which the disease evolves into the progressive forms of MS, with fewer relapses but more overt signs of disability resulting from irreversible damage to the fatty tissue called myelin that surrounds and protects nerve fibers. The ensuing destruction of these neuronal cells

creates scarring (sclerosis) and interferes with the normal transmission of nerve impulses. This, in turn, leads to a variety of highly individualized and unpredictable neurological symptoms, ranging from movement and balance problems to vision impairment. It is believed that a subset of the specific class of white blood cells, CD4+ T-cells, that normally plays an important role in the immune system, becomes autoreactive inflammatory T-cells causing inflammation within the central nervous system that is principally responsible for the relapses and initiation of the neurodegeneration and progression of the disease.

### *Current Treatment Options*

There are currently several approved therapeutic classes for the treatment of MS; interferons (Avonex, Rebif, Betaseron and Betaferon), glatiramer acetate (Copaxone) and a recently approved monoclonal antibody that recognize a specific receptor involved with transport of cells across the blood/brain barrier. These treatments have been shown to reduce annual relapse rates and MRI activity (used to measure the size and number of new brain lesions) in about half of all patients treated. If the patients showing responses continue to be treated over a long period of time, these products can delay conversion of the disease into the progressive forms of MS, characterized by the irreversible neurodegeneration that leads to clinical disabilities. These treatments for RRMS patients, which are effective in only about 50% of patients treated, are also associated with significant toxicity, often causing patients to delay therapy for significant lengths of time. Research indicates that MS patients have abnormalities in FOXP3+ message and protein expression levels in peripheral Treg cells. This observation is the first to link a defect in functional peripheral immunoregulation to an established genetic marker, FOXP3+, previously shown to be involved in maintaining immune tolerance and preventing development of autoimmune diseases.

### **NeuroVax™**

NeuroVax™ is a novel, proprietary immune-based therapy designed to induce the body's own defense system to combat the pathogenic T-cells known to be the primary cause of MS. Short TCR peptides with amino acid sequences mimicking sequences on the surface of the pathogenic T-cells within the central nervous system have been shown in animals to induce immune responses that can cure MS-like disease. The mechanism of action appears to be the induction of regulatory T-cells capable of down regulating the pathogenic T-cells causing the disease. NeuroVax™, containing an adjuvant and a combination of three TCR peptides selected to represent the pathogenic T-cells in about 90% of MS patients, has been shown in clinical trials (see below) to stimulate disease-specific immune cells in essentially all treated patients; a significant percentage of which are regulatory T-cells capable of suppressing autoreactive CD4+ T-cells. NeuroVax™ was designed with the goal of increasing the likelihood of producing disease-specific immune responses capable of controlling the activity of these pathogenic T-cells similar to their control in healthy individuals. Due to its unique mechanism of action, we believe that our TCR peptide vaccine, NeuroVax™, will be a valuable addition to the current therapies for MS, both as a stand alone product and in combination with existing therapies.

### *Clinical Trials History*

Based on results from earlier Phase I clinical trials with single peptides in two different formulations, a 60 patient, Phase I/II clinical trial with the three selected peptides was initiated in November 2000 to evaluate which of the two potential formulations was best for NeuroVax™ in terms of inducing disease-specific immunity. Participants in the Phase I/II clinical trial received monthly injections of either NeuroVax™ or one of two controls over 24 weeks. The placebo controlled blinded trial was designed to monitor safety and to compare immunological responses elicited by the two formulations. The trial had an immunological endpoint and a study period sufficient to monitor these responses. Although the trial was too short to expect to see clinical benefits, a subset of patients was also tracked by MRI analyses; and all patients were monitored for changes in their Expanded Disability Status Scale (EDSS) scores. An interim analysis conducted in February 2002 of data from the first 20 patients enrolled confirmed that the primary immunological endpoint had been met. Patients receiving NeuroVax™ demonstrated a high, statistically significant response compared to the group receiving the same peptides in saline or to the group receiving incomplete Freund's adjuvant (IFA) alone. The primary immunological endpoint was the percentage of patients responding immunologically to the individual peptides as determined using a limiting dilution assay. A total of 37 patients were subsequently evaluated. The results were favorable indicating that 15 out of the 16 IFA peptide treated patients responded immunologically compared to 1 out of the 15 saline peptide treated patients and 0 out of 6 for the IFA alone treated patients. In addition, MRI analyses showed a positive trend suggestive of clinical benefit in that immune responsive patients had fewer new lesions compared to patients who showed no immune responses.

Based on these immunological findings, a 40-patient open label Phase II study was initiated in 2003 to allow patients previously enrolled in the blinded trial above to receive NeuroVax™. These studies were performed at Oregon Health and Science



University (OHSU) in conjunction with the Immune Tolerance Network. The fully-enrolled study was completed at the end of 2005. NeuroVax™ induced strong immune responses in essentially all treated patients.

Results reported during 2005 from a completed Phase I/II study showed that NeuroVax™ restored normal levels of FOXP3+ Treg cells in patients who, at baseline, had statistically significant diminished levels of FOXP3+ Treg cells compared to healthy controls. After 24 weeks, the patients treated with NeuroVax™ who completed the trial showed stimulation of their FOXP3+ Treg cells to levels well above their suppressed baseline levels, and often to levels higher than healthy controls. These elevated levels of FOXP3+ Treg cells activity remained stable through the complete 52 week study. These new data indicate a novel, specific mechanism of action for NeuroVax™ that could restore regulatory functions of the immune system in MS patients that are critical to controlling the pathogenesis of the disease. Although we believe that these earlier clinical trial results are significant, we will need to conduct larger blinded trials to confirm the safety and efficacy of NeuroVax™.

We are currently planning additional Phase II studies of NeuroVax™ to test the clinical benefits of the product. One such study will be conducted primarily in Eastern Europe and will include an evaluation of clinical endpoints including MRI and relapse rate. We also have FDA approval to initiate a second 40-patient trial that will enroll new RRMS patients along with patients previously treated with NeuroVax™. The endpoints of this second trial are immunological in nature, and are designed to yield more direct data on FOXP3+ Treg cells as well as to evaluate different timings for NeuroVax™ administration.

Further, we hold IND applications on similar TCR peptide-based therapies targeted at rheumatoid arthritis and psoriasis, two other autoimmune diseases in which the same mechanism of action may be therapeutic. We may seek to develop or out-license these products, depending upon the availability of resources.

## **HUMAN IMMUNODEFICIENCY VIRUS**

### *Overview*

HIV is the virus that causes acquired immunodeficiency syndrome (AIDS), a condition that slowly destroys the body's immune system and makes the body vulnerable to infections. HIV was first recognized in 1981 and AIDS is now the fourth leading cause of death worldwide. To date there is no known cure. An enormous amount of resources and effort have been invested over the past two decades into the research and development of therapies to slow the progression of HIV/AIDS and in search of a cure.

This disease remains a significant and growing worldwide health concern. Recent studies show that the infection rate is on the rise. According to recent estimates, nearly one million people in the United States are infected with HIV, of which approximately 25% remain unaware of their infection. U.S. mortality rates from AIDS have dropped dramatically as a result of antiretroviral therapy; however, there is concern that these trends will reverse in coming years due to the long-term toxicities associated with drug treatment and the increasing failure of drug therapy due to viral resistance.

### *HIV's Effects on the Body*

The immune system is the body's natural defense mechanism designed to prevent and combat disease. There are two major arms of the human immune system: (1) the T-cell-based or cell-mediated arm, and (2) the B-cell or antibody-based arm, also known as humoral immunity. There are two main types of T-cells — helper T-cells and killer T-cells. Helper T-cells, also known as CD4+ cells, are specialized white blood cells that identify specific pathogens that have invaded body cells and stimulate other immune system forces to attack. Killer T-cells (CTL, mainly CD8 T-cells) work directly to destroy cells within the body that have become infected.

A cell-mediated immune response begins when the immune system recognizes foreign invaders, such as viruses or bacteria within the body. Helper T-cells dispatch killer T-cells to seek and destroy the cells that have been infected by foreign invaders. This response, however, is not always sufficient to eradicate disease since certain diseases can produce substances that suppress the immune response, thus making it important in these cases to provide assistance to the immune system.

HIV is a retrovirus that spreads throughout the body by invading host cells and using the host cells' protein synthesis capability to replicate. The immune system responds by producing antibody and cellular immune responses capable of attacking HIV. While these and other responses are usually sufficient to temporarily arrest progress of the infection and reduce levels of the virus, the virus continues to replicate and slowly destroy the immune system by infecting and killing critical helper CD4+ T-cells. As the

infection progresses and the amount of virus circulating in the body increases, the immune system's control of HIV weakens and the level of T-cells declines steadily to a small fraction of its normal level.

A major reason for the virus-induced destruction of the immune system is that activated CD4+ T-cells themselves are the major cell type infected and subsequently destroyed by the virus. Once HIV enters the body, it binds to and fuses with CD4+ T-cells and the replication process begins. Replication is how HIV makes copies of itself and multiplies. In order to replicate, an HIV particle must transfer its genetic blueprint, which is in the form of ribonucleic acid (RNA), into the genes of the host CD4+ T-cell. Upon accomplishing this task, the virus then reprograms the CD4+ T-cell into a virus-making machine that produces a large number of new infective virions before death of the infected cell. This process repeats itself continuously, and after repeated assaults by viral particles, the CD4+ host cells die. As the number of CD4+ cells decreases, the immune system loses its ability to fight life-threatening infections.

A healthy, uninfected person typically has 800 to 1,200 CD4+ T-cells per cubic millimeter (mm<sup>3</sup>) of blood. During HIV infection, the number of these cells in a person's blood progressively declines. When a person's CD4+ T-cell count falls below 200/mm<sup>3</sup>, he or she becomes particularly vulnerable to the opportunistic infections and cancers that typify AIDS, the end stage of HIV disease. Specifically, people with AIDS often suffer infections of the lungs, intestinal tract, brain, eyes, and other organs, as well as debilitating weight loss, diarrhea, neurological conditions, and cancers such as Kaposi's sarcoma and certain types of lymphomas.

Many scientists believe that HIV causes AIDS by directly inducing the death of CD4+ T-cells or by interfering with their normal function and by triggering other events that weaken a person's immune function. For example, the network of signaling molecules that normally regulate a person's immune response is disrupted during HIV, impairing a person's ability to fight other infections. The HIV-mediated destruction of the lymph nodes and related immunologic organs also plays a major role in causing the immunosuppression.

### *Current Treatment Options*

When HIV first appeared in the United States, there were no FDA approved drugs available to treat the direct effects of the virus, although a select few treatments were available for some of the diseases to which the body was made susceptible by this virus. In 1987, the first antiretroviral drug, known as Zidovudine or AZT, was made commercially available. Since that time, 23 additional antiretroviral drugs in five classes have been developed and commercially approved.

AZT is a nucleoside reverse transcriptase inhibitor (NRTI) that blocks HIV's ability to transcribe or write its own RNA into the DNA needed to reprogram human cells to produce more HIV. Five other NRTI's are also available for HIV treatment. Two other classes of AIDS drugs, non-nucleoside reverse transcriptase inhibitors (NNRTI's) and nucleotide reverse transcriptase inhibitors (NtRTI's), have a similar effect on blocking the reverse transcription process using a different mechanism of action. Protease inhibitors (PI's) and fusion inhibitors inhibit different aspects of HIV's replication cycle. All of these drugs, which are primarily used in combination to maximize their antiretroviral effect, significantly reduce the amount of HIV in a person's body, called the viral load.

While there are an increasing number of options available for the treatment of HIV/AIDS, medical science is far from being able to conquer the virus. The difficulty in treating or preventing HIV is that HIV, being an RNA virus, has a high rate of mutation. Scientists have classified HIV into at least 10 broad subtypes, and within those subtypes, there are many strains.

### *Limitations of Existing Therapies*

When antiretroviral drugs were first introduced in the early 1990s, it was believed that combination highly active antiretroviral therapies (HAART) could constitute a means to fully control HIV. With as many as 140 different approved variations of HAART, this type of treatment had been heralded as capable of lowering virus level to be essentially undetectable in some patients—a great stride in the pharmacological treatment of HIV. Unfortunately, new clinical knowledge about HAART and other antiretroviral treatment strategies has proven that complete control of HIV over time using antiretroviral drugs is unlikely and has underscored several additional drawbacks of drug therapy. These limitations leave a significant void in the arsenal for treating those infected with the virus. A key drawback is that no current therapies enable immune reconstitution in infected individuals. Other limitations include extreme toxicity, resistance, and strict compliance requirements, which are described below.

*High cost of treatment* — While the cost of antiretroviral therapy has dropped dramatically with respect to developing nations in recent years, treatment remains extremely expensive in developed nations like the United States and continues to be prohibitively expensive to be made widely available to patients in developing nations. Less than 5% of people infected with HIV worldwide currently have access to therapy. In the United States, the cost of combination therapy can be greater than \$20,000 per year. The total cost of treating an advanced AIDS patient in a hospital may exceed \$100,000 per year.

*Significant toxicity* — Simply stated, existing antiretroviral drugs given over a long period of time are toxic. As they circulate in the body, they cause harm to healthy cells and induce side effects ranging from fatigue, nausea, vomiting, abdominal pain, and diarrhea, to liver damage and pancreatic problems, low red and white blood cell counts, muscle pain, and wasting. More recently, significant metabolic abnormalities have also been described.

*Strict compliance requirements* — Antiretroviral drugs require strict, frequent, and complicated treatment regimes that often are difficult to comply with. Furthermore, some antiretroviral therapies require a patient to take more than 30 pills daily. Compliance failures decrease efficacy and lead to the emergence of drug-resistant strains of the virus.

*Drug resistance* — The rapid proliferation of HIV inside the body (often billions of virions per day) and its high rate of mutation makes its replication process highly susceptible to change and mutation. Often, one or more of these mutations allow the virus to develop a resistance to antiretroviral drugs' mechanism of action. In other words, as a result of random chance and natural selection, some copies of the virus emerge that are resistant to a drug. In fact, in the United States, where HAART has been available since approximately 1996, almost 80% of those who have been on HAART for more than two years have resistant strains of virus. Furthermore, HIV drug resistant strains are now being discovered in over 20% of newly infected individuals. To date, all drug candidates over time have resulted in the development of or have otherwise experienced resistant strains.

Drug resistance means that a virus can adapt, grow, and multiply in the presence of drugs designed to kill it. HIV is considered to be resistant when a drug or class of drugs is no longer effective against it. Though drug resistance commonly occurs in individuals taking ART, resistant strains of HIV can also be transmitted from one person to another. As a result, it is possible for someone newly diagnosed and not yet on antiretroviral treatment to be infected with a virus that is resistant to one or more of the drugs used in HIV therapy.

Each person's HIV is made up of different types or strains of the virus. Drug resistance develops because HIV replicates very quickly — at a rate of over a billion new copies each day in infected people — and cannot correct mistakes made during the replication process. These mistakes, or mutations, cause some viral strains to become weaker, while other strains become stronger and less susceptible to ART.

If the virus develops resistance, the drug-resistant form multiplies and becomes the dominant strain within the body, reducing the effectiveness of an individual's treatment. According to the National Intelligence Council report, "HIV strains have an amazing ability to recombine to form mosaic viruses. This pace of genetic change forces changes in treatment regimens and has placed unprecedented pressure on the pharmaceutical industry to develop new drugs for continued viral control."

### *Current Treatment Guidelines*

Due to the limitations and chronic use of antiretroviral drug therapies, the Department of Health and Human Services (DHHS) issued guidelines in February 2002, and revised them in October 2004, suggesting that these therapies should be started later in the disease stage. The guidelines were developed by the Panel on Clinical Practices for the Treatment of the Human Immunodeficiency Virus (HIV) Infection, a joint effort of the DHHS and the Henry J. Kaiser Family Foundation. The new guidelines recommend starting antiretroviral therapy when an asymptomatic HIV-infected person's CD4+ T-cell count falls below 350 cells/mm<sup>3</sup>; previous guidelines recommended consideration of therapy for asymptomatic patients with a CD4+ T-cell count lower than 500 cells/mm<sup>3</sup>. Similar guidelines were issued by the British HIV Association (2003 BHIV Association Guidelines), which recommend that treatment of asymptomatic patients should be initiated when the CD4+ count is between 200 and 350 cells/mm<sup>3</sup>.

For asymptomatic HIV-infected patients with CD4+ T-cell counts higher than 350 cells/mm<sup>3</sup>, treatment should be considered when the level of HIV in plasma is high, more than 100,000 copies/ml when using the RT-PCR test. The guidelines continue to recommend antiretroviral therapy for all patients with acute HIV syndrome, those within six months of HIV seroconversion, and

all patients with symptoms ascribed to HIV infection. Thus, a need exists for therapies that would be beneficial to not only extend but also complement existing HIV treatments and to work through different mechanisms of action. (REF: October 29, 2004 report from DHHS)

### *Immune-Based Therapies*

The rapid emergence of HIV drug resistance, the substantial toxicity associated with antiretroviral therapy and the prohibitive costs of providing HAART to the vast majority of HIV infected individuals have created an urgent need for sustainable treatment options for HIV. A growing number of clinical and scientific experts are now promoting the aggressive development of immune-based therapies to complement the existing HIV treatment arsenal. In the history of medicine, no chemical drug has ever permanently eliminated viral infection from the human body. However, the human immune system has worked effectively at protecting humans from a variety of deadly viruses. Despite efforts to come up with a solution to either treat or effectively manage and control the HIV pandemic, there are still millions of infected people around the world who await the next generation of treatments. To this dilemma, the answer could be the human immune system. This involves stimulating the human immune system against HIV so that the body itself can better fight this battle. The key to enabling the immune system to effectively combat HIV could be immune-based therapies and therapeutic vaccines.

Stimulating the immune system to prevent infectious disease has been successfully accomplished using prophylactic/preventive vaccines. The remarkable success of these vaccines has been effective in eliminating many diseases, including the global eradication of smallpox and the virtual extinction of polio worldwide (full eradication is expected for polio within this decade). In fact, the development of the polio vaccine by Dr. Jonas Salk is regarded as one of the most significant public health achievements of the 20th century.

### *Therapeutic Vaccination*

Pharmaceutical researchers have concentrated primarily on finding antiretroviral drugs that prevent HIV from replicating within the body. Others have attempted to find ways to help a person's immune system control the virus on its own. These treatments, termed immune-based therapies or IBT's, are being studied in clinical trials for their ability to extend as well as complement the HIV treatment arsenal by fighting the virus using a different and powerful mechanism of action: stimulating the human immune system.

The concept for an immune-based approach to the treatment of HIV was first proposed by Dr. Salk in a paper published in *Nature* in 1987 wherein he wrote, "The long incubation period between infection and the development of clinical acquired immunodeficiency syndrome (AIDS) may be due to an immune response to the initial infection which persists with health and wanes with disease." Since individuals infected with HIV often live for seven to 10 years after becoming infected, Dr. Salk believed there must be some immune reaction serving to keep these people healthy. This is in contrast to most viral infections where the individual usually exhibits symptoms of the disease soon after infection.

Therefore, Dr. Salk hypothesized that if this natural level of protection could be amplified in a manner to keep the circulating virus below some critical level, then it might be possible to sustain the life of an infected person through a post-infection vaccine approach far longer than without such intervention.

Evidence for the key role of the immune system in fighting HIV has since been seen in the existence of a small subset of infected people, called long-term nonprogressors, who have lived for up to 20 years without disease progression. These individuals have maintained viral loads below the guidelines and often even below the limit of detection. This small number of patients demonstrates that it is possible, in some cases, to successfully contain the virus without the need for antiretroviral drugs. Investigation of these cases has revealed the presence of vigorous HIV-specific helper T-cell responses, which are inversely correlated with viral load, suggesting that the stimulation of such responses would be a critical goal of a therapeutic vaccine.

### *Therapeutic Vaccines Versus Preventive Vaccines*

While preventive vaccines are used to prime a person's immune system before a possible infection occurs, therapeutic vaccines attempt to boost a person's immune system's ability to fight a virus after it has been infected. Dr. Salk's proposed solution was to essentially fool the immune system into thinking it was being attacked by HIV by presenting the virus in a manner that could not

infect or destroy the immune cells, using an inactivated version of HIV. This, he felt, would allow the body to create and maintain a memory of the core proteins making up the virus and to more effectively mount a sustained attack against HIV-infected cells.

### **IR103**

IR103 is our second-generation HIV immunotherapy. It is based on our patented whole-inactivated virus technology, which was indicated to be safe and immunogenic in extensive clinical studies of Remune®, our first-generation HIV product candidate. Preclinical research and recent clinical data show that IR103 is a more potent formulation that combines its whole-inactivated antigen with a synthetic Toll-like receptor (TLR-9) agonist to create enhanced HIV-specific immune responses. This product differs from currently available antiretroviral drug therapies since it is designed to stimulate an HIV-infected individual's immune system to fight the virus.

We recently completed the first part of a 49-patient Phase I/II five-arm, randomized, single-blind, controlled, multi-center clinical study of safety and bioactivity of IR103 in HIV patients on HAART at sites in the United Kingdom and Canada, and plan to report new data as it becomes available in 2006. Preliminary results of this trial, reported in 2005, indicate that IR103 is safe, induces HIV-specific immune responses and greatly enhances IFN-gamma and RANTES mRNA. IFN-gamma and RANTES are considered immune system markers that give an estimate of the robustness of the immune response generated by IR103 in patients.

The second part of this study along with another similar study in Italy will test IR103 as a first-line treatment for drug-naïve HIV-infected individuals not yet eligible for antiretroviral therapy according to current medical guidelines. These studies, which we plan to expand, will ultimately enroll over 200 drug-naïve patients. Along with tracking safety and measuring HIV-specific immune responses, these studies will assess IR103's ability to affect patients' CD4+ counts. CD4+ count is a critical marker of HIV disease progression that is used, along with viral load, to determine when a patient should begin antiretroviral therapy. We believe an immune-based therapy that could stabilize CD4+ counts could be used to delay the initiation of antiretroviral therapy and serve as an important advance in the treatment of HIV. Final data from a 51 drug-naïve patient Phase II Italian study of Remune®, reported in 2005, showed that median absolute CD4+ cell counts of patients that received 3 injections of our first-generation immunotherapy remained stable through week 28, while they declined in patients in the placebo groups. We believe that increased potency of IR103 could translate to a more durable and pronounced effect on CD4+ counts.

In past years, others have attempted to develop immune-based therapies for HIV infection. Most of these therapies were based on the viral envelope glycoprotein gp120 located on the outside of the virus. None of these therapies have proven effective, which may have been due to mutations in the viral envelope. IR103 is based on the core proteins of the virus, which are consistent across multiple strains of HIV. HIV-1 continues to evolve and mutate, and as a result, different strains, or clades, of HIV-1 have emerged worldwide. This creates a moving target for single protein immunogens that are being developed that are clade-specific. Because IR103 is a whole virus originating from a multi-clade virion and contains the core proteins that are more genetically conserved, we postulated that individuals treated with IR103 may be able to elicit broad immune responses to multiple subtypes of HIV-1 found throughout the world. Results from clinical trials suggest this postulate is true.

### **HIV Preventive Program**

We further intend to initiate a scientific program to investigate the use of our patented whole-inactivated HIV antigen technology in a HIV preventive vaccine. Unlike our immunotherapy program, which is designed to treat patients who are already infected with HIV, such a product would be used to prevent new HIV infections. To support this initiative, we have submitted the first of what could be a number of government and foundation contract and grant applications.

### **Clinical Trials History**

HIV is an extremely complex virus. The numerous trials that have been conducted with Remune® have provided us with information about which type of patients may benefit and under what circumstances our immune-based therapy may have utility. Most recently, we have tested Remune® in a follow-up Phase II study in Spain and a Phase II study in Italy. In early 2006 we made a strategic decision to accelerate the development of IR103, rather than pursue a Phase III trial with Remune®.

The Phase II study in Italy was conducted in antiretroviral-naïve patients to examine whether Remune® can induce HIV-specific immune responses in this patient population. A total of 51 patients were randomized to receive Remune® or placebo. Induction

of strong HIV-specific immune responses in these subjects could suggest that Remune® may be useful in delaying disease progression and thereby delaying the need for initiation of antiretroviral therapy.

The follow-up Phase II study in Spain (the "REMIT study") was a rollover study from study STIR-2102 completed in Spain in 2001. Subjects completing STIR-2102 were placed on open-label Remune® before initiation of the REMIT study. In the REMIT study, subjects were randomized to receive either Remune® or IFA placebo while undergoing antiretroviral treatment interruption. Approximately 40 subjects from STIR-2102 participated in the REMIT study.

Both the Italian and REMIT study trials were completed during the fourth quarter of 2004. Data from these trials has shown several positive trends in key markers believed to indicate immune responses against HIV disease, including trends toward stabilization of total CD4+ T-cell counts, increased HIV-specific CD8+ memory T-cells, and decreased levels of activated CD38+ T-cells, following Remune® treatment.

The original Remune® study conducted in Spain (STIR-2102) was a three-year, double-blind and adjuvant-controlled Phase II clinical trial. The study involved 243 HIV-infected patients and was completed in 2001. This trial combined Remune® with antiviral drug therapy and was designed to assess the effect of Remune® on virologic failure.

In May 2001, the data safety monitoring board, or DSMB, for this trial, an independent panel of experts designed to evaluate immunologic and virologic endpoints, concluded that the trial did not meet its primary endpoint, on the basis that the primary endpoint analysis revealed no significant difference between the control group and the Remune® group. The DSMB noted at that time, however, that the study included a subgroup analysis, which seemed to indicate that Remune® may have had a positive effect on viral load in patients who are more immunocompetent, or who have a more robust immune system. The DSMB recommended further studies with Remune® in such patients.

In July 2001, however, the DSMB reconvened to review the final analysis of the trial as defined by the statistical plan of the trial protocol. The DSMB advised that the analysis first reported by the DSMB was insufficient, as it included only the treatment time, but not the complete follow up time of all patients, and did not include the intent-to-treat analysis. In addition, the DSMB, among other things, reviewed the reports of three outside statisticians engaged by us, with the DSMB's concurrence, to independently review the data and noted that these statisticians concurred that the most appropriate primary analysis was the Cox regression model stratified by baseline viral load in an intent-to-treat analysis.

After reviewing the data provided by the trial protocol and the reports and views of the protocol statistician and the three outside statisticians, the DSMB expressed its view that, using the intent-to-treat analysis, Remune® showed a positive impact on controlling virus and that the STIR-2102 study had met its primary endpoint ( $p=0.034$ ).

A Thailand clinical trial, which involved 297 HIV-infected patients, conducted by our collaboration partner, Trinity Medical Group, Co. Ltd., a Thailand company (Trinity), was completed in 1999. The primary endpoint was an increase in CD4+ cells. Trinity determined that the primary endpoint was successfully met in this 40-week clinical trial. Although patients received no antiviral drug therapy, Remune® augmented CD4+ cell counts and enhanced HIV-specific immunity. Further follow-up showed stable or decreased viral load in a majority of the patients that have been examined. Trinity is currently in discussion with the Thai FDA regarding the possible need for additional clinical trials in order to obtain approval for Remune® in Thailand.

In July 2001, Pfizer, Inc. notified us of their decision to terminate their 1998 collaboration with us to develop and commercialize Remune®. In August 2001, we announced our decision not to proceed further with the 550-patient, Phase III pivotal trial which was initiated in late 1999 as part of that collaboration to evaluate whether Remune® plus HAART delays virologic failure in HIV-infected individuals.

In 1999, we discontinued a 2,526-patient, Phase III clinical endpoint trial. The trial was discontinued because differences in clinical endpoints were not observed between treatment groups, and extending the trial would have been unlikely to provide sufficient, additional clinical endpoints to permit statistically significant differences between the treatment groups to be observed in the near term. The primary efficacy endpoint for the trial was disease progression to an AIDS defining condition, or death. At the time the study began, this was the only accepted endpoint for approval by the FDA for vaccines. In 1999, the FDA agreed to accept virologic endpoint trials as the basis of approval for Remune® for future clinical studies.

The results of a Phase I, ten-patient pediatric trial completed by the National Institutes of Health, or NIH, in 1998 were published in the *Journal of Infectious Disease*, and presented at the meeting of the Infectious Disease Society of America, showed that Remune® was safe in children concurrently taking antiviral drug therapy, suggesting that Remune® stimulates HIV-specific immune responses. Furthermore, the results suggested that children receiving the adult dose of Remune® had a significant sustained decrease in viral load (the amount of circulating HIV) compared to children who received a lower dose. The study was then expanded to enroll an additional 22 children who were subsequently treated with open label Remune® at the adult dose.

Previous Phase I and II studies in approximately 350 adult subjects indicated that Remune® is well-tolerated with the most common side effect being injection site reactions. These trials indicated that Remune® is safe, that it may induce HIV-specific immune responses and showed positive trends on the virologic and immunologic markers.

### **IR103 / Remune® Benefits**

Currently available antiviral products have been shown to be effective at reducing the levels of virus in the blood; however, certain limitations in the therapy have prevented the antiviral products from being as effective as originally predicted. The antiviral products may be associated with significant toxicity and eventual viral resistance. In addition, non-compliance with the strict dosage regimen of various combinations of reverse transcriptase and protease inhibitors, or cocktail therapies, may also reduce their effectiveness and can accelerate emergence of resistance. A number of individuals who begin cocktail therapies will discontinue treatment due to resistance, toxicity, lack of compliance or because the cocktail therapy was not effective in reducing the viral load. Not all HIV-infected individuals in the United States use cocktail therapies. Due to the limitations of chronic use of antiviral drug therapies, new guidelines issued by the DHHS suggest starting these therapies later in the disease. Thus, a need exists for therapies that would be useful early in the disease as well as those that complement existing antiviral drug therapies.

IR103/Remune®, unlike antiviral drugs, can induce an HIV-specific response, which is now thought by numerous researchers to be important in controlling HIV replication. Remune® has been administered to over 2,000 patients in over 25 separate clinical trials, has an excellent safety profile, is well tolerated and is easy to administer via intramuscular injection in the deltoid muscle.

Data from clinical trials of Remune® suggest that it may:

- Induce a HIV-specific T-cell response;
- Induce cytokines and chemokines, substances that interfere with the virus attaching to and infecting normal cells;
- Work with antiretroviral drugs as a complementary treatment for HIV infection;
- Work in drug-naïve patients to delay the need for initiation of HAART; and
- Be safe with no adverse side effects.

Although Remune® has been the subject of extensive clinical trials, additional trials will be needed before we would be permitted to submit IR103 or Remune® to the FDA or other regulatory agencies for commercialization.

### **MANUFACTURING**

Our manufacturing facility in King of Prussia, Pennsylvania is dedicated to the manufacture of IR103 and Remune® for clinical trials and, if the product is approved, initial commercial production. In February 1996, we received clearance from the FDA to release the product for use in clinical trials. We rely on a third party for the final inactivation step of the manufacturing process. During 2003, we commenced limited scale-up and validation of our King of Prussia manufacturing facility after a period of inactivity. In January 2004, we completed production of additional doses of IR103 and Remune® for use in our ongoing clinical trials.

Our whole-inactivated antigen is manufactured by first culturing HIV-infected human T-cells. The virus is then purified from this cell culture and inactivated with betapropiolactone, a chemical agent commonly used for viral inactivation, and then physically inactivated with Co gamma irradiation. Each of these procedures alone is capable of inactivating HIV. During processing and

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purification, the outer envelope glycoprotein of the virus, known as gp120, is partially depleted from the inactivated HIV. The gp120 is removed from the viral surface since it is believed that immune responses to it, mainly antibodies, are not therapeutic and the gp120 antigen is where most of the mutations occur. The final envelope-depleted HIV is emulsified in IFA, mixed with a TLR-9 adjuvant (if the product is IR103) and is filled in syringes. IR103 and Remune® are designed to be administered by intramuscular injection once every three months.

We currently cannot estimate at what date, if at all, we will complete the commercial scale-up and validation of our manufacturing facility in substantial compliance with the U.S. FDA's GMP requirements. Currently, our manufacturing facility cannot support the commercial scale production of Remune® or IR103.

NeuroVax™ is currently produced by two third-party manufacturers, both of which are located in southern California. We have the manufacturing expertise to produce this product internally if/when it makes business sense to do so.

## **PATENTS**

*Multiple Sclerosis.* In 1994, the European Patent Office granted us a patent covering processes for vaccinating against diseases resulting from pathogenic responses by specific T-cell populations. In 1997, we were issued a patent covering this TCR peptide vaccine technology in the United States. In 1998 and 1999, we were issued two additional United States patents directed to this technology. These patents include composition and/or method claims for the prevention or treatment of certain autoimmune diseases. In 1999, we obtained exclusive rights to the T-cell receptor peptide intellectual property of Connetics Corporation and XOMA, (US) LLC, which included several issued patents in the U.S. and major markets outside the U.S., creating a broader intellectual property platform for this line of products. We also have patents and patent applications relating to our autoimmune technology on file in the United States and other countries, including members of the European Patent Convention and Japan. These patent applications cover certain compositions and methods relating to the use of T-cell receptor peptide sequences to vaccinate against autoreactive T-cells involved in autoimmune disease. Our issued patents related to autoimmune diseases have expiration dates that range from 2010 to 2019. There can be no assurance that any further autoimmune disease patents will be issued to us or that any issued patents, or any patent that may be issued in the future, will survive opposition or litigation or provide us with any meaningful proprietary protection.

During 2005, we filed a non provisional patent application to cover FOXP3+ Treg cells as a key component of controlling development of not only MS disease but also several other autoimmune diseases. If issued, the patent will give product coverage through 2024 for vaccine products that down regulate development of these autoimmune diseases via replenishing FOXP3+ Treg cells as well as diagnostic applications using FOXP3+.

*HIV Therapy.* In 1993, we received a United States patent relating to Remune®. In 1998 and 1999, additional patents were issued relating to certain products and methods. We have also received similar patents in Australia, certain European countries, Japan, Russia and the Republic of South Africa. We have additional patent applications relating to Remune® and to IR103 on file in the United States, as well as in other countries. Our patent applications cover, in part, certain compositions, products and /or methods of their use for the immunotherapeutic treatment of HIV-infected patients and/or preventive treatment of uninfected individuals. Our issued patents relating to HIV therapy have expiration dates that range from 2010 to 2017. There can be no assurance that any additional HIV-related patents will be issued to us. Further, there can be no assurance that our currently issued patents, or any patent that may be issued to us in the future, will survive opposition or litigation or provide meaningful proprietary protection.

## **COMPETITION**

If successfully developed and approved, NeuroVax™, IR103 and Remune® will compete with numerous existing therapies. There are several drugs currently approved by the FDA for the treatment of MS and HIV. In addition, a number of companies are pursuing the development of novel pharmaceutical products that target MS and HIV, and some companies, including several multinational pharmaceutical companies, are simultaneously marketing several different drugs and may therefore be able to market their own combination drug therapies. We believe that a significant number of drugs currently under development will become available in the future for the treatment of MS and HIV. Although we believe that there is a significant future market for therapeutics to treat MS and HIV infection and other viral diseases, we anticipate that, even if we were to successfully develop our product candidates or if they were approved for commercial marketing, they would face intense and increasing competition in the future as new products enter the market and advanced technologies become available. There can be no assurance that existing products or new products for the treatment of MS and HIV developed by competitors, principally including BIOGEN/Idec,



Teva, Serono, Elan and Novartis (MS), GlaxoSmithKline Plc, Merck & Co., Inc., Gilead (HIV), will not be more effective, and/or more effectively marketed and sold, than our product candidates should they be successfully developed and receive regulatory approval, or any other therapeutic for MS and HIV that may be developed by us. Competitive products or the development by others of a cure or new treatment methods may render our technologies, products and compounds obsolete, uncompetitive or uneconomical before we can recover our development or commercialization expenses incurred with respect to any such technologies or products or compounds. Many of our competitors have significantly greater financial, technical, human, and other resources than us and may be better equipped to develop, manufacture, sell, market and distribute products. In addition, many of these companies have superior experience and credibility in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing pharmaceutical products.

## **GOVERNMENT REGULATION**

Clinical testing, manufacture, promotion and sale of our drug products are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA and corresponding state and foreign regulatory agencies. We believe that NeuroVax™, IR103 and Remune® will be regulated by the FDA as biological drug products under current regulations of the FDA. Biological products must be shown to be safe, pure and potent (i.e., effective) and are subject to the same regulatory requirements as pharmaceutical drug products under the Federal Food, Drug and Cosmetic Act. Non-compliance with applicable requirements can result in, among other things, fines, injunctions, seizure of products, total or partial suspension of product manufacturing and marketing, failure of the government to grant premarket approval, withdrawal of marketing approvals and criminal prosecution.

We also are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act and the Toxic Substances Control Act. Furthermore, existing or additional government regulations may be applied that could prevent or delay regulatory approval of our products, or affect the pricing or distribution of such products.

We are also subject to foreign regulatory requirements governing human clinical trials and pharmaceutical sales that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained before marketing the product in those countries. The approval process may be more or less rigorous from country to country, and the time required may be longer or shorter than that required in the United States.

## **EMPLOYEES**

As of March 15, 2006 we had 38 full-time employees. Of these employees, 30 are engaged in, or directly support, research and development. None of our employees are covered by a collective bargaining agreement.

## **Item 1A. RISK FACTORS**

Our future operating results and the value of our securities are subject to a number of factors, including:

### ***We need more cash immediately, and also on an ongoing basis.***

We have never generated any revenue from product sales. As of December 31, 2005, we had an accumulated deficit of approximately \$348,715,000, cash and cash equivalents of only \$146,000, a working capital deficiency of \$2,986,000 and a deficiency in stockholders' equity of \$5,650,000. Although we raised additional working capital in February and March 2006 in private offerings (2006 Private Placement), the amounts raised are only expected to provide us with additional liquidity through the third quarter of 2006. Because we do not anticipate generating any revenue from our products until at least the beginning of 2012, if at all, we will continue to have negative cash flow.

We need to raise substantial additional capital to fund our operations and repay our loan obligations. We will need to raise substantial funds to continue our operations and to conduct research and development, preclinical studies and clinical trials necessary to bring our potential products to market and to establish manufacturing and marketing capabilities. We will continue to have limited cash resources. There can be no assurance that we will be successful in consummating any financing transaction or, if consummated, that the terms and conditions will not be unfavorable to us. Additionally, there can be no assurance that we will receive any additional proceeds via the exercise of the warrants that we issued in our 2006 Private Placement.

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Under our new strategic plan, we intend to focus our ongoing development efforts on NeuroVax™ and IR103. The timing and amount of our future capital requirements will depend on many factors, including (but not limited to):

- the timing of approval to begin new clinical trials;
- our ability to raise additional funding and the amounts raised, if any;
- the time and cost involved in obtaining regulatory approvals;
- continued scientific progress in our research and development programs;
- the scope and results of preclinical studies and clinical trials;
- the cost of manufacturing scale-up;
- the costs involved in filing, prosecuting and enforcing patent claims;
- competing technological and market developments;
- effective commercialization activities and arrangements;
- the costs of defending against and settling lawsuits; and/or
- other factors not within our control or known to us.

Our access to capital could be limited if we do not progress in:

- obtaining regulatory approvals;
- our research and development programs;
- our preclinical and clinical trials; and/or
- scaling up manufacturing.

Our access to capital also could be limited by:

- overall financial market conditions;
- the security interest in substantially all of our assets in respect of an aggregate principal amount of \$13,385,000;
- our covenant in the Standby Equity Distribution Agreement (the SEDA), which we entered into with Cornell Capital Partners, LP (Cornell Capital) on July 15, 2005, not to, during its term, engage in any other equity financing without the consent of Cornell Capital, which is not to be unreasonably withheld, and a similar covenant made by us in connection with a convertible debenture issued to Cornell Capital; and
- Potential dilution which would occur upon the exercise or conversion of outstanding derivative securities which overlie 2,387,785,000 shares of our common stock.

***Our independent registered public accountants have expressed substantial doubt as to our ability to continue as a going concern.***

As of December 31, 2005, we had an accumulated deficit of \$348,715,000. We have not generated revenues from the commercialization of any product. We expect to continue to incur substantial net operating losses over the next several years, which would imperil our ability to continue operations. We may not be able to generate sufficient product revenue to become

profitable on a sustained basis, or at all, and do not expect to generate significant product revenue before the beginning of 2012, if at all. We have operating and liquidity concerns due to our significant net losses and negative cash flows from operations. As a result of these and other factors, our independent registered public accountants, Levitz, Zacks & Ciceric, indicated, in their report on our 2005 financial statements, that there is substantial doubt about our ability to continue as a going concern.

***Our existing stockholders could be diluted by well over 90% as a result of our 2006 Private Placement and may suffer additional dilution in connection with future financings.***

As part of our 2006 Private Placement, we offered and sold 80 units in a private securities offering, each unit comprising a \$100,000 principal amount 8% Senior Secured Convertible Promissory Note, due January 1, 2008, and a warrant to purchase up to 15,000,000 shares of common stock at a price of \$0.02 per share. The principal plus accrued interest on the notes may be converted into common stock at a conversion price equal to \$0.02 per share. If these notes and warrants are converted and exercised in full, we would be required to issue more than 1,600,000,000 shares of common stock. Additionally, our placement agent for this offering, which is an affiliate of Kevin Kimberlin, a director and our largest stockholder, may have the right to acquire up to an additional 320,000,000 shares of common stock at a price of \$0.02 per share.

Moreover, in our 2006 Private Placement we also issued 53,425,204 shares of common stock and issued other derivative securities convertible or exercisable for 50,000,000 shares of common stock, all at \$0.02. Moreover, the 2006 Private Placement resulted in outstanding derivative securities held by Cornell Capital becoming convertible or exercisable (at \$0.02 per share) for 46,808,000 more shares than previously, and resulted in outstanding convertible notes held by an affiliate of Mr. Kimberlin becoming convertible (at \$0.02 per share) for 229,998,000 more shares of common stock than previously, and resulted in warrants held by an affiliate of Mr. Kimberlin becoming exercisable (at a range of \$0.07 to \$0.32 per share) for 94,776,000 more shares of common stock than previously.

As a result of the 2006 Private Placement, our existing stockholders will, after the conversion and exercise of the notes and warrants, hold only a tiny fraction of the equity interest they currently hold in the Company. On December 31, 2005 we had only 71,660,101 outstanding shares of common stock.

Moreover, even as we were selling or committing these huge numbers of shares for \$0.02 per share, our public market trading price was above \$0.02 per share.

In order to provide adequate capital stock to allow for the full conversion and exercise of these notes and warrants, we intend to seek stockholder approval for an increase in the authorized common stock to a total of 3,500,000,000 shares.

Although our management recognizes the need to secure additional financing, there can be no assurance that we will be successful in consummating any financing transaction or, if consummated, that the terms and conditions of the financing will not be unfavorable to us. Any other future near-term financings will almost certainly involve substantial further dilution of outstanding equity. Any subsequent offerings may also require the creation or issuance of a class or series of stock that by its terms ranks senior to the common stock with respect to rights relating to dividends, voting and/or liquidation.

***Our stock has been delisted from NASDAQ and is subject to penny stock rules, which may make it more difficult for us to raise capital and for you to sell your securities.***

In November 2005, our stock and Class B warrants were delisted from the Nasdaq Stock Market (Nasdaq) due to our failure to satisfy the Nasdaq continued listing criteria. As a result, our stock is currently quoted on the Over-the-Counter Bulletin Board quotation service (OTC). Securities traded on the OTC generally suffer from lower liquidity and greater price volatility. Additionally, because our stock price is currently considered a "penny stock" under regulations of the Securities and Exchange Commission, broker-dealers who buy and sell our securities are subject to rules that impose additional sales practice requirements. These additional burdens imposed upon broker-dealers could discourage broker-dealers from effecting transactions in our common stock, which could severely limit the market liquidity of the common stock and warrants and your ability to sell our securities in the secondary market. Being delisted also hurts our ability to raise additional financing, in part because many investors are unwilling to take large positions in stocks which do not trade on Nasdaq or a major stock exchange.

***Our failure to successfully develop our product candidates may cause us to cease operations.***

We have not completed the development of any products. We are dependent upon our ability to successfully develop our product candidates and our failure to do so may cause us to cease operations.

In May 1999 we discontinued a Phase III clinical endpoint trial of Remune<sup>®</sup> because differences in clinical endpoints were not observed between treatment groups and extending the trial would have been unlikely to provide sufficient additional clinical endpoints. The discontinuation of the Phase III trial has had a material adverse effect on us. Since that time, we have chosen to focus our development efforts on our second-generation HIV therapy, IR103, and NeuroVax<sup>™</sup>. We cannot assure you that either of these drug candidates will succeed in clinical trials or that we, or our corporate collaborators, if any, will ever obtain any regulatory approvals for these drug candidates.

The results of our pre-clinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial financial and other resources to conduct time-consuming research, preclinical studies and clinical trials will be required if we are to develop any products. Delays in planned patient enrollment in clinical trials may result in increased costs, program delays or both. None of our potential products may prove to be safe or effective in clinical trials. Approval by the U.S. FDA, or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, our products may not achieve market acceptance. Any products resulting from our programs may not be successfully developed or commercially available until 2012 or later, if at all.

Moreover, unacceptable toxicity or side effects could occur at any time in the course of human clinical trials or, if any products are successfully developed and approved for marketing, during commercial use of our products. Although preliminary research and clinical evidence have shown our product candidates to be safe, the appearance of any unacceptable toxicity or side effects could interrupt, limit, delay or abort the development of any of our products or, if previously approved, necessitate their withdrawal from the market.

***The lengthy product approval process and uncertainty of government regulatory requirements may delay or prevent us from commercializing products. We must work to re-establish our credibility with the FDA.***

Clinical testing, manufacture, promotion, export and sale of our products are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA, and corresponding state and numerous foreign regulatory agencies worldwide. This regulation may delay or prevent us from commercializing products. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, seizure or recall of products, total or partial suspension of product manufacturing and marketing, failure of the government to grant pre-market approval, withdrawal of marketing approvals and criminal prosecution.

The regulatory process for new therapeutic drug products, including the required preclinical studies and clinical testing, is lengthy and expensive. We may not receive necessary international regulatory or FDA clearances for our drug candidates in a timely manner, or at all. The length of the clinical trial process and the number of patients regulatory agencies will require to be enrolled in the clinical trials in order to establish the safety and efficacy of our products is uncertain.

Even if late-stage clinical trials for our drug candidates are initiated and successfully completed, the FDA and numerous foreign regulatory agencies may not approve these candidates for commercial sale. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals. Regulatory requirements are evolving and uncertain. Future United States or foreign legislative or administrative acts could also prevent or delay regulatory approval of our products. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of any of our products under development. Even if commercial regulatory approvals are obtained, they may include significant limitations on the indicated uses for which a product may be marketed.

In addition, a marketed product is subject to continual regulatory review. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Among the other requirements for regulatory approval is the requirement that prospective manufacturers conform to the FDA's Good Manufacturing Practices, or GMP, requirements. In complying with the FDA's GMP requirements, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to assure that products meet

applicable specifications and other requirements. Failure to comply and maintain compliance with the FDA's GMP requirements subjects manufacturers to possible FDA regulatory action and as a result may have a material adverse effect on us. We, or our contract manufacturers, if any, may not be able to maintain compliance with the FDA's GMP requirements on a continuing basis. Failure to maintain compliance could have a material adverse effect on us.

The FDA has not designated expanded access protocols for our drug candidates as "treatment" protocols. The FDA may not determine that any of our drug candidates meet all of the FDA's criteria for use of an investigational drug for treatment use. Even if one of our candidates is allowed for treatment use, third party payers may not provide reimbursement for the costs of treatment. The FDA also may not consider our product candidates under development to be appropriate candidates for accelerated approval, expedited review or "fast track" designation.

The timing and substance of most FDA decisions are, as a practical matter, discretionary. We believe that there may be significant doubts in the minds of some persons at the FDA regarding our corporate credibility and the viability of our HIV product candidates. Our efforts to re-establish our credibility may not succeed; if we are unsuccessful in our efforts, the FDA approvals that are indispensable if we are to survive and succeed, may be delayed or denied despite any merit our applications may have.

Marketing any drug products outside of the United States will subject us to numerous and varying foreign regulatory requirements governing the design and conduct of human clinical trials and marketing approval. Additionally, our ability to export drug candidates outside the United States on a commercial basis is subject to the receipt from the FDA of export permission, which may not be available on a timely basis, if at all. Approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may be even longer than that required to obtain FDA approval. Foreign regulatory approval processes include all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country.

Before we will be permitted to export either of our drug candidates to foreign countries for clinical use in those countries, we need to meet a number of regulatory requirements. One of those requirements is that we must ensure that we can manufacture the candidate at our United States manufacturing facility in a manner that is in "substantial compliance" with current United States GMP requirements. We must provide the FDA with "credible scientific evidence" that the candidate would be safe and effective under the conditions of proposed use in foreign countries. There can be no assurance, however, that we will successfully meet any or all of these requirements for the export of our drug candidates, and if we are unable to successfully meet all regulatory requirements, we will not be permitted by the FDA to export our candidates to foreign countries for clinical use, even if the foreign governments were to approve such use.

***Our patents and proprietary technology may not be enforceable and the patents and proprietary technology of others may prevent us from commercializing products. Some of our patents expire fairly soon.***

We have a portfolio of 173 patents worldwide. Although we believe these patents to be protected and enforceable, the failure to obtain meaningful patent protection for our potential products and processes would greatly diminish the value of our potential products and processes.

In addition, whether or not our patents are issued, or issued with limited coverage, others may receive patents, which contain claims applicable to our products. Patents we are not aware of may adversely affect our ability to develop and commercialize products. Also, our patents related to HIV therapy have expiration dates that range from 2010 to 2017 and our patents related to autoimmune diseases have expiration dates that range from 2010 to 2019. The limited duration of our patents could diminish the value of our potential products and processes, particularly since we do not expect to generate any revenue from our products sooner than the beginning of 2012, if at all.

The patent positions of biotechnology and pharmaceutical companies are often highly uncertain and involve complex legal and factual questions. Therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. We also rely upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. We also rely on protecting our proprietary technology in part through confidentiality agreements with our current and former corporate collaborators, employees, consultants and some contractors. These agreements may be breached, and we may not have adequate remedies for any breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors. Litigation may be necessary to defend against claims of infringement, to enforce our patents and/or to protect trade secrets. Litigation could result in substantial costs and diversion of management

efforts regardless of the results of the litigation. An adverse result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using proprietary technologies.

Our products and processes may infringe, or be found to infringe, on patents not owned or controlled by us. If relevant claims of third-party patents are upheld as valid and enforceable, we could be prevented from practicing the subject matter claimed in the patents, or be required to obtain licenses or redesign our products or processes to avoid infringement.

***Technological change and competition may render our potential products obsolete.***

The pharmaceutical and biotechnology industries continue to undergo rapid change, and competition is intense and we expect it to increase. Competitors may succeed in developing technologies and products that are more effective or affordable than any that we are developing or that would render our technology and products obsolete or noncompetitive. Many of our competitors have substantially greater experience, financial and technical resources and production and development capabilities than we. Accordingly, some of our competitors may succeed in obtaining regulatory approval for products more rapidly or effectively than we, or develop or acquire technologies and products that are more effective and/or affordable than any that we are developing. In addition, IR103 is not suggested as a possible cure for HIV/AIDS, but merely as a means to delay its progression before other therapies are begun. If a true cure for HIV/AIDS were found, IR103 would be of lesser value.

***Our lack of commercial manufacturing and marketing experience and our dependence on third parties for manufacturing may prevent us from successfully commercializing products.***

We have not manufactured any of our products in commercial quantities. We may not successfully make the transition from manufacturing clinical trial quantities to commercial production quantities or be able to arrange for contract manufacturing and this could prevent us from commercializing products or limit our profitability from our products. Even if our product candidates are successfully developed and receive FDA approval, we have not demonstrated the capability to manufacture a product in commercial quantities. We rely on a third party for the final inactivation step of the IR103 manufacturing process. If the existing manufacturing operations prove inadequate, there can be no assurance that any arrangement with a third party can be established on a timely basis or that we can establish other manufacturing capacity on a timely basis.

We have no experience in the sales, marketing and distribution of pharmaceutical or biotechnology products. Thus, our products may not be successfully commercialized even if they are developed and approved for commercialization and even if we can manufacture them. In addition, our competitors will have significantly greater marketing resources and power than we will.

The manufacturing process of our products involves a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. Moreover, our products can be manufactured only in a facility that has undergone a satisfactory inspection and certification by the FDA. For these reasons, we would not be able to quickly replace our manufacturing capacity if we were unable to use our manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if our manufacturing facilities are deemed not in compliance with the GMP requirements, and the non-compliance could not be rapidly rectified. Our inability or reduced capacity to manufacture our products would prevent us from successfully commercializing our products.

We may enter into arrangements with contract manufacturing companies to expand our own production capacity in order to meet requirements for our products, or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, we may encounter costs, delays and /or other difficulties in producing, packaging and distributing our clinical trials and finished product. Further, contract manufacturers must also operate in compliance with the GMP requirements; failure to do so could result in, among other things, the disruption of our product supplies. Our potential dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and deliver products on a timely and competitive basis.

***We may be unable to enter into additional collaborations.***

Our current development strategy is to seek collaborative arrangements with larger pharmaceutical companies for the clinical development and commercialization of our product candidates. If we are able to enter into such arrangements, we expect that a large portion of the ongoing development costs for our drug candidates would be funded by our collaborative partners. However, we may be unable to negotiate collaborative arrangements on favorable terms, or at all, and our current or future collaborative arrangements may not be successful or continue. If we are unable to enter into favorable collaborative arrangements, we expect

that our future capital requirements would increase and we may be required to delay or curtail development efforts for one or both of our drug candidates.

***Adverse determinations and pressures concerning product pricing, reimbursement and related matters could prevent us from successfully commercializing any of our product candidates.***

Our ability to earn revenue on any of our products will depend in part on the extent to which patient reimbursement for the costs of the products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other organizations. Failure of patients to obtain appropriate cost reimbursement may prevent us from successfully commercializing any of our other products. Third-party payers are increasingly challenging the prices of medical products and services. If purchasers or users of any of our other products are not able to obtain adequate reimbursement for the cost of using the products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products and whether adequate third party coverage will be available. In addition, many HIV patients live in poor countries, which may be unable to afford to pay substantial sums for their citizens' HIV therapies. Political pressure exists to seek to require manufacturers of HIV therapies to supply them at below-market prices to poor persons and/or poor countries, and this pressure may increase in the future.

***Our success in the HIV field may depend upon the acceptance of IR103 by the medical and HIV-activist communities.***

Our ability to market and commercialize IR103 would depend in part on the acceptance and utilization of IR103 by the medical and HIV-activist communities. Physician inertia may be a problem for us as it is for many emerging medical products companies. We will need to develop commercialization initiatives designed to increase awareness about us and IR103 among targeted audiences, including public health and AIDS activists and community-based outreach groups in addition to the investment community. Currently, we have not developed any commercialization initiatives.

***Kevin Kimberlin, a member of our Board of Directors, beneficially owns approximately 43.7% of our outstanding common stock and has the rights to acquire approximately 484,464,000 additional shares of our common stock, which could result in ownership of up to approximately 86.3% of our outstanding shares and could allow him to control or influence stockholder votes.***

Kevin B. Kimberlin, a member of our Board of Directors, together with his affiliates and/or related parties, currently owns of record approximately 43.7% of our outstanding shares of common stock. He and they also have the right to acquire, through the conversion of indebtedness and the exercise of options and warrants beneficially owned by them, approximately 484,464,000 additional shares. If his/their indebtedness, options and warrants were to be converted and exercised in full, Mr. Kimberlin and his affiliates would own approximately 86.3% of our outstanding shares of common stock on a post-conversion/exercise basis. Although if, in connection therewith or earlier, all of our other \$0.02 derivative securities were also converted or exercised in full, Mr. Kimberlin and his affiliates would only own approximately 22.0% of our common stock.

As a result of ownership of our common stock and the ability to acquire additional shares, Mr. Kimberlin and his affiliates and/or related persons have the ability to influence, and possibly control, substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. If your interests as a stockholder are different from his interests, you may not agree with his decisions and you might be adversely affected thereby.

***Mr. Kimberlin is also a secured creditor.***

As collateral for the Mortgage Note, which has a principal amount of \$4,735,000 and matures on January 1, 2009, parties affiliated with and/or related to Kevin Kimberlin have a perfected security interest in our intellectual property and other assets. Pursuant to the security agreement, we must comply with covenants with respect to these assets. The security interests and covenants could impair our ability to enter into collaborative and licensing arrangements.

***We have significant indebtedness that will mature before our operations can repay it.***

After our 2006 Private Placement, we had \$8,650,000 of secured debt due on or before January 1, 2008 and \$4,735,000 of secured debt due on January 1, 2009. We will not have any product revenues before those dates. There can no assurance that we can pay, refinance or extend this debt.

***Legal proceedings could require us to pay substantial amounts of money and impair our operations.***

Between July 2001 and 2003, several complaints were filed in the United States District Court for the Southern District of California seeking an unspecified amount of damages on behalf of an alleged class of persons, who purchased shares of our Common Stock at various times between May 17, 1999 and July 6, 2001. The complaints have been consolidated into a single action under the name *In re Immune Response Securities Litigation* by order of the Court, and a consolidated, amended complaint was filed in July 2003. The consolidated, amended complaint names us and certain of our former officers as defendants, as well as Agouron Pharmaceuticals, Inc. and one of its officers. The consolidated, amended complaint alleges that we, Agouron and/or such officers violated federal securities laws by misrepresenting and failing to disclose certain information about the results of clinical trials of Remune<sup>®</sup>. On October 31, 2003 the defendants filed motions to dismiss the consolidated, amended complaint. The court denied these motions on June 7, 2005.

On July 5, 2005, a shareholder derivative complaint was filed in the Superior Court of the State of California in the County of San Diego against certain of our current and former officers and directors, seeking an unspecified amount of damages. We are also named as a nominal defendant in the complaint, which alleges, among other things, that such officers and directors breached their fiduciary duties by causing the misrepresentation of our financial results and failing to correct our publicly reported financial results and guidance, and engaged in certain improper acts including abuse of control, gross mismanagement and waste of corporate assets from May 1999 to the present.

Although we intend to vigorously defend the actions, we cannot now predict or determine the outcome or resolution of these proceedings, or to estimate the amounts of, or potential range of, loss with respect to these proceedings. In addition, the timing of the final resolution of these proceedings is uncertain. The range of possible resolutions of these proceedings could include judgments against us or our former officers or settlements that could require substantial payments by us, which could have a material adverse impact on our financial position, results of operations and cash flows. These proceedings also might require substantial attention of our management team and therefore, regardless of whether we win or lose the litigation, divert their time and attention from our business and operations.

***We have hired a new CEO.***

On October 31, 2005, we hired Joseph F. O'Neill as Chief Executive Officer and President. Executive leadership transition periods are often difficult, due to learning curve issues, cultural differences and friction caused by changes in strategy and style. In addition, Dr. O'Neill has no experience as an executive of a for-profit corporation.

***Hazardous materials and environmental matters could expose us to significant costs.***

We may be required to incur significant costs to comply with current or future environmental laws and regulations. Although we do not currently manufacture commercial quantities of our product candidates, we produce limited quantities of these products for our clinical trials. Our research and development and manufacturing processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and some waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an incident, we could be held liable for any damages that result, and any liability could exceed our resources. Current or future environmental laws or regulations may have a material adverse effect on our operations, business and assets.

***Product liability exposure may expose us to significant liability.***

We face an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of our technology or prospective products is alleged to have resulted in adverse effects. We may not be able to avoid significant liability exposure. We may not have sufficient insurance coverage, and we may not be able to obtain sufficient coverage at a reasonable cost. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could hurt our financial performance. Even if we avoid liability exposure, significant costs could be incurred that could hurt our financial performance and condition.



***Our certificate of incorporation and bylaws include provisions that could make attempts by stockholders to change management more difficult.***

The approval of 66 2/3% of our voting stock is required to approve specified transactions and to take specified stockholder actions, including the calling of special meetings of stockholders and the amendment of any of the anti-takeover provisions, including those providing for a classified board of directors, contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan, we have distributed a dividend of one preferred stock purchase right for each outstanding share of Common Stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved by our Board of Directors and may have the effect of deterring hostile takeover attempts. The substantial aggregate equity positions of Mr. Kimberlin and his affiliates would make a hostile takeover attempt very unlikely. The practical effect of these provisions is to require a party seeking control of us to negotiate with our Board of Directors, which could delay or prevent a change in control. These provisions could limit the price that investors might be willing to pay in the future for our securities and make attempts by stockholders to change management more difficult.

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits us from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person first becomes an “interested stockholder,” unless the business combination is approved in a prescribed manner. The application of Section 203 also could have the effect of delaying or preventing a change of control.

***We are seeking stockholder approval for a reverse stock split, which could negatively affect the price and liquidity of our common stock.***

We are seeking stockholder approval to give the Board of Directors the authority to implement a reverse stock split within a range of 1:10 to 1:100. If the Board of Directors was to effect such a reverse stock split, as currently planned, the market price of our common stock may not continue at a level in proportion to the reduction in the number of outstanding shares resulting from the reverse stock split. For example, if the Board of Directors decided to implement a reverse stock split at a ratio of 1:100, the post-split market price of our common stock might not continue at a level at least 100 times greater than the pre-split price. Accordingly, the total market capitalization of our common stock after a reverse stock split, if implemented, could be lower than the total market capitalization before the reverse stock split. In fact, companies that effect reverse stock splits often do experience declining market prices thereafter. Additionally, the liquidity of our common stock could be affected adversely by the reduced number of shares outstanding after the reverse stock split.

**Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Item 1C. EXECUTIVE OFFICERS OF THE REGISTRANT**

The following sets forth certain information regarding our executive officers as of March 15, 2006:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Joseph F. O’Neill, M.D.	53	President and Chief Executive Officer
Michael K. Green	50	Chief Operating Officer and Chief Financial Officer
Georgia Theofan, Ph.D.	49	Vice President, Clinical Development
Peter Lowry	44	Vice President, Manufacturing

*Joseph F. O’Neill, M.D.*  
*President and Chief Executive Officer*

Dr. O’Neill joined us in October 2005. Most recently, Dr. O’Neill was the Deputy Coordinator and Chief Medical Officer in the Office of the U.S. Global AIDS Coordinator, Department of State from August 2003 to August 2005. Prior to joining the State Department, Dr. O’Neill served as the Director of the White House Office of National AIDS Policy from July 2002 to August 2003. Prior to his White House appointment, he served as Acting Director of the Office of HIV/AIDS Policy in the Department of Health

and Human Services from 2001 to July 2002. From 1997 to the end of 2001, Dr. O'Neill served as Associate Administrator for HIV/AIDS in the Health Resources and Services Administration's HIV/AIDS Bureau. In this capacity, he directed the national Ryan White Comprehensive AIDS Resources Emergency (CARE) Act program that provides medical care and treatment, social services and pharmaceuticals to people living with HIV/AIDS throughout the United States, the District of Columbia, Puerto Rico and U.S. territories. In addition, he serves on a number of advisory boards including the Robert Wood Johnson Foundation's Promoting Excellence in End of Life Care program and the Brazilian Association for Palliative Care. Dr. O'Neill is a graduate of the School of Medicine of the University of California at San Francisco and holds degrees in business administration, public health, health and medical sciences from the University of California at Berkeley. He is board certified in internal medicine.

*Michael K. Green*  
*Chief Operating Officer and Chief Financial Officer*

Mr. Green joined us in October 2003, bringing over 25 years of extensive finance, business and accounting experience in various technology industries in both the United States and Australia. Mr. Green was promoted from Vice President, Finance to Chief Operating Officer on October 31, 2005, while retaining his Chief Financial Officer position. Mr. Green served as Senior Vice President and Chief Financial Officer of Synbiotics Corporation, a publicly traded animal health company, from May 1991 to September 2002 and as Chief Financial Officer of Immunopharmaceuticals Inc., a human pharmaceutical company, from May 1991 to October 1993, where he was responsible for all finance, accounting, administrative, human resource and MIS matters. Before that Mr. Green spent 13 years with Price Waterhouse in various offices in the United States and Australia where he is a C.P.A. and a Chartered Accountant. Mr. Green co-authored the Price Waterhouse guidebook titled "Taking Your Company Public," and the Price Waterhouse lecture series titled "Initial Public Offerings for Smaller Businesses." Mr. Green holds a Bachelor of Business Studies degree from the New South Wales Institute of Technology in Sydney, Australia.

*Georgia Theofan, Ph.D.*  
*Vice President, Clinical Development*

Dr. Theofan was appointed to the position of Vice President, Clinical Development in January 2003. Dr. Theofan has been with us since November 1995, and has more than 17 years experience in the biotechnology industry. Since joining us, Dr. Theofan has been responsible for managing the operations of clinical trials in HIV, as well as cancer and autoimmune disease. She has over 40 publications in peer-reviewed scientific journals and is a co-inventor on nine patents. Dr. Theofan received a Ph.D. in Biology from the University of Notre Dame, and a Bachelor's Degree in Biology from New York University. She also served as a post doctoral fellow at the University of Rochester in New York, and the University of California at both the Riverside and San Diego campuses.

*Peter Lowry*  
*Vice President, Manufacturing*

Mr. Lowry was promoted to Vice President, Manufacturing in March 2006, and is currently responsible for all manufacturing and quality operations at the King of Prussia, Pennsylvania facility. Mr. Lowry joined us in June 1995, and has over 15 years experience in biopharmaceutical research, bioprocess development, and large scale GMP manufacturing. He served as Executive Director, Manufacturing at our Pennsylvania facility from April 2002 to August 2004. From 1995 to April 2002, he headed quality control operations at both the Pennsylvania and California facilities. From April 2002 to August 2004, Mr. Lowry served as Senior Director, Operations, responsible for the manufacturing of all clinical trial products in support of our HIV program. He currently serves on the Biotechnology Program Advisory Committee of Montgomery College. Prior to joining the us, Mr. Lowry was head of Viral Biochemistry at Advanced Biotechnologies Inc. Mr. Lowry holds a bachelors degree in Biochemistry from Rutgers College.

## **Item 2. PROPERTIES**

We lease a 31,200 square foot office facility located in Carlsbad, California. Under the terms of the lease, which expires on March 31, 2008, monthly rent on the facility is approximately \$23,684. We occupy 13,046 square feet of this facility as our headquarters and we have subleased the remaining 18,154 square feet beginning March 15, 2003 through to the end of the lease, a term of 60.5 months. The monthly sublet rent is \$10,315 per month with a 3% maximum annual percentage rent increase.

The lessor held a standby letter of credit for \$600,000 as an additional security deposit. In January 2006, we did not renew the standby letter of credit. Under the terms of the lease if there is no standby letter of credit in place, we must provide an additional \$600,000 security deposit to be held by the landlord. The restricted security of \$600,000 (a certificate of deposit), which was collateral for the previous standby letter of credit, reverted to an escrow account for our benefit controlled by the landlord after the expiration of the standby letter of credit.

We also lease a 52,500 square foot manufacturing facility located in King of Prussia, Pennsylvania. Under the terms of the lease, which expires on October 31, 2011, we have two five-year options to extend. Current monthly rent on the facility is \$45,787.

We also lease a 50,600 square foot facility located adjacent to our manufacturing facility in King of Prussia, Pennsylvania which is currently not being used. Under the terms of the lease, which expires on October 31, 2011, and has two five-year options to extend, current monthly rent on the facility is approximately \$30,084. We are trying to sublease this property. However, current market conditions are not favorable and there can be no assurance that we will be able to locate a subtenant.

**Item 3. LEGAL PROCEEDINGS**

Between July 2001 and 2003, several complaints were filed in the United States District Court for the Southern District of California seeking an unspecified amount of damages on behalf of an alleged class of persons, who purchased shares of our common stock at various times between May 17, 1999 and July 6, 2001. The complaints have been consolidated into a single action under the name *In re Immune Response Securities Litigation* by order of the Court, and a consolidated, amended complaint was filed in July 2003. The consolidated, amended complaint names us and certain of our former officers as defendants, as well as Agouron Pharmaceuticals, Inc. and one of its officers. The consolidated, amended complaint alleges that we, Agouron and/or such officers violated federal securities laws by misrepresenting and failing to disclose certain information about the results of clinical trials of Remune<sup>®</sup>. On October 31, 2003 the defendants filed motions to dismiss the consolidated, amended complaint. The court denied these motions on June 7, 2005.

On July 5, 2005, a shareholder derivative complaint was filed in the Superior Court of the State of California in the County of San Diego against certain of our current and former officers and directors, seeking an unspecified amount of damages. We are also named as a nominal defendant in the complaint, which alleges, among other things, that such officers and directors breached their fiduciary duties by causing the misrepresentation of our financial results and failing to correct our publicly reported financial results and guidance, and engaged in certain improper acts including abuse of control, gross mismanagement and waste of corporate assets from May 1999 to the present.

Although we intend to vigorously defend the actions, we cannot now predict or determine the outcome or resolution of these proceedings, or to estimate the amounts of, or potential range of, loss with respect to these proceedings. In addition, the timing of the final resolution of these proceedings is uncertain. The range of possible resolutions of these proceedings could include judgments against us or our former officers or settlements that could require substantial payments by us, which could have a material adverse impact on our financial position, results of operations and cash flows. These proceedings also might require substantial attention of our management team and therefore, regardless of whether we win or lose the litigation, divert their time and attention from our business and operations.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**PART II**

**Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Price Range of Common Stock**

Our common stock previously traded on the Nasdaq SmallCap Market under the symbol IMNR through November 23, 2005. Since that time, our stock has traded on the "Pink Sheets" under the symbol IMNR.PK from November 25, 2005 through December 16, 2005 and on the OTC Bulletin Board ("OTCBB") under the symbol IMNR.OB beginning December 19, 2005. The following table sets forth the range of high and low sales prices for our common stock on the applicable market for the periods indicated since January 1, 2004.

<u>2004</u>	<u>High</u>	<u>Low</u>
January 1 – March 31, 2004	\$2.15	\$1.49
April 1 – June 30, 2004	2.45	1.10
July 1 – September 30, 2004	1.30	0.63
October 1 – December 31, 2004	1.70	0.85
<u>2005</u>	<u>High</u>	<u>Low</u>
January 1 – March 31, 2005	\$1.74	\$0.76
April 1 – June 30, 2005	0.88	0.51
July 1 – September 30, 2005	0.85	0.45
October 1 – December 31, 2005	0.55	0.08

On March 8, 2006, the last reported sales price of our common stock on the OTC Bulletin Board was \$0.13 per share. As of March 8, 2006, our common stock was held by approximately 1,143 stockholders of record.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock. As part of the March 2006 Private Placement, the convertible notes contain a covenant that restricts us from paying common stock dividends, and therefore we will not be paying any cash dividends in the foreseeable future.

**Securities Authorized for Issuance under Equity Compensation Plans**

The following table provides information as of December 31, 2005 regarding compensation plans (including individual compensation arrangements) under which equity securities of The Immune Response Corporation are authorized for issuance.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</u>
Equity compensation plans approved by security holders	6,196,000	\$ 1.33	1,862,000
Equity compensation plans not approved by security holders**	6,750,000	0.42	—
<b>Total</b>	<b>12,946,000</b>	<b>\$ 0.85</b>	<b>1,862,000</b>

\*\* There are two individual compensation arrangements, one of which we granted to John N. Bonfiglio (a 750,000–share stock option) in January 2003. The second option was granted to Joseph F. O’Neill (a 6,000,000–share stock option) in October 2005. 3,000,000 shares of the option will vest upon achievement of specified milestones, and the remaining 3,000,000 will time–vest over two years in eight quarterly installments.

## **Item 6. SELECTED FINANCIAL DATA**

The following selected financial data have been derived from our audited financial statements as of and for the fiscal years ended December 31, 2005, 2004, 2003, 2002 and 2001. The following selected financial data should be read in conjunction with our financial statements, the related notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Form 10–K.

	Years Ended December 31,				
	2005	2004	2003	2002	2001
(in thousands, except per share data)					
<b>Statement of Operations Data:</b>					
Total revenues	\$ 44	\$ 323	\$ 66	\$ 47	\$ 9,953
Net loss	(17,313)	(29,959)	(28,799)	(30,835)	(15,943)
Net loss attributable to common stockholders	(18,534)	(30,325)	(42,050)	(30,835)	(16,277)
Net loss per share – basic and diluted:					
Net loss	(0.32)	(0.65)	(1.02)	(3.07)	(1.89)
Net loss attributable to common stockholders	(0.34)	(0.66)	(1.49)	(3.07)	(1.93)
As of December 31,					
	2005	2004	2003	2002	2001
(in thousands)					
<b>Balance Sheet Data:</b>					
Total assets	\$5,416	\$15,696	\$20,972	\$14,565	\$17,498
Long–term obligations, net of discounts	7,643	2,584	5,929	4,643	1,349

## **Item 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion contains forward–looking statements concerning our liquidity, capital resources, financial condition, results of operation and timing of anticipated revenues and expenditures. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Factors that could cause or contribute to such differences include those discussed under “Risk Factors,” as well as those discussed elsewhere in this Form 10–K. The following discussion should be read in conjunction with our financial statements and notes thereto included elsewhere in this Form 10–K. Except for our ongoing obligation to disclose material information as required by federal securities laws, we undertake no obligation to publicly release the result of any revisions to these forward–looking statements that may be indicated in order to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

### **Overview**

We are an immuno–pharmaceutical company whose products are in the development stage. We have a critical need to raise cash both in the near term and the medium term. Nonetheless, we believe our products could prove to have substantial value as part of a therapy for patients infected with MS or HIV.

## Liquidity and Capital Resources

We have had to engage in several financing transactions in 2006 and 2005 (as well as prior years) to obtain enough cash to maintain our operations.

As of December 31, 2005, we had an accumulated deficit of \$348,715,000. We have not generated revenues from the commercialization of any product. We expect to continue to incur substantial net operating losses over the next several years, which would imperil our ability to continue operations. We may not be able to generate sufficient product revenue to become profitable on a sustained basis, or at all, and do not expect to generate significant product revenue before the beginning of 2012, if at all. We have operating and liquidity concerns due to our significant net losses and negative cash flows from operations. As a result of these and other factors, our independent registered public accountants, Levitz, Zacks & Ciceric, indicate, in their report on the 2005 financial statements, that there is substantial doubt about our ability to continue as a going concern. We believe, in fact, that although we were essentially out of cash at December 31, 2005, our current cash resources, including the Private Placement of \$8,000,000 in convertible debt completed in March 2006, are sufficient to fund our planned operations through the third quarter of 2006. We will need to raise additional capital before the third quarter of 2006. In 2005 our common stock was delisted from the Nasdaq SmallCap Market.

Since our inception in 1986, we have financed our activities primarily from public and private sales of equity, funding from collaborations with corporate partners, investment income and the issuance of capital stock, convertible notes and warrants to Cornell Capital Partners, LP ("Cornell Capital") and Cheshire Associates LLC ("Cheshire") and other entities affiliated with or related to Kevin Kimberlin, who is one of our directors and our principal stockholder.

On July 15, 2005, we entered into a \$15,000,000 Standby Equity Distribution Agreement ("SEDA") with Cornell Capital. Under the agreement, Cornell Capital committed to provide up to \$15,000,000 of funding to be drawn down over a 24-month period at our discretion, subject to an effective registration. The maximum amount of each draw is \$500,000, and there must be at least five trading days between draws. The SEDA prohibits us from, during its term, issuing securities in an equity financing without the consent of Cornell Capital, which consent is not to be unreasonably withheld.

Through December 31, 2005, we had made twelve draws under the SEDA for net proceeds of \$3,461,500 and issued 11,182,484 shares of common stock at an average price per share of \$0.3095. There are currently no registered shares available for further use of the remaining portion of the SEDA. We do not anticipate using the SEDA for our future financing needs. Under the SEDA and Nasdaq rules, we were required to obtain stockholder approval before drawing down the bulk of the SEDA funding. We received such stockholder approval on September 27, 2005.

We also issued 725,353 shares of common stock to Cornell Capital as a one-time commitment fee, and we issued 14,085 shares of common stock to Monitor Capital, Inc. as a placement agent fee. We registered for resale, on Form S-1, the shares of common stock which were sold to Cornell Capital under the SEDA, and the shares issued as a commitment fee and the placement agent fee.

On August 4, 2005, we borrowed \$1,000,000 in cash from Cornell Capital against a convertible debenture (the "Debenture"). The outstanding principal balance must be repaid in equal monthly installments beginning in October 2005 and ending on August 4, 2006 and bears 12% interest per annum, payable monthly.

The Debenture is secured by substantially all our assets plus a pledge of a substantial amount of stock. The outstanding principal amount of the Debenture is now convertible, at the holder's option, into our common stock at a conversion price of \$0.02.

In addition, we issued 500,000 common stock warrants, exercisable for five years at an exercise price of \$0.924 per share, to Cornell Capital in connection with the Debenture. These warrants are now exercisable for 23,100,000 shares at \$0.02 per share. We could raise an additional \$462,000 if all the 23,100,000 warrants issued to Cornell Capital in connection with the August 2005 Debenture are exercised for cash. However, there is no assurance that all or any portion of the warrants will be exercised by Cornell Capital or by any subsequent holders. Finally, we paid Cornell Capital a commitment fee of \$100,000 cash in connection with the Debenture. We also paid Cornell Capital a \$10,000 structuring fee, in cash.

On April 29, 2005, we entered into a Note Exchange Agreement with Cheshire to exchange 8% Convertible Secured Promissory Notes with outstanding principal amounts totaling \$5,741,000 (the "8% Notes"), previously issued by us, for a new secured 2007

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Mortgage Note with a principal amount of \$5,741,000 (the "Mortgage Note"). In connection with this agreement, Cheshire converted a separate convertible promissory note, which had a maturity date of May 3, 2005 and an outstanding principal amount of \$1,467,000, into 1,007,000 shares of our common stock at a conversion price of \$1.457 per share. All of the notes bore interest at a fixed rate of 8% per year and were secured by our intellectual property.

In addition, pursuant to the agreement, we paid all accrued interest as of April 29, 2005 on the 8% Notes and on the converted note. This constituted a prepayment, as such interest had not been due until the original maturity dates of the 8% Notes and the converted note. Aggregate interest paid was \$1,340,000. Also, the notes exchange and the note conversion transactions resulted in a non-cash charge to operations in the second quarter of 2005 for \$1,201,000 representing beneficial inducement cost.

On September 21, 2005, we entered into and closed a Shares Exchange Agreement with Cheshire to exchange Cheshire's 688,146 shares of our Series A Convertible Preferred Stock (the "Preferred Shares"), previously issued by us, for 9,643,060 newly-issued shares of our common stock. These newly-issued shares also included payment for all accumulated dividends of \$637,000 on the Preferred Shares in the form of 1,385,308 shares of common stock.

The Shares Exchange Agreement transaction resulted in a non-cash charge to net loss attributable to common stockholders in the third quarter of 2005 for \$950,000 representing beneficial inducement cost.

As of December 31, 2005, we had outstanding approximately \$5,354,000 (net of discount of \$694,000, plus accrued interest of \$307,000) of convertible, related party secured debt, namely the Mortgage Note. Under the terms of the agreement, the Mortgage Note has the same terms and conditions as the 8% Notes had, except that (a) the 8% Notes would have matured at various dates in 2005, but the Mortgage Note has a maturity date of May 31, 2007, and (b) the Mortgage Note has a conversion price, subject to possible future adjustment, of \$0.70 per share (the closing price of our common stock on April 29, 2005). At this conversion price, the Mortgage Note will be convertible into 8,201,000 shares of common stock. The 8% Notes had higher conversion prices. The agreement also involved a reduction, to \$0.70 per share, of the exercise prices of the associated warrants that were previously issued with the 8% Notes. Furthermore, as part of the agreement, Cheshire waived all anti-dilution protection under the Mortgage Note and these warrants for the \$15,000,000 SEDA financing that we obtained from Cornell Capital.

On February 8, 2006 we entered into and consummated a Note Exchange Agreement and a Note Revision Agreement with Cheshire. These agreements pertained to the Mortgage Note previously issued by us and held by Cheshire, with a principal balance (before the agreements) of \$5,740,928. Under the Note Exchange Agreement, we issued 53,425,204 shares of newly-issued common stock to Cheshire in exchange for \$1,005,683 of principal of, and \$62,821 of accrued interest on, the Mortgage Note.

This transaction resulted in antidilution adjustments under the terms of some of the outstanding derivative securities. Most notably, as a result of "ratchet" antidilution provisions in the Debenture and common stock warrants held by Cornell Capital, the conversion price and exercise price of those securities were reduced to \$0.02 per share. As a result the \$500,000 outstanding principal balance of the Debenture, which had previously been convertible into 791,765 shares of common stock (at \$0.6315 per share), became convertible into 25,000,000 shares of common stock; and the warrants, which had previously been exercisable for 500,000 shares of common stock (at \$0.924 per share), became exercisable for 23,100,000 shares of common stock.

We no longer have enough authorized but unissued shares of common stock to enable the conversion or exercise of Cornell Capital's securities for these expanded numbers of shares of common stock. Indeed, the Note Exchange Agreement issuance necessitated even invading the share reserves which had been previously established to underlie most of our derivative securities, other than Cornell Capital's previously-established share reserves.

Under the Note Revision Agreement, the maturity date of the Mortgage Note was extended from May 31, 2007 to January 1, 2009 and in consideration for that extension we reduced the conversion price of the remaining \$4,735,245 principal amount of the Mortgage Note to \$0.02 per share of common stock. Accrued interest on the Mortgage Note will also be convertible at \$0.02 per share of common stock. Before the Note Exchange Agreement, the conversion price of the Mortgage Note had been \$0.70 per share. The difference between conversion of \$4,735,245 at \$0.70 per share and conversion of \$4,735,245 at \$0.02 per share is 229,997,599 additional shares of common stock. We no longer have enough authorized but unissued shares of common stock to enable the conversion of the Mortgage Note into this expanded number of shares of common stock.

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On February 9, 2006, in exchange for \$250,000 cash, we issued to Qubit Holdings, LLC ("Qubit"), which is owned and managed by independent trustees for the children of Mr. Kimberlin, a \$250,000 promissory note, secured by substantially all of our assets, bearing interest at 8% per annum, maturing on January 1, 2008, and convertible into our common stock at \$0.02 per share, plus 37,500,000 short-term warrants to purchase our common stock at \$0.02 per share. Qubit also granted us the right to, until August 8, 2006, put to Qubit another \$250,000 secured convertible note of like tenor and another 37,500,000 short-term warrants of like tenor, and to thereupon receive another \$250,000 cash. We no longer have enough authorized but unissued shares of common stock to enable the conversion or exercise of the derivative securities issued or issuable to Qubit.

Our 2006 Private Placement of secured convertible notes and warrants to accredited investors, which began on February 10, 2006 and successfully raised gross proceeds of \$8,000,000, had its final closing on March 7, 2006. In the 2006 Private Placement, pursuant to subscription agreements, we issued notes with an aggregate principal amount of \$8,000,000, convertible into an aggregate of 400,000,000 shares of common stock at \$0.02 per share. The notes mature on January 1, 2008, bear interest at 8% per annum, and share (with Cheshire, Cornell Capital and Qubit, for their previously secured notes), a first-priority security interest in substantially all of our assets. The first \$6,000,000 of the 2006 Private Placement notes sold (other than to our directors) are further supported by a guaranty limited to the value of the proceeds of certain shares of private-company preferred stock owned by Spencer Trask Intellectual Capital Company LLC, an affiliate of Kevin Kimberlin. In addition, we issued to all of the noteholders a total of 1,200,000,000 warrants to purchase our common stock at \$0.02 per share. These warrants will expire in two tranches, with the last tranche expiring 160 days after a registration statement, with regard to the common shares underlying them, is declared effective by the SEC.

We could raise an additional \$21,600,000 if all the warrants issued in our 2006 Private Placement are exercised for cash. However, there can be no assurances that all or any portion of the warrants will be exercised by the initial purchasers or by any subsequent holders.

We currently do not have enough authorized but unissued shares of common stock to allow for conversion or exercise of our outstanding derivative securities, or of any equity securities which we might try to offer in any future financings. Therefore it is essential to our ability to carry on that we amend our certificate of incorporation to increase the number of authorized shares of common stock manyfold. We are seeking stockholder approval for such an amendment.

As we use our current cash balances, we continue to look for alternative sources of funding which, even if available, may be on terms substantially less favorable. In any event, the SEDA prohibits us from, during its term, issuing securities in an equity financing without the consent of Cornell Capital, which consent is not to be unreasonably withheld. The Debenture contains a similar provision. If we are unable to raise adequate capital, we may be required to delay, or reduce the scope of, our research or development of NeuroVax™, IR103 and Remune®, or take other measures to cut costs, which would have a material adverse effect on us and likely result in our inability to continue as a going concern.

We will need to raise very substantial additional funds over several years to conduct research and development, preclinical studies and clinical trials necessary to bring potential products to market and to establish manufacturing and marketing capabilities. We anticipate that for the foreseeable future, the scale-up of the manufacturing process for NeuroVax™, IR103 and Remune® and the cost of producing clinical supplies for ongoing and future NeuroVax™, IR103 and Remune® studies will continue to represent a significant portion of our overall expenditures. Overall, future NeuroVax™, IR103 and Remune® research and development expenditures are expected to increase from current levels in the event additional financing is obtained. Future spending for research and development may further increase if we enter into additional collaborations, but there can be no assurance that we will enter into any such collaborations. We anticipate additional capital improvements of approximately \$2,000,000 to scale-up and improve the manufacturing process for IR103 and Remune® through 2006. Other anticipated costs with respect to NeuroVax™, IR103 and Remune®, including investment in inventory, will depend on many factors including the need for additional clinical trials and other factors, which will influence our determination of the appropriate continued investment of our financial resources in these programs.

Our future capital requirements will depend on many factors including whether the 2006 warrants will be exercised by the initial purchasers or by any subsequent holders. Other capital requirement factors include continued scientific progress in our research and development programs, the scope and results of preclinical studies and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, the costs involved in paying any settlements or judgments in class actions, competing technological and market developments, the cost of manufacturing scale-up and inventories, effective commercialization activities and arrangements and other factors not within our control. We intend to seek additional funding through additional research and development agreements with suitable corporate collaborators



and through public or private financing, if available. However, we cannot provide assurance that such collaboration arrangements or any public or private financing will be available on acceptable terms, if at all. If we raise funds through future equity arrangements, significant further dilution to stockholders will result. Our 2006 Private Placement diluted the interest of our prior stockholders to an extreme degree.

## Results of Operations

### *Year Ended December 31, 2005 Compared to Year Ended December 31, 2004*

We recorded revenues for the twelve months ended December 31, 2005 of \$44,000 as compared to \$323,000 for the corresponding period in 2004. In September 2004, we transferred to NovaRx Corporation (“NovaRx”) our in–license rights to certain cancer–related technology and received an initial payment of \$150,000. We recognized this payment as revenue and fully recognized the remaining deferred revenue of \$121,000 for previous sublicense agreements with NovaRx. All other revenues were from the amortization of other multi–year out–licenses of technology. We expect no additional revenues earlier than the beginning of 2012, if at all unless they are earned through corporate collaborations or new research and development agreements. We have not received any revenues from the sale of products and do not expect to derive revenue from the sale of any products earlier than the beginning of 2012, if at all. This is an extension from previous best–case estimates, because of our decision to focus our HIV efforts on IR103 instead of on commencing a Phase III trial with Remune®.

Our research and development expenditures for the twelve months ended December 31, 2005 were \$10,485,000 as compared to \$12,900,000 for the corresponding period in 2004. The decrease in research and development expenses during 2005 is attributable to decreased HIV clinical development activity and manufacturing scale–up activities for Remune® and IR103 as compared to the corresponding periods in 2004; as well as the absence in 2005 of NeuroVax™ manufacturing costs incurred in the first quarter of 2004.

Expenses associated with our continued scale–up of the manufacturing process for IR103 and Remune®, the cost of producing clinical supplies for ongoing and future NeuroVax™, IR103 and Remune®, studies and additional clinical trials for NeuroVax™ are expected to increase during the next several quarters as we focus our financial resources on NeuroVax™ and IR103. There can be no assurance that we will be able to obtain other financing needed to continue our research and development efforts.

General and administrative expenses for the twelve months ended December 31, 2005 were \$3,739,000 as compared to \$4,678,000 for the corresponding period in 2004. These figures include \$(197,000) and \$206,000 of non–cash (benefit)/expense in 2005 and 2004, respectively, related to the repricing of employee stock options in 2003, all representing variable accounting for the repriced options. The reductions in general and administrative expenses year–to–year reflect ongoing cost containment efforts, including lower facilities, insurance and legal costs in 2005 as compared to 2004.

Interest expense decreased to \$2,020,000 for the twelve months ended December 31, 2005 as compared to \$2,968,000 for the corresponding period in 2004. The decrease is attributable to lower accretion of discount after entering into the Note Exchange Agreement, which extended the due dates of the debt we owe to Cheshire until May 31, 2007. Also during the second quarter of 2005, we converted approximately \$1,467,000 of debt we owe to Cheshire into common stock, but this reduction was offset by issuing the Debenture to Cornell Capital for \$1,000,000.

On September 21, 2005, we entered into and closed a Shares Exchange Agreement with Cheshire to exchange Cheshire’s 688,146 Preferred Shares, previously issued by us, for 9,643,000 newly–issued shares of our common stock. The newly–issued shares also included payment for all accumulated dividends of \$637,000 on the Preferred Shares in the form of 1,385,308 shares of common stock. The Shares Exchange Agreement transaction resulted in a \$950,000 charge to net loss attributable to common stockholders in the third quarter of 2005 representing beneficial inducement cost. This was a one–time, non–cash charge.

As part of the Note Exchange Agreement we entered into with Cheshire on April 29, 2005, we exchanged 8% Convertible Secured Promissory Notes with outstanding principal amounts totaling \$5,741,000, previously issued by us, for a new secured 2007 Mortgage Note with a principal amount of \$5,741,000. Also in connection with this agreement, Cheshire converted a separate convertible promissory note, which had a maturity date of May 3, 2005 and an outstanding principal amount of \$1,467,000, into 1,007,000 shares of our common stock at a conversion price of \$1.457 per share. The notes exchange and the note conversion transactions resulted in a \$1,201,000 charge to operations in the second quarter of 2005 representing beneficial inducement cost. This was a one–time, non–cash charge.

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Our net loss per share decreased during 2005 as a result of decreased operating expenses for research and development and general and administrative expenses from 2004; and the decrease is also attributable to lower beneficial inducement costs in 2005 of \$1,201,000 for common stock exchanged and \$950,000 for the conversion of the Series A convertible preferred versus beneficial inducement cost of \$4,923,000 and a charge for loss on the extinguishment of debt of \$4,935,000, both of which occurred during 2004. The decrease in net loss per share is compounded by the increase in our weighted average number of shares outstanding, due to several securities issuance transactions during 2005.

*Year Ended December 31, 2004 Compared to Year Ended December 31, 2003.*

We recorded revenues for the twelve months ended December 31, 2004 of \$323,000 as compared to \$66,000 for the corresponding period in 2003. In September 2004, we transferred to NovaRx Corporation (“NovaRx”) our in-license rights to certain cancer-related technology and received an initial payment of \$150,000. We recognized this payment as revenue and fully recognized the remaining deferred revenue of \$121,000 for previous sublicense agreements with NovaRx. We have no future contractual obligations under either the in-licensing or out-licensing agreements. NovaRx also agreed to pay us an additional \$900,000 due on or before August 2007. We will recognize this amount as revenue only upon collection, due to the uncertainty of NovaRx’s ability to pay the fee at this time. All other revenues were from the amortization of other multi-year out-licenses of technology.

Our research and development expenditures for the twelve months ended December 31, 2004 were \$12,900,000 as compared to \$11,100,000 for the corresponding period in 2003. The increase in research and development expenses is attributable to our increased HIV clinical development activity, manufacturing scale-up activities for Remune® and IR103 and the cost of acquiring clinical supplies of NeuroVax™.

General and administrative expenses for the twelve months ended December 31, 2004 were \$4,700,000 as compared to \$5,600,000 for the corresponding period in 2003. These figures include \$206,000 and \$439,000 of non-cash expense in 2004 and 2003 related to the repricing of employee stock options in 2003, all representing variable accounting for the repriced options. The reductions in general and administrative expenses year-to-year reflect ongoing cost containment efforts, including lower facilities, insurance and legal costs in 2004 as compared to 2003.

During 2003 we changed accounting systems and as a result wrote off \$438,000 related to the capitalized software carrying value of the replaced accounting system.

During May 2003, we disposed of excess assets, and in August 2003, we negotiated an early lease termination for our Carlsbad, California headquarters facility resulting in exit and disposal related costs of approximately \$1,400,000. During 2003, we recorded an additional charge of \$2,000,000 related to the estimated net rental expense of our vacant manufacturing facility in Pennsylvania.

Interest expense decreased to \$3,000,000 for the twelve months ended December 31, 2004 as compared to \$8,300,000 for the corresponding period in 2003. Actual interest paid decreased in 2004, net of non-cash accretion, due to the pay off of equipment debt in 2003. The decrease in 2004 from 2003 is due to an overall reduction in the level of debt.

In January 2004, Cheshire converted \$3,899,000 of convertible promissory notes into Series A Convertible Preferred stock, which resulted in additional beneficial inducement cost of \$4,923,000 and a charge for loss on the extinguishment of debt of \$4,935,000, both recognized upon conversion. These were one-time, non-cash charges.

Our net loss per share decreased during 2004 as a result of the decreased net loss (which decrease was, itself, almost entirely due to the absence in 2004 of the \$13,200,000 of deemed stock dividend in 2003) and by the increase in our weighted average number of shares outstanding, due to several securities issuance transactions, as compared to 2003.

### **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions in certain circumstances that affect amounts reported in the accompanying financial statements and related footnotes. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. However, application

of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. Historically, there have been no significant differences in estimates recorded for impairment of intangibles and long-lived assets or exit and disposal related costs. We do not believe there is a great likelihood that materially different amounts would be reported related to the accounting policies described below.

#### *Pro Forma Stock-Based Compensation*

We measure stock-based employee compensation using the intrinsic value method of accounting in accordance with Accounting Principles Board, APB, Opinion No. 25, "Accounting for Stock Issued to Employees." Because we establish the exercise price based on the fair market value of our common stock at the date of grant, the options have no intrinsic value upon grant, and therefore generally no expense is recorded. Equity instruments issued to non-employees for goods or services are accounted for at fair value and are marked to market until service is complete or a performance commitment date is reached.

As required under FAS No. 123, "Accounting for Stock-Based Compensation," and FAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," the pro forma effects of stock-based compensation on net loss and net loss per common share have been estimated at the date of grant using the Black-Scholes option-pricing model. As of December 31, 2005, no revisions to the assumptions used in the Black-Scholes option-pricing model have been made.

In December 2004, the FASB issued FAS No. 123R, "Share-Based Payment." This statement is a revision to FAS No. 123, "Accounting for Stock-Based Compensation," and it supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends FAS No. 95, "Statement of Cash Flows." Generally the approach in FAS No. 123R is similar to the approach described in FAS No. 123. However, FAS No. 123R will require all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values.

FAS No. 123R must be adopted no later than January 1, 2006. We will be adopting FAS No. 123R on January 1, 2006. FAS No. 123R permits public companies to adopt its requirements using one of two methods, the modified prospective or the modified retrospective method. We have chosen to adopt the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of FAS No. 123 for all awards granted to employees before the effective date of FAS No. 123R that remain unvested on the effective date.

As permitted by FAS No. 123, we currently account for share-based payments to employees using APB Opinion No. 25's intrinsic value method; and as such, we generally recognize no compensation cost for employee stock options. Accordingly, the adoption of FAS No. 123R's fair value method will have a material impact on our results of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because it will depend in part on levels of share-based payments granted in the future. However, had we adopted FAS No. 123R in prior periods using the Black-Scholes valuation model, the impact of that standard would have approximated the impact of FAS No. 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1 to our financial statements.

#### *Intangibles and Other Long-Lived Assets*

We believe that patents and other proprietary rights are important to our business. Licensed technology is recorded at cost and is amortized over its estimated useful life. In December 1999, we acquired licenses to certain patent technology, which are being amortized over seven years. Changes in our estimates of useful lives may have a material effect on our financial statements.

We evaluate potential impairment of long-lived assets in accordance with FAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." FAS No. 144 requires that certain long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable based on expected undiscounted cash flows that result from the use and eventual disposition of the asset. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset.

The Company tests fixed assets and licensed technology annually for impairment and in interim periods if certain events occur that might affect the carrying value of a long-lived asset. For 2005 and 2004, the Company determined that no impairment adjustment was required for fixed assets or licensed technology.

### Exit and Disposal Costs

During May 2003, we disposed of excess assets, and during August 2003, we negotiated an early lease termination for our former vacated headquarters facility in southern California, resulting in exit and disposal related costs of approximately \$1,400,000. During 2003, we recorded an additional charge of \$2,000,000 related to the estimated net rental expense of our vacant manufacturing facility in Pennsylvania. These costs have been accounted for in accordance with Emerging Issues Task Force 94-3.

### Contractual Obligations and Commitments

The following table quantifies our future contractual obligations and commitments as of December 31, 2005 (amounts in thousands):

	Payments due by year						Total
	2006	2007	2008	2009	2010	Thereafter	
Operating leases	\$ 1,210	\$ 1,246	\$ 1,076	\$ 1,005	\$ 1,035	\$ 885	\$ 6,457
Short-term Convertible Debenture (1)	856						856
Convertible Promissory Note, related party (2)		6,699					6,699
Total	\$2,066	\$7,945	\$1,076	\$ 1,005	\$ 1,035	\$ 885	\$14,012

- (1) Short-term Convertible Debenture is convertible into our common stock at the option of the holder; amounts include accrued and future interest.
- (2) Convertible Promissory Note, related party is convertible into our common stock at the option of the holder; amounts include accrued and future interest.

In February 2006, the obligations and commitments under the Convertible Promissory Note, related party were reduced to \$4,735,000 and deferred to a 2009 maturity date. In addition, in the 2006 Private Placement we issued convertible promissory notes which (including accrued and future interest) would represent an obligation of \$9,488,000 payable in 2008.

### Recent Accounting Pronouncements

In December 2004, the FASB issued FAS No. 123R, "Share-Based Payment." This statement is a revision to FAS No. 123, "Accounting for Stock-Based Compensation," it supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends FAS No. 95, "Statement of Cash Flows." Generally the approach in FAS No. 123R is similar to the approach described in FAS No. 123. However, FAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements.

FAS No. 123R must be adopted no later than January 1, 2006. We will be adopting FAS No. 123R on January 1, 2006. FAS No. 123R permits public companies to adopt its requirements using one of two methods, the modified prospective or the modified retrospective method. We have chosen to adopt the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of FAS No. 123 for all awards granted to employees before the effective date of FAS No. 123R that remain unvested on the effective date.

As permitted by FAS No. 123, we currently account for share-based payments to employees using APB Opinion No. 25's intrinsic value method; and as such, we generally recognize no compensation cost for employee stock options. Accordingly, the adoption of FAS No. 123R's fair value method will have a material impact on our results of operations, although it will have no impact on our overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because it will depend in part on levels of share-based payments granted in the future. However, had we adopted FAS No. 123R in prior periods using the Black-Scholes valuation model, the impact of that standard would have approximated the impact of FAS No. 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1 to our financial statements.

FAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. We cannot estimate what those

amounts will be in the future (because they depend on, among other things, when employees exercise stock options, and whether we will be in a taxable position). There is no tax impact related to the prior periods since we are in a net loss position.

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We invest our excess cash primarily in U.S. government securities and money market accounts. These instruments have maturities of two years or less when acquired. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions. Furthermore, our debt is at fixed rates. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

**Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**Item 9A. CONTROLS AND PROCEDURES**

Joseph O'Neill, our principal executive officer, and Michael Green, our principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Securities Exchange Act Rule 13a-15(e)) have concluded that, as of December 31, 2005, our disclosure controls and procedures are effective.

**Item 9B. OTHER INFORMATION**

Not applicable.

**PART III**

**Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information required by this item (other than biographical information with respect to executive officers) is incorporated by reference from the information under the captions "Election of Directors" and "Other Matters" contained in our 2006 Annual Meeting Proxy Statement to be filed with the Securities and Exchange Commission. Biographical information regarding executive officers is contained in Part I of this Form 10-K. Information regarding Section 16 reporting compliance is incorporated by reference to such Proxy Statement under the heading "Section 16 Beneficial Ownership Reporting Compliance." Information regarding our code of ethics is incorporated by reference to such Proxy Statement under the heading "Code of Ethics."

**Item 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference from the information under the captions "Election of Directors" and "Other Matters" contained in our 2006 Annual Meeting Proxy Statement to be filed with the Securities and Exchange Commission.

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item is incorporated by reference from the information under the captions “Election of Directors” and “Other Matters” contained in our 2006 Annual Meeting Proxy Statement to be filed with the Securities and Exchange Commission.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information required by this item is incorporated by reference from the information under the captions “Election of Directors” and “Other Matters” contained in our 2006 Annual Meeting Proxy Statement to be filed with the Securities and Exchange Commission.

**Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference from the information under the caption “Relationship with Auditors” contained in our 2006 Annual Meeting Proxy Statement to be filed with the Securities and Exchange Commission.

**PART IV**

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) (1) Financial Statements

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

Financial Statements of The Immune Response Corporation

Reports of Independent Registered Public Accounting Firms	F-2
Balance Sheets at December 31, 2005 and 2004	F-4
Statements of Operations for the three years ended December 31, 2005	F-5
Statements of Stockholders’ (Deficit) Equity and Comprehensive Loss for the three years ended December 31, 2005	F-6
Statements of Cash Flows for the three years ended December 31, 2005	F-7
Notes to Financial Statements	F-8

(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or the notes thereto.

(3) Exhibits

<b>Exhibit</b>	<b>Description</b>
3(i) (20)	Integrated copy of the Restated Certificate of Incorporation, as amended.
3(ii) (1)	Restated Bylaws.
10.28 (2)**	Form of Indemnification Agreement entered into between us and our officers and directors.
10.47 (3)	Rights Agreement dated February 26, 1992, between us and First Interstate Bank, Ltd., as Rights Agent.

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<u>Exhibit</u>	<u>Description</u>
10.61 (7)	Amendment No. 1 to Rights Agreement (Exhibit 10.47) dated April 17, 1997, between us and Harris Trust Company of California.
10.73 (5)	Lease dated November 1, 1999 by and between us and Brandywine Operating Partnership, L.P.
10.74 (4)	Lease dated May 22, 2000 by and between us and Brandywine Operating Partnership, L.P.
10.79 (6)	Note Purchase Agreement dated as of November 9, 2001, between us and Kevin Kimberlin Partners, L.P.
10.81 (6)	Warrant Agreement dated as of November 9, 2001, between us and Kevin Kimberlin Partners, L.P.
10.82 (6)	Intellectual Property Security Agreement dated as of November 9, 2001, between us and Kevin Kimberlin Partners, L.P.
10.83 (7)	Amendment No. 2 to Rights Agreement (Exhibit 10.47) dated December 20, 2001, between us, Harris Trust and Savings Bank (successor agent to Mellon Investor Services, which was successor agent to ChaseMellon Shareholder Services, L.L.C., which was successor agent to First Interstate Bank, Ltd.) and Computershare Trust Company, Inc. as successor Rights Agent.
10.84 (8)	Amendment No. 1 dated February 14, 2002 to Note Purchase Agreement, dated as of November 9, 2001, between us, Kevin Kimberlin Partners, L.P. and Oshkim Limited Partnership.
10.86 (8)	Warrant Agreement dated as of February 14, 2002, between us and Oshkim Limited Partnership.
10.87 (8)	Amendment No. 1 dated February 14, 2002 to Intellectual Property Security Agreement dated as of November 9, 2001, between us, Kevin Kimberlin Partners, L.P. and Oshkim Limited Partnership.
10.88 (9)	Amendment No. 3 to Rights Agreement dated as of February 20, 2002, between us and Computershare Trust Company, Inc. (successor agent to Harris Trust and Savings Bank, which was successor agent to Mellon Investor Services, which was successor agent to ChaseMellon Shareholder Services, L.L.C., which was successor agent to First Interstate Bank Ltd.).
10.90 (10)	Amendment No. 2 dated May 3, 2002 to the Note Purchase Agreement dated as of November 9, 2001, between us, Kevin Kimberlin Partners, L.P. and Oshkim Limited Partnership.
10.91 (10)	8% Convertible Promissory Note dated May 3, 2002 issued to Oshkim Limited Partnership (as subsequently amended pursuant to Exhibit 10.169).
10.92 (10)	Warrant Agreement dated as of May 3, 2002 between us and Oshkim Limited Partnership (as subsequently amended pursuant to Exhibit 10.169).
10.95 (11)	Amendment No. 3 dated July 11, 2002 to the Note Purchase Agreement dated as of November 9, 2001, between us, Kevin Kimberlin Partners, L.P., Oshkim Limited Partnership and The Kimberlin Family 1998 Irrevocable Trust.
10.98 (11)	8% Convertible Secured Promissory Note dated July 30, 2002 issued to The Kimberlin Family 1998 Irrevocable Trust (as subsequently amended pursuant to Exhibit 10.123).
10.99 (11)	Warrant Agreement dated as of July 30, 2002 between us and The Kimberlin Family 1998 Irrevocable Trust (as subsequently amended pursuant to Exhibit 10.169).
10.100 (11)	Amendment No. 2 dated July 11, 2002 to the Intellectual Property Security Agreement dated as of November 9, 2001, between us, Kevin Kimberlin Partners, L.P., Oshkim Limited Partnership and The Kimberlin Family 1998 Irrevocable Trust.

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<u>Exhibit</u>	<u>Description</u>
10.102 (12)	Letter Agreement dated August 8, 2002 between us and Kevin Kimberlin Partners, L.P., Oshkim Limited Partnership and the Kimberlin Family 1998 Irrevocable Trust.
10.113 (12)	8% Convertible Secured Promissory Note dated November 12, 2002 issued to Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.114 (12)	Warrant Agreement dated as of November 12, 2002 between us and Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.115 (13)	Warrant Agreement dated December 10, 2002, by and between us and Computershare Trust Company as Warrant Agent.
10.116 (13)	Purchase Agreement dated December 10, 2002 by and between us and purchasers of the Private Placement of the Unit Purchase Options.
10.117 (19)	8% Convertible Secured Promissory Note dated as of November 15, 2002 issued to Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.118 (19)	Warrant Agreement dated as of November 15, 2002, between us and Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.119 (19)	8% Convertible Secured Promissory Note dated as of November 20, 2002 issued to Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.120 (19)	Warrant Agreement dated as of November 20, 2002, between us and Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.121 (19)	8% Convertible Secured Promissory Note dated as of November 27, 2002 issued to Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.122 (19)	Warrant Agreement dated as of November 27, 2002, between us and Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.123 (19)	8% Convertible Secured Promissory Note dated as of December 10, 2002 issued to Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.124 (19)	Warrant Agreement dated as of December 10, 2002, between us and Cheshire Associates LLC (as subsequently amended pursuant to Exhibit 10.169).
10.129 (14)	Amendment No. 3 to the License and Collaboration Agreement dated September 29, 2000 between us and Trinity Medical Group USA, Inc.
10.130 (14)	Amendment No. 2 to the License and Collaboration Agreement dated September 29, 2000 between us and Trinity Medical Group USA, Inc.
10.131 (15)	Amendment No. 1 to the License and Collaboration Agreement dated September 29, 2000 between us and Trinity Medical Group USA, Inc.
10.132 (16)	Assignment Agreement between Trinity Medical Group, Ltd. and Trinity USA dated August 3, 2000.
10.133 (17)	License and Collaboration Agreement between Trinity Medical Group, Ltd. and us dated September 15, 1995.
10.134 (14)	Amendment No. 1 to Stock Purchase Agreement between Trinity Medical Group, Ltd. and us dated September 15, 1995.



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<b>Exhibit</b>	<b>Description</b>
10.135 (18)	Stock Purchase Agreement between Trinity Medical Group, Ltd. and us dated September 15, 1995.
10.145 (20)	Securities Purchase Agreement dated October 10, 2003 by and between us and the purchasers identified in the signature pages thereto.
10.146 (20)	Registration Rights Agreement dated October 10, 2003 by and between us and the purchasers identified in the signature pages thereto.
10.147 (20)	Warrants dated as of October 10, 2003 issued to Rodman & Renshaw, Inc.
10.148 (20)	Warrant dated as of October 10, 2003 issued to Cardinal Securities, LLC.
10.149 (21)**	Stock Option Agreement, dated January 13, 2003, by and between us and John N. Bonfiglio, Ph.D.
10.150 (21)**	The Immune Response Corporation 2003 Stock Plan.
10.150.1 (31)**	2003 Stock Plan, as amended through June 14, 2005.
10.151 (22)	Amendment No. 4 to Rights Agreement dated as of April 1, 2003, between us and Computershare Trust Company, Inc.
10.152 (23)**	Employment Agreement by and between us and John N. Bonfiglio (as subsequently continued pursuant to Exhibit 10.165).
10.153 (23)**	Employment Agreement by and between us and Michael K. Green.
10.154 (23)**	Amendment to Employment Agreement by and between us and Michael K. Green.
10.155 (24)	Lease dated December 15, 1997 by and between us and The Childs Family Investment Partnership, L.P. and the A.J. Gardner Family Trust, U/T/A 3/5/81.
10.156 (25)	Securities Purchase Agreement dated as of April 29, 2004 by and between us and the purchasers identified in the signature pages thereto.
10.157 (25)	Form of Warrant (included in Exhibit 10.156).
10.158 (25)	Registration Rights Agreement dated as of April 29, 2004 by and between us and the purchasers identified in the signature pages thereto.
10.159 (27)	Framework Agreement, effective as of August 16, 2004, between The Immune Response Corporation and NovaRx Corporation.
10.160 (27)	Novation Agreement, effective as of August 16, 2004, by and between us, NovaRx Corporation and Sidney Kimmel Cancer Center.
10.161 (27)	Novation Agreement, effective as of August 16, 2004, by and between us, NovaRx Corporation and Masayoshi Namba, M.D.
10.162 (26)**	The Immune Response Corporation 401(k) Stock Match Plan.
10.162.1 (32)**	401(k) Stock Match Plan, as amended June 14, 2005.
10.163 (28)**	Stock Option Grant Notice and Agreement dated December 1, 2004 by and between us and John N. Bonfiglio.

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<b>Exhibit</b>	<b>Description</b>
10.164 (28)**	Discretionary Bonus Plan Awards dated December 1, 2004 as granted to the named executive officers.
10.165 (28)**	Letter Agreement for continued employment by and between us and John N. Bonfiglio dated December 20, 2004.
10.166 (28)**	Stock Option Grant Notices and Agreement dated December 20, 2004 by and between us and John N. Bonfiglio.
10.167 (28)**	Letter Agreement dated February 3, 2005 between us and Robert E. Knowling, Jr.
10.168 (28)**	Inducement Stock Option Grant Notice and Inducement Stock Option Grant Agreement dated February 9, 2005 between us and Robert E. Knowling, Jr.
10.168.1 (30)**	Termination of Inducement Stock Option.
10.169 (29)	Note Exchange Agreement dated as of April 29, 2005 between us and Cheshire Associates LLC.
10.170 (33)	Standby Equity Distribution Agreement dated July 15, 2005 between us and Cornell Capital Partners, LP.
10.171 (33)	Placement Agent Agreement dated July 15, 2005 between us, Monitor Capital, Inc. and Cornell Capital Partners, LP.
10.172 (33)	Escrow Agreement dated July 15, 2005 between us, Cornell Capital Partners, LP and David Gonzalez, Esq.
10.173 (33)	Registration Rights Agreement dated July 15, 2005 between us and Cornell Capital Partners, LP.
10.174 (34)	Securities Purchase Agreement dated August 4, 2005 between us and Cornell Capital Partners, LP.
10.175 (34)	Secured Convertible Debenture dated August 4, 2005 in favor of Cornell Capital Partners, LP.
10.176 (34)	Warrant dated August 4, 2005 in favor of Cornell Capital Partners, LP.
10.177 (34)	Security Agreement dated August 4, 2005 between us and Cornell Capital Partners, LP.
10.178 (34)	Investor Registration Rights Agreement dated August 4, 2005 between us and Cornell Capital Partners, LP.
10.179 (34)	Pledge and Escrow Agreement dated August 4, 2005 between us, Cornell Capital Partners, LP and David Gonzalez, Esq.
10.180 (34)	Insider Pledge and Escrow Agreement dated August 4, 2005 between us, Cornell Capital Partners, LP, Cheshire Associates LLC and David Gonzalez, Esq.
10.181 (34)	Pledge Inducement Agreement dated August 4, 2005 between us and Cheshire Associates LLC.
10.182 (34)	Warrant Agreement dated August 4, 2005 between us and Cheshire Associates LLC.
10.183 (35)	Shares Exchange Agreement, dated as of September 21, 2005, between us and Cheshire Associates LLC.
10.184 (35)	Antidilution Amendment/Waiver Re Shares Exchange Agreement, dated as of September 21, 2005, from Cornell Capital Partners, LP.

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<b>Exhibit</b>	<b>Description</b>
10.185 (36)	Pledge and Escrow Agreement dated September 30, 2005 between us, Cornell Capital Partners, LP and David Gonzalez, Esq.
10.186 (37)**	Employment Letter Agreement dated October 26, 2005, and effective October 31, 2005 between us and Dr. Joseph F. O'Neill.
10.187 (37)**	Inducement Stock Option Grant Notice and Option Agreement dated October 31, 2005 between us and Dr. Joseph F. O'Neill.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on Signature Page).
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(a).
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(a).
32.1	Certification pursuant to Section 1350 of Chapter 63 of 18 U.S.C. as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(b).
32.2	Certification pursuant to Section 1350 of Chapter 63 of 18 U.S.C. as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(b).

- (1) Incorporated by reference to Exhibit 4.2 to our Registration Statement on Form S–8, No. 33–62940.
- (2) Incorporated by reference to the exhibits of the same number to our Registration Statement on Form S–1, No. 33–31057.
- (3) Incorporated by reference to Exhibit 5.1 to our Report on Form 8–K filed March 4, 1992.
- (4) Incorporated by reference to the Exhibit of the same number filed with our June 30, 2000 Form 10–Q.
- (5) Incorporated by reference to the Exhibits of the same number filed with our December 31, 1999 Form 10–K.
- (6) Incorporated by reference to Exhibits 4.1, 4.2, 4.3 and 10.1 filed with our 8–K dated November 14, 2001.
- (7) Incorporated by reference to Exhibits 4.2 and 4.3 filed with our Registration Statement on Form 8–A dated December 26, 2001.
- (8) Incorporated by reference to Exhibits 4.1, 4.2, 4.3 and 10.1 filed with our Form 8–K dated February 14, 2002.
- (9) Incorporated by reference to Exhibit 4.4 filed with our Registration Statement on Form 8–A dated February 21, 2002.
- (10) Incorporated by reference to the Exhibit of similar name filed with our March 31, 2002 Form 10–Q.
- (11) Incorporated by reference to the Exhibit of the same number filed with our June 30, 2002 Form 10–Q.
- (12) Incorporated by reference to the Exhibit of the same number filed with our September 30, 2002 Form 10–Q.
- (13) Incorporated by reference to Exhibits 4.2 and 10.1 to our Registration Statement on Form S–3, No. 33–101856.
- (14) Incorporated by reference to Exhibits 10.1, 10.2 and 10.6 filed with our Form 8–K dated June 26, 2002.
- (15) Incorporated by reference to Exhibit 10.3 to Amendment No. 1 to Form SB–2 filed by Trinity Medical Group USA, Inc. on December 22, 2000 with the SEC.
- (16) Incorporated by reference to Exhibit 10.4 to Amendment No. 1 to Form SB–2 filed by Trinity Medical Group USA, Inc. on December 22, 2000 with the SEC.
- (17) Incorporated by reference to Exhibit 10.7 to Amendment No. 1 to Form SB–2 filed by Trinity Medical Group USA, Inc. on December 22, 2000 with the SEC.
- (18) Incorporated by reference to Exhibit 10.8 to Amendment No. 1 to Form SB–2 filed by Trinity Medical Group USA, Inc. on December 22, 2000 with the SEC.
- (19) Incorporated by reference to the Exhibit of the same number filed with our December 31, 2002 Form 10–K.
- (20) Incorporated by reference to the Exhibit of the same number filed with our September 30, 2003 Form 10–Q.

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- (21) Incorporated by reference to Exhibits 10.1 and 10.2 filed with our Registration Statement on Form S-8, No. 333-103957.
- (22) Incorporated by reference to Exhibit 4.5 filed with our Registration Statement on Form 8-A dated October 28, 2003.
- (23) Incorporated by reference to the Exhibit of similar name filed with our December 31, 2003 Form 10-K.
- (24) Incorporated by reference to the Exhibit of the same number filed with our March 31, 2004 Form 10-Q.
- (25) Incorporated by reference to Exhibits 10.1, 10.2 and 10.3 filed with our Registration Statement on Form S-3, No. 333-115678.
- (26) Incorporated by reference to Exhibit 99.1 filed with our Registration Statement on Form S-8, No. 333-116826.
- (27) Incorporated by reference to the Exhibit of the same number filed with our Form 8-K dated September 2, 2004.
- (28) Incorporated by reference to the Exhibit of the same number filed with our December 31, 2004 Form 10-K.
- (29) Incorporated by reference to the Exhibit of the same number filed with our Form 8-K dated April 29, 2005.
- (30) Incorporated by reference to the Exhibit of the same number with our Form 8-K dated June 17, 2005.
- (31) Incorporated by reference to Exhibit 99.1 filed with our Registration Statement on Form S-8, No. 333-126829.
- (32) Incorporated by reference to Exhibit 99.1 filed with our Registration Statement on Form S-8, No. 333-126828.
- (33) Incorporated by reference to the Exhibits of the same numbers filed with our Registration Statement on Form S-1, No. 333-126833.
- (34) Incorporated by reference to the Exhibits of the same numbers filed with our Form 8-K dated August 9, 2005.
- (35) Incorporated by reference to the Exhibits of the same numbers filed with our Form 8-K dated September 21, 2005.
- (36) Incorporated by reference to the Exhibit of the same number filed with our Form 8-K dated September 27, 2005.
- (37) Incorporated by reference to the Exhibits of the same numbers filed with our September 30, 2005 Form 10-Q.

\*\* Indicates 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.

### THE IMMUNE RESPONSE CORPORATION

By: /s/ Michael K. Green  
Michael K. Green,  
Chief Operating Officer and Chief Financial  
Officer

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

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Joseph F. O'Neill and Michael K. Green his attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any amendments to this Report and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may do or cause to be done by virtue hereof.

<u>/s/ Robert E. Knowling, Jr.</u> Robert E. Knowling, Jr.	Chairman of the Board of Directors	March 28, 2006
<u>/s/ Joseph F. O'Neill</u> Joseph F. O'Neill	Chief Executive Officer, President and Director (Principal Executive Officer)	March 28, 2006
<u>/s/ Michael K. Green</u> Michael K. Green	Chief Operating Officer, Chief Financial Officer, Secretary (Principal Financial Officer and Principal Accounting Officer)	March 28, 2006
<u>/s/ Kevin B. Kimberlin</u> Kevin B. Kimberlin	Director	March 28, 2006
<u>/s/ James B. Glavin</u> James B. Glavin	Director	March 28, 2006
<u>/s/ Martyn Greenacre</u> Martyn Greenacre	Director	March 28, 2006
<u>/s/ Alan S. Rosenthal</u> Alan S. Rosenthal	Director	March 28, 2006
<u>/s/ Kevin L. Reilly</u> Kevin L. Reilly	Director	March 28, 2006
<u>/s/ David P. Hochman</u> David P. Hochman	Director	March 28, 2006

**Exhibit Index**

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31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(a).
32.1	Certification pursuant to Section 1350 of Chapter 63 of 18 U.S.C. as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(b).
32.2	Certification pursuant to Section 1350 of Chapter 63 of 18 U.S.C. as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(b).

**THE IMMUNE RESPONSE CORPORATION**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors  
And Stockholders of  
**The Immune Response Corporation**

We have audited the accompanying balance sheets of The Immune Response Corporation as of December 31, 2005 and 2004, and the related statements of operations, stockholders' (deficit) equity and comprehensive loss, and cash flows for each of the years in the two year period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of The Immune Response Corporation as of December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred net losses since inception, has an accumulated deficit of \$348,715,000, has a stockholders' deficit of \$5,650,000, and has a working capital deficiency of \$2,986,000 as of December 31, 2005. The Company has negative cash flows from operations and does not have, and does not expect to have for the foreseeable future, a product from which to generate revenue. These factors, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**/s/ LEVITZ, ZACKS & CICERIC**  
**Certified Public Accountants**  
San Diego, California  
March 17, 2006



## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of  
The Immune Response Corporation:

We have audited the accompanying consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for the year December 31, 2003 (which statements are incorporated herein by reference to the annual report to stockholders for the year ended December 31, 2003). These consolidated financial statements and schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedules based on our audits.

We conducted our audit 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 consolidated financial statements and schedules are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements and schedules, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and schedules. We believe that our audit provides a reasonable basis for our opinion.

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

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has historically reported substantial net losses and negative cash flows from operations, and to date has not produced and for the foreseeable future is not expected to produce a viable product from which to generate revenues. These matters raise serious liquidity concerns. As of December 31, 2003, the Company had an accumulated deficit of \$299,856,000. Management estimates that its available cash resources as of December 31, 2003 will be sufficient to fund planned operations through September 30, 2004. Management is also attempting to raise additional capital to fund its operations beyond September 30, 2004. These operating and liquidity issues, amongst other concerns, raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

/s/ BDO Seidman, LLP

Costa Mesa, California  
February 27, 2004

**THE IMMUNE RESPONSE CORPORATION**  
**BALANCE SHEETS**  
(in thousands, except for share amounts)

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 146	\$ 8,798
Prepaid expenses	<u>291</u>	<u>364</u>
Total current assets	437	9,162
Property and equipment, net	3,583	4,431
Licensed technology, net	706	1,413
Deposits and other assets (\$600 restricted as security for letter of credit)	<u>690</u>	<u>690</u>
	<u>\$ 5,416</u>	<u>\$ 15,696</u>
<b>Liabilities and Stockholders' (Deficit) Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,039	\$ 494
Accrued expenses	1,753	1,316
Short-term convertible debenture, net of discount of \$490 plus accrued interest of \$15 at December 31, 2005	325	—
Current portion of convertible promissory notes, related party, net of discount of \$1,807 plus accrued interest of \$1,151 at December 31, 2004	—	6,552
Current portion of deferred rent and accrued excess lease costs	274	212
Current portion of deferred revenue	<u>32</u>	<u>44</u>
Total current liabilities	<u>3,423</u>	<u>8,618</u>
Long-term deferred rent and accrued excess lease costs, net of current portion	2,160	2,423
Long-term deferred revenue, net of current portion	129	161
Convertible promissory notes, related party, net of discount of \$694 plus accrued interest of \$307 at December 31, 2005	5,354	—
Total long-term liabilities	<u>7,643</u>	<u>2,584</u>
Commitments and contingencies (Note 11)		
Stockholders' (deficit) equity:		
Preferred stock, \$.001 par value, 10,000,000 shares authorized; 688,146 Series A convertible shares issued and outstanding at December 31, 2004 with a liquidation preference aggregating \$4,484	—	13,952
Subscribed common stock	237	—
Common stock, \$.0025 par value, 170,000,000 shares authorized; 71,660,101 and 48,627,099 shares issued and outstanding at December 31, 2005 and 2004, respectively	179	122
Warrants	21,201	20,827
Additional paid-in capital	321,448	299,408
Accumulated (deficit)	<u>(348,715)</u>	<u>(329,815)</u>
Total stockholders' (deficit) equity	<u>(5,650)</u>	<u>4,494</u>
	<u>\$ 5,416</u>	<u>\$ 15,696</u>

See accompanying notes to financial statements.

**THE IMMUNE RESPONSE CORPORATION**  
**STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

	Years ended December 31,		
	2005	2004	2003
Revenues:			
Licensed research revenue	\$ 15	\$ 294	\$ 37
Contract research revenue	29	29	29
	<u>44</u>	<u>323</u>	<u>66</u>
Expenses:			
Research and development	10,485	12,900	11,140
General and administrative	3,739	4,678	5,587
Impairment loss	—	—	438
Exit and disposal related costs	—	—	3,428
	<u>14,224</u>	<u>17,578</u>	<u>20,593</u>
Other income and (expense):			
Interest expense — (primarily related party) including \$1,452, \$2,360 and \$7,065 of non-cash accretion in 2005, 2004 and 2003, respectively	(2,020)	(2,968)	(8,308)
Investment income	88	122	36
Beneficial inducement cost	(1,201)	(4,923)	—
Loss on extinguishment of debt	—	(4,935)	—
	<u>(3,133)</u>	<u>(12,704)</u>	<u>(8,272)</u>
Net loss	(17,313)	(29,959)	(28,799)
Deemed stock dividend	—	—	(13,251)
Less preferred stock dividends	(271)	(366)	—
Less preferred stock beneficial inducement cost	(950)	—	—
Net loss attributable to common stockholders	<u>\$(18,534)</u>	<u>\$(30,325)</u>	<u>\$(42,050)</u>
Basic and diluted loss per share:			
Net loss	<u>\$ (0.32)</u>	<u>\$ (0.65)</u>	<u>\$ (1.02)</u>
Net loss attributable to common stockholders	<u>\$ (0.34)</u>	<u>\$ (0.66)</u>	<u>\$ (1.49)</u>
Weighted average number of shares outstanding	<u>54,740</u>	<u>46,106</u>	<u>28,188</u>

See accompanying notes to financial statements.

**THE IMMUNE RESPONSE CORPORATION**  
**STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY AND COMPREHENSIVE LOSS**  
(in thousands)

	<u>Preferred Stock</u>		<u>Common Stock</u>			<u>Additional Paid-in</u>		<u>Accumulated Deficit</u>	<u>Total Stockholders' (Deficit) Equity</u>	<u>Comprehensive Income (Loss)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Warrants</u>	<u>Capital</u>	<u>Other</u>			
Balance at December 31, 2002		\$	19,671	\$ 49	\$13,684	\$250,656	\$ 2	\$(257,806)	\$ 6,585	
Issuance of common stock and warrants in private placement, net of issuance costs of \$1,278			6,002	15	5,356	5,351			10,722	
Conversion of convertible notes into common stock			1,613	4		4,996			5,000	
Conversion of convertible note into common stock for warrant exercise			1,775	4	(502)	2,859			2,361	
Induced exercise of warrants, net			5,217	13	(1,476)	7,938			6,475	
Warrants redeemed or cancelled			2,421	6	(710)	3,920			3,216	
Deemed stock dividend as a result of induced warrant exercise			3,496	9	1,364	11,878		(13,251)	0	
Equity issued in conjunction with consulting contracts			478		61	872			933	
Issuance of common stock in conjunction with debt issuance			167	1		384			385	
Issuance of common stock for employee stock plans			361	1		404			405	
Fair value for repriced						439			439	

employee stock options										
Fair value for options granted to nonemployees						649			649	
Change in unrealized gain on marketable securities							2		2	\$ 2
Net loss								(28,799)	(28,799)	(28,799)
Balance at December 31, 2003	0	0	41,201	102	17,777	290,346	4	(299,856)	8,373	<u>\$ (28,797)</u>
Conversion of convertible notes into Series A convertible preferred stock, net of issuance costs of \$24	688	13,952							13,952	
Issuance of common stock and warrants in private placement, net of issuance costs of \$1,946			6,771	17	3,374	7,318			10,709	
Unit Purchase Options and warrants exercised			226	1	(276)	385			110	
Warrants expired					(48)	48			0	
Equity issued in conjunction with consulting contracts			109	1		118			119	
Issuance of common stock for employee stock and 401K plans			320	1		433			434	
Fair value for repriced employee stock options						206			206	
Fair value for options granted to nonemployees						554			554	
Change in unrealized gain on marketable securities							(4)		(4)	\$ (4)
Net loss								(29,959)	(29,959)	(29,959)
Balance at December 31,	688	13,952	48,627	122	20,827	299,408	0	(329,815)	4,494	<u>\$ (29,963)</u>

2004

Conversion of Series A convertible preferred stock into common stock, including beneficial inducement cost	(688)	(13,952)	8,258	21		14,881	(950)	0
Accumulated dividends on Series A convertible preferred stock paid with common stock			1,385	3		634	(637)	0
Conversion of convertible note into common stock combined with remaining convertible note modifications			1,007	2	164	2,501		2,667
Issuance of common stock in Standby Equity Distribution Agreement, net of issuance costs of \$771			11,922	30		3,185		3,215
Warrants issued and note discount for convertible debenture					242	477		719
Subscribed stock							237	237
Unit Purchase Options and warrants exercised			30		(32)	50		18
Equity issued in conjunction with consulting contracts			40			42		42
Issuance of common stock for employee 401K plan			391	1		281		282
Fair value for repriced employee stock options						(197)		(197)
						186		186

Fair value for options granted to nonemployees											
Net loss									(17,313)	(17,313)	\$ (17,313)
Balance at December 31, 2005	<u>0</u>	<u>\$ 0</u>	<u>71,660</u>	<u>\$179</u>	<u>\$21,201</u>	<u>\$321,448</u>	<u>\$237</u>	<u>\$ (348,715)</u>	<u>\$ (5,650)</u>	<u>\$ (17,313)</u>	

See accompanying notes to financial statements.

**THE IMMUNE RESPONSE CORPORATION**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years ended December 31,		
	2005	2004	2003
<b>Cash Flows From Operating Activities:</b>			
Net loss	\$ (17,313)	\$ (29,959)	\$ (28,799)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,632	1,626	1,799
Operating expenses paid with common stock and warrants	324	355	933
Stock option adjustments	(11)	760	1,088
Deferred revenue	(44)	(174)	(55)
Deferred rent	2	193	—
Accrued excess lease costs	(203)	—	1,778
Related party accrued interest	496	576	810
Related party accrued interest paid upon convertible notes exchanged and extended	(1,340)	—	—
Accretion of notes, related party	1,113	2,360	7,065
Accretion of convertible debenture	339	—	—
Beneficial inducement cost	1,201	4,923	—
Loss on extinguishment of debt	—	4,935	—
Interest expense converted into Series A convertible preferred stock	—	219	—
Impairments of investment and long-term assets	—	—	438
(Gain) loss on sale of fixed assets	—	14	(65)
Changes in operating assets and liabilities:			
Prepaid expenses	73	8	48
Accounts payable	545	(657)	(175)
Accrued expenses	451	204	125
Net cash used in operating activities	<u>(12,735)</u>	<u>(14,617)</u>	<u>(15,010)</u>
<b>Cash Flows From Investing Activities:</b>			
Purchase of property and equipment	(77)	(420)	(147)
Proceeds from sale of property and equipment, net	—	4	215
Other	—	—	206
Net cash provided by (used in) investing activities	<u>(77)</u>	<u>(416)</u>	<u>274</u>
<b>Cash Flows From Financing Activities:</b>			
Net proceeds from common stock sold under the Standby Equity Distribution Agreement			
	3,461	—	—
Net proceeds from convertible debenture			
	890	—	—
Subscribed stock for the Standby Equity Distribution Agreement			
	237	—	—
Payments on convertible debenture			
	(200)	—	—
Net proceeds from private placement of common stock			
	—	10,709	10,722
Payments of equipment notes and capital leases			
	—	—	(1,082)
Proceeds from issuances of convertible promissory notes and warrants, related party			
	—	—	3,899
Net proceeds from exercise of stock warrants			
	—	—	9,691
Net proceeds from exercises of Unit Purchase Options			
	18	110	—
Net offering costs for equity transactions			
	(246)	(23)	—
Net proceeds from common stock purchases through employee plans			
	—	197	405
Net cash provided by financing activities	<u>4,160</u>	<u>10,993</u>	<u>23,635</u>
Net increase (decrease) in cash and cash equivalents	(8,652)	(4,040)	8,899
Cash and cash equivalents — beginning of year	8,798	12,838	3,939
Cash and cash equivalents — end of year	<u>\$ 146</u>	<u>\$ 8,798</u>	<u>\$ 12,838</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>			
Interest paid	\$ 1,412	\$ 25	\$ 219



**Supplemental Disclosure of Noncash Information:**

Series A convertible preferred stock converted into common stock	\$ 13,952	\$ —	\$ —
Beneficial inducement cost for the Series A convertible preferred stock conversion	\$ 950	\$ —	\$ —
Common stock issued for payment of accumulated dividends on Series A convertible preferred stock	\$ 637	\$ —	\$ —
Promissory notes and interest converted into common stock	\$ 1,467	\$ —	\$ 7,361
Debt discount allocated to convertible debenture for warrants and beneficial conversion cost	\$ 719	\$ —	\$ —
Promissory notes and interest converted into Series A convertible preferred stock	\$ —	\$ 4,118	\$ —
Common stock and warrants issued for offering costs	\$ 525	\$ 805	\$ 1,707
Common stock and warrants issued for consulting services	\$ 42	\$ 119	\$ 933
Common stock issued for 401K plan	\$ 282	\$ 236	\$ —
Value allocated to common stock as debt discount	\$ —	\$ —	\$ 385
Settled warrants upon expiration to paid-in capital, no common stock issued	\$ —	\$ 48	\$ —

See accompanying notes to financial statements.

## THE IMMUNE RESPONSE CORPORATION NOTES TO FINANCIAL STATEMENTS

### **Note 1 — The Company and its Significant Accounting Policies:**

#### ***The Company***

The Immune Response Corporation (the “Company”), a Delaware corporation, is an immuno–pharmaceutical company focused on developing products to treat autoimmune and infectious diseases. The Company’s lead immune–based therapeutic product candidates are NeuroVax™, for the treatment of multiple sclerosis (“MS”), and IR103, for the treatment of human immunodeficiency virus (“HIV”). Both of these therapies are in Phase II of clinical development and are designed to stimulate pathogen–specific immune responses aimed at slowing or halting the rate of disease progression.

NeuroVax™ is based on the Company’s patented T–cell receptor (“TCR”) peptide technology. In addition to MS, the Company has open Investigational New Drug Applications (“IND”) with the FDA for clinical evaluation of TCR peptide–based immune–based therapies for rheumatoid arthritis and psoriasis. IR103 is based on the Company’s patented whole–inactivated virus technology, co–invented by Dr. Jonas Salk, and tested in extensive clinical studies of Remune®, the Company’s first–generation HIV product candidate. IR103 is a more potent formulation that combines its whole–inactivated antigen with a synthetic Toll–like receptor (“TLR–9”) agonist to create enhanced HIV–specific immune responses. The Company is currently testing IR103 in two Phase II clinical studies as a first–line treatment for drug–naïve HIV–infected individuals not yet eligible for antiretroviral therapy according to current medical guidelines.

All of the Company’s products are still in the development stage, and the Company has never had revenues from the sale of products. The Company was founded in 1986.

#### ***Principles of Consolidation***

Effective January 1, 2005, the Company and its wholly–owned subsidiary were merged into one company through a statutory tax–free reorganization. There was no financial statement impact as a result of this merger. The financial statements for the years ended December 31, 2004 and 2003 include the accounts of the Company and its wholly–owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

#### ***Segment Reporting***

The Company has determined that it operates in one business segment dedicated to pharmaceutical research.

#### ***Financial Statement Preparation***

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

#### ***Cash and Cash Equivalents***

Cash and cash equivalents consist of cash, money market funds, time deposits and treasury securities with remaining maturities at the date of acquisition of less than three months. The carrying amounts approximate fair value due to the short maturities of these instruments.

The Company invests its excess cash in U.S. government securities and money market accounts. The Company has established guidelines relative to diversification and maturities that are intended to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

### ***Fair Value of Financial Instruments***

Financial instruments consist of cash and cash equivalents, accounts payable, accrued expenses and short-term and long-term convertible debt obligations. With the exception of our convertible promissory notes, related party (see Note 5), the fair value of these financial instruments approximates their carrying amount as of December 31, 2005 and 2004 due to the nature of or the short maturity of these instruments.

### ***Property and Equipment***

Property and equipment are recorded at cost and are depreciated or amortized over their estimated useful lives using the straight-line method. Property and equipment have useful lives ranging from three to seven years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remaining terms of the related leases.

### ***Licensed Technology***

Licensed technology is recorded at cost and amortized over its estimated useful life. In December 1999, the Company acquired licenses to certain TCR patent technology, which is being amortized over seven years. Accumulated amortization was \$4,238,000 and \$3,532,000 at December 31, 2005 and 2004, respectively. Amortization expense was \$706,000 for each of the three years in the period ended December 31, 2005. Amortization expense is expected to be \$706,000 in 2006.

### ***Long-lived Assets***

The Company accounts for long-lived assets in accordance with Financial Accounting Standard, FAS, No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." The Company tests fixed assets and licensed technology annually for impairment and in interim periods if certain events occur that might affect the carrying value of a long-lived asset. For 2005 and 2004, the Company determined that no impairment adjustment was required for fixed assets or licensed technology.

During 2003, the Company changed accounting systems and as a result wrote off \$438,000 related to the capitalized remaining carrying value of the replaced accounting system.

### ***Comprehensive Income***

The Company accounts for comprehensive income in accordance with FAS No. 130, "Reporting Comprehensive Income." The Company reports the accumulated balance of other comprehensive income or loss separately in the equity section of the balance sheets. The only component of other comprehensive income is unrealized gain or loss on marketable securities.

### ***Revenues Under Collaborative Agreements***

The Company earns revenue from licensing its proprietary technology and performing services under research and development contracts. Any initial fees under license and option agreements, under which the Company also provides research and development services, are recognized over the term of the research and development or other relevant period. Payments for options to a license for the Company's technology are recognized over the option period. Revenues from the achievement of milestones are recognized over the remaining development period. Revenues under research and development contracts are recognized as the services are performed. Advance payments received in excess of amounts earned are classified as deferred revenue.

### ***Research and Development Costs***

All research and development costs are charged to expense as incurred.

### ***Deferred Rent***

The Company records rent expense on a straight-line basis over the term of the leases. Due to the escalation of rent payments on an annual basis, the difference between the lower payments in earlier years and the straight-line expense is recorded as a deferred liability, which amortizes during the second half of lease terms as the payments exceed the monthly straight-line expense.

### **Exit and Disposal Related Costs**

In June 2002, the FASB issued FAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." FAS No. 146 addresses accounting and reporting for costs associated with exit or disposal activities and supersedes Emerging Issues Task Force Issue, EITF, No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)." FAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured initially at fair value when the liability is incurred. FAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. Transactions previously accounted for under EITF No. 94-3 are not changed by FAS No. 146. The Company applied EITF No. 94-3 during 2002 prior to the issuance of FAS No. 146 (see Note 7).

### **Stock-based Compensation**

The Company measures its stock-based employee compensation using the intrinsic value method of accounting in accordance with Accounting Principles Board, APB, Opinion No. 25, "Accounting for Stock Issued to Employees." Because the Company establishes the exercise price based on the fair market value of the Company's stock at the date of grant, the options have no intrinsic value upon grant, and therefore no expense is recorded. Equity instruments issued to non-employees for goods or services are accounted for at fair value and are marked to market until service is complete or a performance commitment date is reached.

As required under FAS No. 123, "Accounting for Stock-Based Compensation," and FAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," the pro forma effects of stock-based compensation on net loss and net loss per common share have been estimated at the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Years Ended December 31,		
	2005	2004	2003
Risk-free interest rate	4.11%	3.405%	2.843%
Volatility	118%	139%	163%
Expected life in years	5	5	5
Dividend yield	0.0%	0.0%	0.0%

For purposes of pro forma disclosures, the estimated fair value of the options is assumed to be amortized to expense over the options' vesting periods. The pro forma effects of recognizing compensation expense under the fair value method on net loss and net loss per common share were as follows (in thousands, except for loss per share):

	Years Ended December 31,		
	2005	2004	2003
Net loss (attributable to common stockholders) — as reported	\$(18,534)	\$(30,325)	\$(42,050)
Stock-based employee compensation expense(benefit) included in net loss	(197)	206	439
Fair value of stock-based employee compensation expense	(1,524)	(2,345)	(2,547)
Net loss (attributable to common stockholders) — pro forma	\$(20,255)	\$(32,464)	\$(44,158)
Net loss (attributable to common stockholders) per share (basic and diluted) — as reported	\$ (0.34)	\$ (0.66)	\$ (1.49)
Net loss (attributable to common stockholders) per share (basic and diluted) — pro forma	\$ (0.37)	\$ (0.70)	\$ (1.57)

### **Income Taxes**

All income tax amounts have been computed in accordance with FAS No. 109, "Accounting for Income Taxes." Under this statement, the liability method is used to account for deferred income taxes. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Valuation allowances are established against deferred tax assets when the realization is uncertain.

### **Net Loss Per Share**

Basic and diluted net loss per share is computed using the weighted average number of common shares outstanding during the period. Potentially dilutive securities are excluded from the diluted net loss per share calculation, as the effect would be antidilutive. As of December 31, 2005, potentially dilutive shares not included are 12,900,000 shares for outstanding employee stock options, 8,200,000 shares issuable under a convertible note payable, related party, 1,300,000 shares issuable under a convertible debenture, 16,600,000 shares issuable under warrants outstanding, 9,400,000 shares issuable under Class B Warrants outstanding and 1,900,000 shares issuable under an option issued to the placement agent for the private offering in December 2002.

### **Recent Accounting Pronouncement**

In December 2004, the FASB issued FAS No. 123R, "Share-Based Payment." This statement is a revision to FAS No. 123, "Accounting for Stock-Based Compensation," it supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends FAS No. 95, "Statement of Cash Flows." Generally the approach in FAS No. 123R is similar to the approach described in FAS No. 123. However, FAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements.

FAS No. 123R must be adopted no later than January 1, 2006. The Company will be adopting FAS No. 123R on January 1, 2006. FAS No. 123R permits public companies to adopt its requirements using one of two methods. The Company has chosen to adopt the modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of FAS No. 123 for all awards granted to employees before the effective date of FAS No. 123R that remain unvested on the effective date.

As permitted by FAS No. 123, the Company currently accounts for share-based payments to employees using APB Opinion No. 25's intrinsic value method; and as such, the Company generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of FAS No. 123R's fair value method will have a material impact on the Company's results of operations, although it will have no impact on the Company's overall financial position. The impact of adoption of FAS No. 123R cannot be predicted at this time because it will depend in part on levels of share-based payments granted in the future. However, had the Company adopted FAS No. 123R in prior periods using the Black-Scholes valuation model, the impact of that standard would have approximated the impact of FAS No. 123 as described in the disclosure of pro forma net loss and net loss per share in Note 1.

FAS No. 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. The Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options, and whether the Company will be in a taxable position). There is no tax impact related to the prior periods since the Company is in a net loss position.

### **Note 2 — Going Concern:**

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses since inception, has an accumulated deficit of \$348,715,000, cash and cash equivalents of only \$146,000, a working capital deficiency of \$2,986,000 and a deficiency in stockholders' equity of \$5,650,000 as of December 31, 2005. The Company will not generate meaningful revenues in the foreseeable future.

These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. Our independent registered public accountants, Levitz, Zacks & Ciceric, indicate in their audit report on the 2005 financial statements that there is substantial doubt about our ability to continue as a going concern.

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The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

In March 2006, the Company completed a private placement unit offering (the "2006 Private Placement") (see Note 12). The Company believes that its current resources, including this offering, are sufficient to fund its planned operations, including necessary capital expenditures and clinical trials, through the third quarter of 2006. The Company is attempting to raise additional capital to fund operations beyond the third quarter of 2006; however, no assurance can be given that the Company will be able to obtain additional financing when and as needed in the future.

**Note 3 — Components of Selected Balance Sheet Accounts:**

Property and equipment consists of the following (in thousands):

	December 31,	
	2005	2004
Furniture and fixtures	\$ 348	\$ 347
Equipment	3,444	3,379
Leasehold improvements	7,693	7,682
Purchased software	88	88
	11,573	11,496
Less accumulated depreciation and amortization	(7,990)	(7,065)
	<u>\$ 3,583</u>	<u>\$ 4,431</u>

Accrued expenses consist of the following (in thousands):

	December 31,	
	2005	2004
Accrued compensation and benefits	\$ 750	\$ 665
Accrued clinical expenses	653	311
Other accrued liabilities	350	340
	<u>\$1,753</u>	<u>\$1,316</u>

Deferred rent and accrued excess lease costs consist of the following (in thousands):

	December 31,	
	2005	2004
Deferred rent	\$ 364	\$ 362
Accrued excess lease costs	2,070	2,273
	2,434	2,635
Less current portion deferred rent	(35)	(9)
Less current portion accrued excess lease costs	(239)	(203)
	<u>\$2,160</u>	<u>\$2,423</u>

**Note 4 — Short-Term Convertible Debenture:**

On August 4, 2005, the Company borrowed \$1,000,000 in cash from Cornell Capital Partners, LP ("Cornell Capital") against a secured convertible debenture (the "Debenture"). As of December 31, 2005, the Company had outstanding approximately \$325,000 (net of discount of \$490,000 plus accrued interest of \$15,000) on the Debenture. The outstanding principal balance must be repaid in equal monthly installments beginning in October 2005 and ending on August 4, 2006 and bears 12% interest per annum, payable monthly. The outstanding principal amount of the Debenture is convertible at the option of Cornell Capital into shares of the Company's common stock at a conversion price of \$0.6315 per share, which was 80% of the volume weighted average price on August 4, 2005. The Company also issued a warrant to purchase 500,000 shares of common stock,

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exercisable for five years at an exercise price of \$0.924 per share, to Cornell Capital in connection with the Debenture. Finally, the Company paid Cornell Capital a commitment fee of \$100,000 cash in connection with the Debenture. The Company also paid Cornell Capital a structuring fee of \$10,000 in cash.

On February 8, 2006, the Company entered into the Note Exchange and Note Revision Agreements which resulted in “ratchet” antidilution adjustments under the terms of the Debenture and warrant. The conversion price and exercise price of the Debenture and warrant were reduced to \$0.02 per share. As a result, the \$500,000 outstanding principal balance of the Debenture as of February 1, 2006, which had previously been convertible into 791,765 shares of common stock, became convertible into 25,000,000 shares of common stock, and the warrant became exercisable for 23,100,000 shares versus 500,000 shares of common stock (see Note 12).

In March 2006, Cornell Capital executed a conversion notice for \$31,760 of the Debenture and a partial exercise of 500,000 warrants all for \$0.02 per share (see Note 12).

The Debenture is secured by substantially all of the Company’s assets and a pledge of 14,285,705 shares of common stock, of which 4,959,705 were pledged on August 4, 2005 and 9,326,000 were pledged on September 30, 2005. The 14,285,705 pledged shares are held in escrow as collateral for the Debenture. The pledged shares are accounted for as contingently issuable shares and are not included in the calculation of the weighted average number of shares for purposes of calculating net loss per share or in the calculation of the 71,660,101 shares issued and outstanding on the balance sheet at December 31, 2005.

From August 4, 2005 through September 30, 2005, the Company’s obligation was further secured by a pledge of 6,000,000 shares of the Company’s common stock from Cheshire Associates LLC (“Cheshire”), an affiliate of Kevin Kimberlin, a director and major stockholder of the Company. The Company issued common stock warrants to Cheshire as an inducement to pledge the 6,000,000 shares temporarily to Cornell Capital. The warrants are exercisable at any time between August 2005 and August 2010 at an exercise price of \$0.78 per share for 114,000 shares equal to 2,000 shares times the 57 days that Cheshire’s shares were pledged to Cornell Capital. These warrants are subject to weighted average antidilution protection for the investor. On February 8, 2006, the Company entered into the Note Exchange and Note Revision Agreements which resulted in an antidilution adjustment to the warrants (see Notes 6 and 12).

### **Note 5 — Convertible Promissory Notes, Related Party:**

Convertible promissory notes, related party consists of the following (in thousands):

	December 31,	
	2005	2004
Convertible promissory notes, related party – face amount	\$ 5,741	\$ 7,208
Discount for warrants and beneficial conversion	(5,676)	(7,143)
Accretion of discount recorded as interest expense	4,982	5,336
Accrued interest payable at maturity	307	1,151
Convertible promissory notes, related party — net	5,354	6,552
Less current portion	—	6,552
Long-term portion	\$ 5,354	\$ —

Due to the Company’s inability to borrow from recognized lending institutions, the Company has had to enter into borrowing transactions entirely with a related party that include large amounts of derivative securities granted in conjunction with the debt. Based on the nature of the related party relationship, the estimated fair value of the convertible promissory notes approximates their carrying amount as of December 31, 2005.

In November 2001, the Company entered into the Note Purchase Agreement and Intellectual Property Security Agreement with an accredited investor. From November 2001 through December 31, 2002, the Company privately placed a total of \$15,700,000 in convertible promissory notes (the “8% Notes”) and warrants. The investor, Kevin Kimberlin Partners, L.P. (“KKP”), is an

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affiliate of Kevin Kimberlin, a director and major stockholder of the Company. Subsequently, the Note Purchase Agreement has been amended to add and assign all the 8% Notes to Cheshire. Throughout 2002 and 2003 various transactions were completed, which converted approximately \$8,492,000 in 8% Notes into common stock (see Note 6). At December 31, 2004, the remaining balance of the 8% Notes was \$7,208,000.

On April 29, 2005, the Company entered into a Note Exchange Agreement with Cheshire to exchange the 8% Notes with outstanding principal amounts totaling \$5,741,000, previously issued by the Company, for a new secured 2007 Mortgage Note with a principal amount of \$5,741,000 (the "Mortgage Note"). Under the terms of the agreement, the Mortgage Note has the same terms and conditions as the 8% Notes had, except that (a) the 8% Notes would have matured at various dates in 2005, but the Mortgage Note has a maturity date of May 31, 2007, and (b) the Mortgage Note has a conversion price of \$0.70 per share (the closing price of the Company's common stock on April 29, 2005) convertible into 8,201,000 shares of the Company's common stock at any time, at the option of the investor. The 8% Notes had higher conversion prices.

In connection with this agreement, Cheshire converted a separate convertible promissory note, which had a maturity date of May 3, 2005 and an outstanding principal amount of \$1,467,000, into 1,007,000 shares of the Company's common stock at a conversion price of \$1.457 per share. In addition, pursuant to the agreement, the Company paid all accrued interest as of April 29, 2005 on the 8% Notes and on the converted note. This constituted a prepayment, as such interest had not been due until the original maturity dates of the 8% Notes and the converted note. Aggregate interest paid was \$1,340,000. Also, the notes exchange and the note conversion transactions resulted in a non-cash charge to operations in the second quarter of 2005 for \$1,201,000 representing beneficial inducement cost.

The agreement also involved a reduction, to \$0.70 per share, of the exercise prices of the associated warrants that were previously issued with the 8% Notes. These warrants are currently exercisable for 8,634,000 shares of common stock, and immediately before the agreement had a weighted average exercise price of \$1.41. Furthermore as part of the agreement, Cheshire waived all anti-dilution protection under the Mortgage Note and these warrants for the \$15,000,000 Standby Equity Distribution Agreement ("SEDA") financing that the Company obtained from Cornell Capital in July 2005.

As of December 31, 2005, the Company had outstanding approximately \$5,354,000 (net of discount of \$694,000, plus accrued interest of \$307,000) of convertible, related party secured debt, namely the Mortgage Note.

Each note has 100% warrant coverage (see Note 6). The warrants are for a term of ten years. The warrants are exercisable into shares of the Company's common stock at any time, at the option of the investor. Both the conversion price of the Mortgage Note and the exercise prices of the warrants provide future antidilution protection for the investor excluding the Cornell Capital financing.

Subsequent to December 31, 2005, the Mortgage Note and its related warrants have been adjusted for antidilution pursuant to the Note Exchange Agreement, the Note Revision Agreement and the 2006 Private Placement (see Note 12).

Following is a summary of the various terms and conversion features of the 8% Notes as of December 31, 2004 and the effects of the April 2005 conversion and Note Exchange Agreement with the remaining balance on the Mortgage Note as of December 31, 2005:

Issuance Date	Maturity Date	Convertible Notes Principal	At Issuance		After Dilution Adjustments	
			# of Shares	Conversion Price	# of Shares	Conversion Price
03-May-02	03-May-05	\$ 1,467,178	850,636	\$ 1.7248	1,006,986	\$ 1.4570
12-Nov-02	12-Nov-05	4,847,608	4,243,354	1.1424	4,704,131	0.70
15-Nov-02	15-Nov-05	200,000	174,581	1.1456	193,648	0.70
20-Nov-02	20-Nov-05	200,000	184,638	1.0832	202,613	0.70
27-Nov-02	27-Nov-05	215,000	264,518	0.8128	272,462	0.70
10-Dec-02	30-Jul-05	278,320	187,851	1.4816	217,624	0.70
Balance as of 31-Dec-04		7,208,106	5,905,578		<u>6,597,464</u>	
29-Apr-05		(1,467,178)	(850,636)			
31-Dec-05	31-May-07	<u>\$ 5,740,928</u>	<u>5,054,942</u>		<u>8,201,325</u>	<u>\$ 0.7000</u>



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Following is a summary of the various terms and exercise features of the warrants issued in conjunction with the 8% Notes and adjustments for activity during 2005 as of December 31, 2005:

Issuance Date	Expiration Date	Fair Value Allocated to Warrants	At Issuance		After Dilution Adjustment or Terms Modifications	
			# of Shares	Exercise Price	# of Shares	Exercise Price
09–Nov–01	09–Nov–11	\$1,076,000	433,426	\$5.7680	614,990	\$ 4.0651
14–Feb–02	14–Feb–12	906,000	429,000	4.1440	584,640	3.0408
03–May–02	03–May–12	2,038,000	2,319,109	2.1560	2,822,784	0.7000*
12–Nov–02	12–Nov–12	2,697,000	4,243,354	1.4280	4,887,883	0.7000*
15–Nov–02	15–Nov–12	107,000	174,581	1.4320	201,191	0.7000*
20–Nov–02	20–Nov–12	72,000	184,638	1.3540	210,881	0.7000*
27–Nov–02	27–Nov–12	103,000	264,518	1.0160	286,544	0.7000*
10–Dec–02	30–Jul–12	154,000	187,851	1.8520	224,422	0.7000*
Balance as of 31–Dec–04		7,153,000	8,236,477		9,833,335	
29–Apr–05	Repricing adjustment	165,000	—		—	(to \$0.70*)
04–Aug–05	Inducement warrant	46,000	114,000	0.7800	114,000	0.7800
Balance as of 31–Dec–05		<u>\$7,364,000</u>	<u>8,350,477</u>		<u>9,947,335</u>	

The cash proceeds of the notes were allocated pro-rata between the relative fair values of the notes and warrants at issuance using the Black–Scholes valuation model for valuing the warrants. After allocating the proceeds between the note and warrant, an effective conversion price was calculated for the convertible note to determine the beneficial conversion discount for each note. The value of the beneficial conversion discount is recorded as additional discount to the note. The resultant combined discount to the note is accreted back to the note principal balance over the term of the note and recorded as interest expense. The following is a summary of the allocation of the cash proceeds to the relative fair values of the notes and warrants and the components of the discount recorded upon issuance of each note (in thousands):

Issuance Date	Fair Value Allocation at Issuance			Components of Note Discount			
	Convertible Notes	Warrants	Notes	Beneficial		Total Discount	
				Warrants	Cost		
09–Nov–01	\$ 2,000	\$ 1,076	\$ 924	\$ 1,076	\$ 924	\$ 2,000	
14–Feb–02	2,000	906	1,094	906	639	1,545	
03–May–02	4,000	2,038	1,962	2,038	1,962	4,000	
12–Nov–02	4,848	2,697	2,151	2,697	2,151	4,848	
15–Nov–02	200	107	93	107	93	200	
20–Nov–02	200	72	128	72	72	144	
27–Nov–02	215	103	112	103	103	206	
10–Dec–02	278	154	124	154	124	278	
03–Jun–03	(4,195)	(2,081)	(2,114)	(2,081)	(1,659)	(3,740)	
07–Jul–03	(2,338)	(1,191)	(1,147)	(1,191)	(1,147)	(2,338)	
31–Dec–04	7,208	3,881	3,327	3,881	3,262	7,143	
29–Apr–05	(1,467)	(748)	(719)	(748)	(719)	(1,467)	
Remaining Balance of Mortgage Note as of 31–Dec–05		<u>\$ 5,741</u>	<u>\$ 3,133</u>	<u>\$ 2,608</u>	<u>\$ 3,133</u>	<u>\$ 2,543</u>	<u>\$ 5,676</u>

**Note 6 — Stockholders' Equity:**

**Series A Convertible Preferred Stock Exchanged for Common Stock**

On September 21, 2005, the Company entered into and closed a Shares Exchange Agreement with Cheshire to exchange Cheshire's 688,146 shares of the Company's Series A Convertible Preferred Stock (the "Preferred Shares"), previously issued, for 9,643,060 newly-issued shares of the Company's common stock. These newly-issued shares also included payment for all accumulated dividends at a rate of 9% of \$637,000 on the Preferred Shares in the form of 1,385,308 shares of common stock.

The Shares Exchange Agreement transaction resulted in a non-cash charge to net loss attributable to common stockholders in the third quarter of 2005 for \$950,000 representing beneficial inducement cost.

### **Short-term Convertible Notes, Related Party converted into Series A Convertible Preferred Stock**

On January 7, 2004, Cheshire converted \$3,899,000 of previously issued, short-term convertible notes plus accrued interest of approximately \$219,000 into 688,146 shares of Series A Convertible Preferred Stock ("Series A") at \$5.984 per share. At December 31, 2004, accumulated but undeclared dividends on the Series A amounted to \$366,000. The liquidation preference at December 31, 2004 aggregated \$4,484,000.

The conversion of \$2,080,000 of short-term convertible notes into Series A resulted in a non-cash charge to operations of approximately \$4,923,000 in the first quarter of 2004 as a beneficial inducement cost, representing the difference between the fair value of the common stock into which the Series A was convertible (at the most preferential rate) compared to the fair value of the common stock into which the related debt was convertible in accordance with FAS No. 84, "Induced Conversions of Convertible Debt." Conversion of the remaining \$1,819,000 of the short-term convertible notes resulted in a non-cash charge to operations of approximately \$4,935,000 in the first quarter of 2004 as a loss on the extinguishment of debt, representing the difference between the carrying value of the related debt and the fair value of the Series A issued.

### **Common Stock**

In June 2003, the Company issued \$1,000,000 of unsecured promissory notes to accredited investors, which bear interest at the rate of 12% per annum. In conjunction with the the issuance of the notes, the Company issued 166,665 shares of common stock to the investors. The Company recorded a discount on the loan of \$385,000 as the fair value allocation between the stock granted and the loan principal. The notes and interest were repaid in July 2003 with proceeds from the Class A warrant incentive share offering.

During June 2003, Cheshire converted \$4,200,000 of principal on notes issued in November 2001, February 2002, part of the principal of the May 2002 note and all accrued and unpaid interest of \$805,000 into 1,613,572 shares of the Company's common stock. The balance of the May 2002 note and all accrued and unpaid interest thereon was transferred to two new notes in the approximate amounts of \$2,400,000 and \$1,400,000, respectively.

During July 2003, the Company raised \$9,300,000 in gross proceeds (offering costs totaled \$447,000) through the voluntary exercise of 6,992,236 of the Company's Class A warrants. The proceeds included \$6,900,000 in cash and the cancellation of a \$2,400,000 convertible note previously issued to Cheshire as payment for the aggregate exercise price for the purchase of 1,774,888 shares and 1,774,888 Class B warrants. The Company issued an additional 3,496,118 shares equal to one half share of common stock for each Class A warrant exercised as an incentive to induce holders of the Class A warrants to exercise their Class A warrants and to allow the Company to obtain a "lock-up" on the shares of common stock issued to the holders of such exercised Class A warrants in the December 2002 unit offering and the shares of the common stock issued upon the exercise of the Class A warrants (including the additional one half share of common stock), prohibiting the sale of such common stock for 270 days, with the "lock-up" period expiring on April 4, 2004. The incentive shares issued as part of the offering represent a deemed dividend for participating in the voluntary exercise and resulted in a charge to accumulated deficit in the third quarter of \$11,887,000. Additionally, on July 30, 2003, the Company exercised its option to redeem the remaining outstanding Class A warrants on September 3, 2003 (subsequently extended to September 8, 2003) resulting in the exercise of 2,420,862 outstanding Class A warrants and gross proceeds of approximately \$3,216,000. Approximately 109,000 remaining Class A warrants were redeemed by the Company at \$.01 each for a total cost of \$1,090. As a result of the voluntary exercise and redemption, the Company reclassified \$2,688,000 from common stock warrants to paid-in capital representing the value originally ascribed to the Class A warrants. On February 6, 2004, the Company released the market-trading lockup restriction for 17,480,600 shares of common stock plus 977,800 Unit Purchase Options.

On October 10, 2003, the Company raised \$10,722,000, net of \$1,278,000 of offering costs, in connection with a private placement of 5,940,594 shares of common stock and accompanying warrants to purchase 2,970,297 shares of common stock. In connection with this private placement, the Company issued an additional 61,576 shares of common stock and warrants to purchase 594,059 shares of common stock to Rodman & Renshaw, Inc., the placement agent for that offering, and other service providers.

On April 30, 2004 the Company raised \$10,709,000, net of \$1,141,000 of cash offering costs, in connection with a private placement of 6,771,429 shares of common stock at \$1.75 per share to a number of institutional investors. Investors also received five-year warrants to purchase an aggregate of approximately 2,031,429 shares of common stock at \$2.75 per share with an allocated value of \$2,569,000. The investors were not affiliated with the Company, except for one investor that is an affiliate of Cheshire; that investor purchased 342,857 shares and 102,857 warrants for \$600,000. In connection with this private

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placement, the Company issued additional warrants to purchase 541,714 shares of common stock to Rodman & Renshaw, Inc., the placement agent for this offering, with a value of \$805,000, representing non-cash offering costs.

During April 2005, Cheshire converted \$1,467,000 of principal on a convertible promissory note, which had a maturity date of May 3, 2005, into 1,006,986 shares of the Company's common stock at a conversion price of \$1.457 per share.

For the year ended December 31, 2005, the Company issued 40,000 shares of its common stock for consulting services performed during 2005 equal to \$42,000 and issued 391,034 shares of its common stock for an employee 401(k) stock matching contribution expense equal to \$282,000. For the year ended December 31, 2004, the Company issued 108,954 shares of its common stock for consulting services performed during 2004 equal to \$119,000 and issued 182,378 shares of its common stock for an employee 401(k) stock matching contribution expense equal to \$237,000. For the year ended December 31, 2003, the Company issued 230,920 shares of its common stock for consulting services performed during 2003 equal to \$376,000 and 31,914 shares of its common stock for legal services equal to \$75,000. As of December 31, 2003, the Company accrued \$421,000 for consulting services that were paid in 214,838 shares of its common stock during 2004.

### **Standby Equity Distribution Agreement**

On July 15, 2005, the Company entered into a SEDA with Cornell Capital, to support the continued development of its product candidates. Under the agreement, Cornell Capital committed to provide up to \$15,000,000 of funding to be drawn down over a 24-month period at the Company's discretion. The maximum amount of each draw is \$500,000, and there must be at least five trading days between draws.

Through December 31, 2005, the Company has made twelve draws under the SEDA for net proceeds of \$3,461,500 and issued 11,182,484 shares of common stock at an average price per share of \$0.3095.

Under the SEDA, each draw is actually a sale by the Company to Cornell Capital of newly-issued common stock, in the quantity required to equate to the desired cash proceeds. Cornell Capital pays 97% of, or a 3% discount to, the lowest daily volume weighted average price of the Company's common stock during the five consecutive trading day period immediately following the date of notification to Cornell Capital that the Company desires to access the SEDA. In addition, Cornell Capital retains 5% of each cash payment under the SEDA. The Company also issued 725,353 shares of common stock to Cornell Capital as a one-time commitment fee. The 3% discount, the 5% retainage fee and the 725,353 shares of common stock are considered to be underwriting discounts payable to Cornell Capital. The Company registered for resale, on Form S-1, the shares of common stock to be sold to Cornell Capital under the SEDA. Following the February 2006 Note Exchange and Note Revision Agreements, there are currently no registered shares available for use by the Company with the SEDA.

The Company engaged Monitor Capital, Inc., a registered broker-dealer, to act as placement agent in connection with the SEDA. The Company paid Monitor Capital, Inc. 14,085 shares of common stock on July 15, 2005, as a fee under a Placement Agent Agreement.

### **Common Stock Warrants**

Following is a summary of warrants outstanding as of December 31, 2005:

Types of Warrants	Amount	Warrants Outstanding	Range of Exercise	Warrant
			Prices	Call Price
Related party warrants (Note 5)	\$ 7,364,000	9,947,335	\$ .70 – \$4.0651	none
Class B warrants	2,635,000	9,413,107	\$ 1.77	\$ 3.32
Unit Purchase Options	2,203,000	1,858,982	\$ 0.885	none
October 2003 warrants	5,356,000	3,564,356	\$ 3.32	\$ 8.00
April 2004 warrants	3,374,000	2,573,143	\$ 2.75	none
August 2005 warrant	196,000	500,000	\$ 0.924	none
Other	73,000	21,433	\$ 2.00 – \$5.36	none
	<u>\$21,201,000</u>	<u>27,878,356</u>		

The weighted average exercise price of all outstanding warrants is equal to \$1.72 at December 31, 2005.

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The publicly traded Class A warrants were voluntarily exercised, with the remainder being called by the Company, in July 2003. Upon exercise of the Class A warrants, warrant holders received Class B warrants. As of December 31, 2005, there were Class B warrants outstanding to purchase 9,413,107 shares of the Company's common stock. Each Class B warrant entitles the holder to purchase initially one share of the Company's common stock. The Class B warrants have an initial exercise price of \$1.77. The Class B warrants have a term of five years from their issuance. Upon 30 days prior written notice to the holders of the Class B warrants, the Company has the right, but not the obligation, to redeem from the holders the Class B warrants at any time after the date of issuance, at a price of \$0.01 per Class B warrant, if the average of the closing bid prices of the Company's common stock for any 10 consecutive trading days ending within 30 days prior to the date of the notice of redemption is greater than or equal to \$3.32, subject to any stock splits, combinations or other adjustments.

Spencer Trask Ventures Inc., an affiliate of Kevin Kimberlin, the placement agent in the Company's December 2002 private placement, and its transferees, hold Unit Purchase Options ("UPO") at December 31, 2005 exercisable for 1,858,982 shares of the Company's common stock, Class A warrants to purchase an aggregate of 1,265,542 shares of the Company's common stock issuable upon exercise of the common stock portion of the UPO and Class B warrants, issuable upon exercise of the Class A warrants, to purchase an aggregate of 1,437,658 shares of the Company's common stock. The Class A and B warrants have initial exercise prices of \$1.33 and \$1.77, respectively. During 2005, 30,000 UPO's were exercised for 30,000 shares of the Company's common stock resulting in net proceeds of approximately \$50,000. During 2004, approximately 265,000 UPO's and Class A warrants were exercised for 225,864 shares of the Company's common stock resulting in net proceeds of approximately \$110,000. The common stock portion of the UPO's expires December 10, 2007. The Class A and Class B warrant portion of the UPO's both expire 5 years from their respective issuance dates.

During July 2003, the Company agreed to issue an additional 500,000 shares in consideration of the holders of the placement agent unit options agreement not to exercise their unit options until April 4, 2004. The additional 500,000 shares represented a deemed dividend for participating in the voluntary lock-up and resulted in a charge to accumulated deficit in 2003 of \$1,364,000. On February 6, 2004, the Company released the market-trading lockup restriction for 17,480,600 shares of common stock plus 977,800 UPO's.

In connection with the October 10, 2003 private placement, warrants were issued to purchase 3,564,356 shares of the Company's common stock. The warrants have an initial exercise price of \$3.32 per share. These warrants will expire, if not earlier exercised or redeemed, on October 10, 2008. Upon 5 business days' prior written notice to the holders of the warrants, the Company has the right, but not the obligation, to redeem from the holders the warrants at any time after the date of issuance, at a price of \$0.05 per warrant, if the average of the closing bid prices of the Company's common stock for any 20 consecutive trading days is greater than or equal to \$8.00, subject to any stock splits, combinations or other adjustments.

In connection with the April 30, 2004 private placement, warrants were issued to purchase 2,573,143 shares of the Company's common stock. The warrants have an initial exercise price of \$2.75 per share. These warrants will expire, if not earlier exercised or redeemed, on April 30, 2009.

In connection with the August 4, 2005 Debenture, warrants were issued to purchase 500,000 shares of common stock, exercisable for five years at an exercise price of \$0.924 per share, to Cornell Capital. The Company also issued common stock warrants to Cheshire as an inducement to pledge 6,000,000 shares of common stock temporarily to Cornell Capital. The warrants will be exercisable at any time between August 2005 and August 2010 at an exercise price of \$0.78 per share for 114,000 shares equal to 2,000 shares times the 57 days that Cheshire's shares were pledged to Cornell Capital.

The Note Exchange and Note Revision Agreements which were entered into on February 8, 2006, resulted in an antidilution adjustment under the terms of the warrants held by Cornell Capital. The exercise price of the warrants was reduced to \$0.02 per share. As a result the warrants, which had previously been exercisable for 500,000 shares of common stock (at \$0.924 per share), became exercisable for 23,100,000 shares of common stock (see Note 12).

As a result of the Note Exchange Agreement, the Note Revision Agreement and the 2006 Private Placement, all of the related party warrants held by Cheshire were adjusted for antidilution under the terms of the warrants, including the 114,000 warrants issued to Cheshire as part of the Debenture transaction with Cornell Capital. As of December 31, 2005, the warrants were exercisable for 9,947,335 shares of common stock ranging in exercise prices of \$0.70 up to \$4.0651 per share. Following the

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2006 subsequent events, the warrants were exercisable for 104,723,277 shares of common stock ranging in exercise prices of \$0.07 up to \$0.32 per share (see Note 12).

For the year ended December 31, 2003, the Company issued \$61,000 in warrants for consulting services exercisable for 83,933 shares of its common stock, of which 75,000 expired unexercised during 2004.

**Stock Options**

The Company has three stock option plans to grant options to purchase common stock to employees and certain directors of the Company and certain other individuals. The plans authorize the Company to issue or grant qualified and non-qualified options to purchase up to 14,808,000 shares of its common stock. As of December 31, 2005, there were approximately 1,862,000 shares available for grant.

Under the terms of the plans, options may be granted at not less than 100% and 85% of fair market value as of the date of grant for incentive and non-qualified options, respectively. To date, options have generally been issued at 100% of fair market value. Except for certain directors and consultants, these options primarily become exercisable over two to four years from the date of grant.

During April 2003, the Company repriced and accelerated the vesting of stock options to purchase 788,555 shares previously granted to employees and outside directors. The weighted average share price was reduced from \$11.66 per share to \$1.12 per share. This repricing was expensed using the intrinsic valuation method required under APB No. 25. The Company recorded additional employee compensation expense/(benefit) of \$(197,000), \$206,000 and \$439,000 for the repriced options during the years ended December 31, 2005, 2004 and 2003, respectively.

Activity with respect to the various stock plans is summarized as follows (in thousands):

	Stock Options Outstanding	Weighted Average Price
Balance at December 31, 2002	1,137	\$ 12.95
Granted	4,275	1.29
Exercised	(361)	1.12
Cancelled	<u>(1,252)</u>	10.09
Balance at December 31, 2003	3,799	1.89
Granted	2,309	1.53
Exercised	(137)	1.43
Cancelled	<u>(418)</u>	3.18
Balance at December 31, 2004	5,553	1.66
Granted	8,529	0.49
Exercised	—	—
Cancelled	<u>(1,136)</u>	2.03
Balance at December 31, 2005	<u>12,946</u>	\$ 0.85

Following is a summary of the options outstanding as of December 31, 2005:

Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Life In Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
\$0.32 – \$0.32	6,150,000	9.83	\$ 0.32	46,901	\$ 0.32
\$0.67 – \$1.12	3,528,960	7.37	0.96	2,829,961	1.02
\$1.19 – \$1.88	2,619,034	7.78	1.40	2,450,991	1.40
\$1.92 – \$54.76	646,464	6.36	2.94	629,033	2.96
\$73.00 – \$73.00	<u>1,562</u>	0.41	73.00	<u>1,562</u>	73.00
	<u>12,946,020</u>	8.57	\$ 0.85	<u>5,958,448</u>	\$ 1.40

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The weighted average fair value of options granted during 2005, 2004 and 2003 was \$0.41, \$1.39 and \$1.12, respectively.

At December 31, 2005, 87,400,000 shares of common stock were reserved for the exercise of stock options, employee stock purchase plan, employee 401(k) stock match plan, exercise of warrants, conversion of convertible notes payable, shares issuable under the SEDA, contingent warrants and contingent shares subject to milestones per the amendments to the Company's License and Collaboration Agreement.

At December 31, 2005, the Company had sufficient authorized and registered shares to satisfy its commitments of all existing derivative instruments and accordingly no additional liability existed or was recorded pursuant to Emerging Issues Task Force No. 2000-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock."

### **Stockholder Rights Plan**

The Company has a Stockholder Rights Plan that provides for the distribution of a preferred stock purchase right (a "Right") as a dividend for each share of the Company's common stock of record held at the close of business on March 12, 1992, as well as all future stock issuances. Under certain conditions involving an acquisition by any person or group of 15% or more of the common stock, the Rights permit holders (other than the 15% holder) to purchase the Company's common stock at a 50% discount upon payment of an exercise price of \$150 per Right. The Rights Agreement was amended to provide that the completion of financings with affiliates of Mr. Kimberlin would not trigger the 15% acquisition threshold. In addition, in the event of certain business combinations, the Rights permit the purchase of the common stock of an acquirer at a 50% discount. Under certain conditions, the Rights may be redeemed by the Board of Directors in whole, but not in part, at a price of \$0.01 per Right. The Rights have no voting privileges and are attached to and automatically trade with our common stock. The Rights Agreement was amended to extend the expiration date from February 26, 2002 to February 26, 2012.

### **Note 7 — Exit and Disposal Related Costs:**

During May 2003, the Company disposed of excess assets, and in August 2003 the Company negotiated an early lease termination for the Company's former, vacated Carlsbad, California headquarters facility resulting in exit and disposal related costs of \$1,388,000.

During the fourth quarter of 2003, the Company recorded expense of \$2,040,000 related to the estimated net rental expense of a vacant facility in King of Prussia, Pennsylvania, due to the inability to find a subtenant. This expense was in addition to an estimated expense recorded in 2002 for this facility. These amounts were recorded as a deferred liability and are being amortized, which offsets the cash paid out currently as rent.

### **Note 8 — Revenues and Expenses Under Collaborative Agreements:**

In September 2004, the Company transferred to NovaRx Corporation ("NovaRx") its in-license rights to certain cancer-related technology and received an initial payment of \$150,000. The Company recognized this payment as revenue and fully recognized the remaining deferred revenue of \$121,000 for previous sublicense agreements with NovaRx. The Company had previously in-licensed this technology from The Sidney Kimmel Cancer Center and Dr. Masayoshi Namba. The Company will have no future contractual obligations under either the in-licensing or out-licensing agreements. NovaRx also agreed to pay the Company an additional \$900,000 due on or before August 2007. The Company will recognize this revenue when received, due to the uncertainty of NovaRx's ability to pay. All other revenues recognized were from the amortization of other multi-year out-licensing contracts covering various intellectual property that the Company owns.

### **Note 9 — Income Taxes:**

At December 31, 2005, the Company had federal, California and Pennsylvania tax net operating loss carryforwards ("NOLs") of approximately \$278 million, \$83 million and \$52 million, respectively, which expire from 2006 to 2025. The difference between the federal and California NOLs is primarily attributable to capitalized research and development expenses for California and the 50% limitation of California NOLs prior to years before 2002. We have had numerous equity transactions that have resulted in a change in ownership of the Company in 2003 as defined by Section 382 of the Internal Revenue Code of 1986, as amended.

Due to this change in the Company's ownership, the utilization of both federal and state NOLs generated prior to July 2003 is

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limited to approximately \$5 million per year. As a result of this limitation, approximately \$136 million of the Company's federal, California and Pennsylvania NOLs more than likely will expire before they can be utilized.

The Company has not completed an analysis for any new changes in ownership that might have occurred in 2005; but following the February 2006 and the March 2006 Private Placement, these equity transaction have more than likely resulted in a change in ownership of the Company as defined by Section 382. Due to this probable change in the Company's ownership, the utilization of both federal and state NOLs generated prior to 2006 will be severely limited, if any.

The Company also has federal and California research and development tax credit carryforwards of approximately \$10.9 million and \$4.9 million, respectively, which expire from 2006 to 2025. Pursuant to Section 383 of the Internal Revenue Code of 1986, as amended, the utilization of these credits will also be limited as a result of the 2003 change in ownership of the Company, as discussed above.

The components of the Company's deferred tax assets as of December 31, 2005 and 2004 are as follows (in thousands):

	December 31,	
	2005	2004
Net operating loss carryforwards	\$ 88,911	\$ 80,009
Unused research and development credits	15,807	15,416
Capitalized research and development	15,219	15,867
Depreciation	1,160	1,172
Deferred rent and excess lease reserves	1,067	1,163
Impairment charges	458	458
Other accrued expenses	130	190
Deferred revenue	71	90
	<u>122,823</u>	<u>114,365</u>
Valuation allowance	<u>(122,823)</u>	<u>(114,365)</u>
	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance changed by \$8,458,000 in 2005 from 2004. The valuation allowance for federal and state deferred tax assets at December 31, 2005 and 2004 is due to management's determination that as a result of the Company's liquidity concerns, accumulated deficit and uncertainty as to future taxable income, it is more likely than not that the deferred tax assets will not be realized in the future.

**Note 10 — Selected Quarterly Financial Data (Unaudited):**

The following is a summary of the unaudited quarterly results of operations for the years ended December 31, 2005 and 2004. Net loss per share has been computed using the weighted average shares outstanding during each quarter. Quarterly earnings per share are calculated on an individual basis, and because of rounding and changes in the weighted average shares outstanding during the year, the summation of the quarters may not equal the amount calculated for the year as a whole. All amounts are in thousands except per share amounts.

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
<b>2005</b>				
Licensed research revenue	\$ 4	\$ 4	\$ 4	\$ 3
Contract research revenue	7	7	7	8
Operating expenses	<u>(3,644)</u>	<u>(3,572)</u>	<u>(3,305)</u>	<u>(3,703)</u>
Loss from operations	<u>(3,633)</u>	<u>(3,561)</u>	<u>(3,294)</u>	<u>(3,692)</u>
Other income and (expense)	<u>(699)</u>	<u>(1,585)</u>	<u>(357)</u>	<u>(492)</u>
Net loss	<u>(4,332)</u>	<u>(5,146)</u>	<u>(3,651)</u>	<u>(4,184)</u>
Preferred stock dividend	<u>(93)</u>	<u>(92)</u>	<u>(86)</u>	<u>—</u>
Preferred stock beneficial inducement cost	<u>—</u>	<u>—</u>	<u>(950)</u>	<u>—</u>
Net loss attributable to common stockholders	<u>\$(4,425)</u>	<u>\$ (5,238)</u>	<u>\$ (4,687)</u>	<u>\$ (4,184)</u>
Net loss per share	<u>\$ (0.09)</u>	<u>\$ (0.10)</u>	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>
Net loss per share attributable to common stockholders	<u>\$ (0.09)</u>	<u>\$ (0.11)</u>	<u>\$ (0.09)</u>	<u>\$ (0.06)</u>

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	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
<b>2004</b>				
Licensed research revenue	\$ 7	\$ 7	\$ 277	\$ 3
Contract research revenue	7	7	7	8
Operating expenses	(4,201)	(4,485)	(4,068)	(4,824)
Loss from operations	(4,187)	(4,471)	(3,784)	(4,813)
Other income and (expense)	(10,589)	(716)	(700)	(699)
Net loss	(14,776)	(5,187)	(4,484)	(5,512)
Preferred stock dividend	(89)	(92)	(93)	(92)
Net loss attributable to common stockholders	\$(14,865)	\$(5,279)	\$(4,577)	\$(5,604)
Net loss per share	\$ (0.36)	\$ (0.11)	\$ (0.09)	\$ (0.11)
Net loss per share attributable to common stockholder	\$ (0.36)	\$ (0.11)	\$ (0.09)	\$ (0.12)

**Note 11 — Commitments and Contingencies:****Commitments**

The Company leases its offices and manufacturing facility under non-cancelable operating leases. The remaining terms on the three facility leases range from three to six years and are subject to certain minimum and maximum annual increases. Two of the three facility leases can be renewed for two additional five-year periods beyond their expiration in 2011.

Future minimum rental payments due under the Company's non-cancelable operating leases are as follows (in thousands):

	Years Ending December 31.
2006	\$ 1,210
2007	1,246
2008	1,076
2009	1,005
2010	1,035
Thereafter	885
	<u>\$ 6,457</u>

Total rent expense for the years ended December 31, 2005, 2004 and 2003 was \$863,000, \$1,192,000 and \$1,202,000, respectively.

**Contingencies**

Between July 2001 and 2003, several complaints were filed in the United States District Court for the Southern District of California seeking an unspecified amount of damages on behalf of an alleged class of persons, who purchased shares of the Company's common stock at various times between May 17, 1999 and July 6, 2001. The complaints have been consolidated into a single action under the name *In re Immune Response Securities Litigation* by order of the Court, and a consolidated, amended complaint was filed in July 2003. The consolidated, amended complaint names the Company and certain of the Company's former officers as defendants, as well as Agouron Pharmaceuticals, Inc. and one of its officers. The consolidated, amended complaint alleges that the Company, Agouron and/or such officers violated federal securities laws by misrepresenting and failing to disclose certain information about the results of clinical trials of Remune®. On October 31, 2003 the defendants filed motions to dismiss the consolidated, amended complaint. The court denied these motions on June 7, 2005.

On July 5, 2005, a shareholder derivative complaint was filed in the Superior Court of the State of California in the County of San Diego against certain of the Company's current and former officers and directors, seeking an unspecified amount of damages.



The Company is also named as a nominal defendant in the complaint, which alleges, among other things, that such officers and directors breached their fiduciary duties by causing the misrepresentation of the Company's financial results and failing to correct the Company's publicly reported financial results and guidance, and engaged in certain improper acts including abuse of control, gross mismanagement and waste of corporate assets from May 1999 to the present.

Although the Company intends to vigorously defend the actions, the Company cannot now predict or determine the outcome or resolution of these proceedings, or to estimate the amounts of, or potential range of, loss with respect to these proceedings. In addition, the timing of the final resolution of these proceedings is uncertain. The range of possible resolutions of these proceedings could include judgments against the Company or the Company's former officers or settlements that could require substantial payments by the Company, which could have a material adverse impact on the Company's financial position, results of operations and cash flows. These proceedings also might require substantial attention of the Company's management team and therefore, regardless of whether the Company wins or loses the litigation, divert their time and attention from the Company's business and operations.

## **Note 12 — Subsequent Events:**

### ***Standby letter of credit***

In January 2006, the Company did not renew the standby letter of credit for \$600,000 issued for the benefit of the landlord of the Company's Carlsbad, California headquarters. Under the terms of the lease if there is no standby letter of credit in place, the Company must provide an additional \$600,000 security deposit to be held by the landlord. The restricted security of \$600,000 (a certificate of deposit), which was collateral for the previous standby letter of credit, reverted to an escrow account for the benefit of the Company controlled by the landlord after the expiration of the standby letter of credit.

### ***SEDA***

Subsequent to December 31, 2005, the Company has made four draws under the SEDA for net proceeds of \$1,375,500 and issued 28,536,351 shares of common stock at an average price per share of \$0.0482. The \$237,000 of subscribed common stock at December 31, 2005 represented an early cash prepayment on the first SEDA draw in January 2006.

### ***February 2006 Note Exchange and Note Revision Agreements***

On February 8, 2006 the Company entered into and consummated a Note Exchange Agreement and a Note Revision Agreement with Cheshire. These agreements pertained to the Mortgage Note previously issued by the Company and held by Cheshire, with a principal balance (before the agreements) of \$5,740,928.

Under the Note Exchange Agreement, the Company issued 53,425,204 shares of newly-issued common stock to Cheshire in exchange for \$1,005,683 of principal of, and \$62,821 of accrued interest on, the Mortgage Note.

This transaction resulted in antidilution adjustments under the terms of some of the outstanding derivative securities. Most notably, as a result of "ratchet" antidilution provisions in the Debenture and common stock warrants held by Cornell Capital, the conversion price and exercise price of those securities were reduced to \$0.02 per share. As a result the \$500,000 outstanding principal balance of the Debenture, which had previously been convertible into 791,765 shares of common stock (at \$0.6315 per share), became convertible into 25,000,000 shares of common stock; and the warrants, which had previously been exercisable for 500,000 shares of common stock (at \$0.924 per share), became exercisable for 23,100,000 shares of common stock.

The Company no longer has enough authorized but unissued shares of common stock to enable the conversion or exercise of Cornell Capital's securities for these expanded numbers of shares of common stock. Indeed, the Note Exchange Agreement issuance necessitated even invading the share reserves which had been previously established to underlie most of the Company's derivative securities, other than Cornell Capital's previously-established share reserves.

Under the Note Revision Agreement, the maturity date of the Mortgage Note was extended from May 31, 2007 to January 1, 2009 and in consideration for that extension the Company reduced the conversion price of the remaining \$4,735,245 principal amount of the Mortgage Note to \$0.02 per share of common stock. Accrued interest on the Mortgage Note will also be convertible at \$0.02 per share of common stock. Before the Note Exchange Agreement, the conversion price of the Mortgage Note had been \$0.70 per share. The difference between conversion of

\$4,735,245 at \$0.70 per share and conversion of \$4,735,245 at \$0.02 per share is 229,997,599 additional shares of common stock. The Company no longer has enough authorized but unissued shares of common stock to enable the conversion of the Mortgage Note into this expanded number of shares of common stock.

In addition, the Note Exchange Agreement and the Note Revision Agreement resulted in weighted-average antidilution adjustments under various warrants held by Cheshire resulting in them becoming exercisable for an aggregate of 31,727,025 shares of common stock, instead of the 9,947,335 shares of common stock for which they had been exercisable as December 31, 2005, and at a blended exercise price of \$0.33 instead of at a blended exercise price of \$1.05.

On February 9, 2006, in exchange for \$250,000 cash, the Company issued to Qubit Holdings, LLC ("Qubit"), which is owned and managed by independent trustees for the children of Mr. Kimberlin, a \$250,000 promissory note, secured by substantially all of the Company's assets, bearing interest at 8% per annum, maturing on January 1, 2008, and convertible into our common stock at \$0.02 per share, plus 37,500,000 short-term warrants to purchase our common stock at \$0.02 per share. Qubit also granted the Company the right to, until August 8, 2006, put to Qubit another \$250,000 secured convertible note of like tenor and another 37,500,000 short-term warrants of like tenor, and to thereupon receive another \$250,000 cash. The Company no longer has enough authorized but unissued shares of common stock to enable the conversion or exercise of the derivative securities issued or issuable to Qubit.

### **March 2006 Private Placement**

The Company's 2006 Private Placement of secured convertible notes and warrants to accredited investors, which began on February 10, 2006 and successfully raised gross proceeds of \$8,000,000, had its final closing on March 7, 2006. In the 2006 Private Placement, pursuant to subscription agreements, the Company issued notes with an aggregate principal amount of \$8,000,000, convertible into an aggregate of 400,000,000 shares of common stock at \$0.02 per share. The notes mature on January 1, 2008, bear interest at 8% per annum, and share (with Cheshire, Cornell Capital and Qubit, for their previously secured notes), a first-priority security interest in substantially all of the Company's assets. The first \$6,000,000 of the 2006 Private Placement notes sold (other than to the Company's directors) are further supported by a guaranty limited to the value of the proceeds of certain shares of private-company preferred stock owned by Spencer Trask Intellectual Capital Company LLC ("STIC"), an affiliate of Kevin Kimberlin. In addition, the Company issued to all of the noteholders a total of 1,200,000,000 warrants to purchase the Company's common stock at \$0.02 per share. These warrants will expire in two tranches, with the last tranche expiring 160 days after a registration statement, with regard to the common shares underlying them, is declared effective by the SEC.

The Company has provided a Registration Rights Agreement to register the underlying shares of common stock for the convertible notes, the warrants, the placement agent warrants and the STIC warrants. The Company will file a registration statement with the SEC within 45 days after March 7, 2006 (the "Filing Deadline"); or in the event of an SEC delay because we do not have enough authorized shares of common stock to register at the time of the filing, the Company has within ten business days following stockholder approval of an amendment to its certificate of incorporation to increase its authorized shares of common stock to file such registration statement (the "Dismissal Deadline"). If the Filing or Dismissal Deadline, as applicable, is not met, the Company will be required to pay liquidated damages to the investors equal to 1% of the aggregate amount invested for each 30-day period or pro rata for any portion of a period following the missed applicable Deadline until the registration statement is filed. The liquidated damages are payable in cash or additional shares of common stock as determined by each investor.

Among the investors in the 2006 Private Placement were several of the Company's affiliates, including direct or indirect investment by Company directors and officers: Joseph O'Neill (\$25,000 note and 3,750,000 warrants), Martyn Greenacre (\$25,000 note and 3,750,000 warrants), David Hochman (\$25,000 note and 3,750,000 warrants), Kevin Reilly (\$25,000 note and 3,750,000 warrants), Alan Rosenthal (\$25,000 note and 3,750,000 warrants), Michael Green (\$100,000 note and 15,000,000 warrants), Peter Lowry (\$25,000 note and 3,750,000 warrants), and Georgia Theofan (\$50,000 note and 7,500,000 warrants).

The Company also agreed, in order to induce STIC to provide a guaranty limited to the value of the proceeds of certain shares of private-company preferred stock for the benefit of the first \$6,000,000 (other than those sold to the Company's directors) of the 2006 Private Placement notes, to issue to STIC, for every month that the limited guaranty remains in place, a number of seven-year warrants to purchase the Company's common stock at \$0.02 per share equal to 1% of the common stock then underlying the first \$6,000,000 of the 2006 Private Placement notes, to the extent the notes are then outstanding.

The Company also paid commissions and fees to the placement agent, Spencer Trask Ventures, Inc. (“STVI”), for its services in connection with the 2006 Private Placement. STVI, which is an affiliate of Mr. Kimberlin and also of the Company’s director, David Hochman, received \$800,000 in cash and seven-year placement agent warrants to purchase 80,000,000 shares of common stock at \$0.02 per share. In addition, if and when the 2006 Private Placement warrants are exercised STVI is to receive a commission equal to 10% of the warrant exercise proceeds in cash plus seven-year placement agent warrants to purchase a number of shares of the Company’s common stock equal to 20% of the number of exercised warrants. The Company also reimbursed STVI’s expenses and provided it with certain “tail” and first refusal rights. STVI has chosen to share some of this compensation with its employees and/or its selected dealers. STVI will retain 17,203,500 warrants of the 80,000,000 warrants. As to the 240,000,000 potential warrants issuable upon investor exercise of the warrants issued in the 2006 Private Placement, STVI will earn a prorata share of warrants at approximately 21.5%, which would be 51,610,500, if all the investor warrants were exercised in full.

In addition, the 2006 Private Placement (including the placement agent warrants) resulted in weighted-average antidilution adjustments under various warrants held by Cheshire resulting in them becoming exercisable for an aggregate of 104,723,277 shares of common stock, instead of the 31,727,025 shares of common stock for which they had been exercisable before the 2006 Private Placement, and at a blended exercise price of \$0.10 instead of at a blended exercise price of \$0.33.

None of the above derivative securities will be able to be converted into or exercised for common stock, in accordance with their terms, unless the Company obtains stockholder approval for and then effectuates an amendment of the Company’s certificate of incorporation to significantly increase our authorized number of shares of common stock.

Cheshire has further agreed to convert a total of another \$1,700,000 of principal and accrued interest on the Mortgage Note into 85,000,000 shares of common stock at \$0.02 per share, upon the effectuation of such amendment of the Company’s certificate of incorporation.

#### ***Cornell Note Conversion and Warrant Exercise***

On March 8, 2006, Cornell Capital converted \$31,670 of the outstanding principal balance of the Debenture into 1,583,500 shares of common stock pursuant to the terms of the Debenture at the adjusted \$0.02 per share. Following the conversion, the outstanding principal balance of the Debenture was \$468,330.

On March 9, 2006, Cornell Capital partially exercised the warrant issued in August 2005, delivering \$10,000 in cash to purchase 500,000 shares of common stock pursuant to the adjusted terms of the warrant at \$0.02 per share. Following this transaction, the warrant is exercisable for 22,600,000 shares of common stock.

After this conversion and exercise, the Company no longer has any authorized but unissued shares of common stock available to enable the further conversion or exercise of Cornell Capital’s remaining derivative securities for the expanded numbers of shares of common stock that resulted from the “ratchet” antidilution provisions in February 2006.

#### ***Accounting Treatment for the February and March 2006 Transactions***

Pursuant to Emerging Issues Task Force No. 2000-19, “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock,” the Company will have to record a liability for the insufficient number of underlying common shares committed for all derivative instruments at the date of each such event and mark each liability to market as of each balance sheet date. The recording of these liabilities will create a significant charge as an offset against equity during the first quarter of 2006. The Company has not yet quantified this charge.

The Company is in the process of obtaining stockholder approval to amend the Company’s certificate of incorporation to significantly increase our authorized number of shares of common stock. The stockholder vote is scheduled for April 11, 2006. If and when the Company has sufficient shares to satisfy its commitments of all existing derivative instruments and accordingly no liability exists, the fair market value of the derivative securities on the approval date will be reclassified to equity from liabilities.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Immune Response Corporation  
Carlsbad, California

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (File No. 333-101086, File No. 333-64526, File No. 333-81945, File No. 333-106812, File No. 333-103957, File No. 333-116826, File No. 333-116828, File No. 333-126828, File No. 333-126829, File No. 333-130499) and Forms S-3 (File No. 333-101856, File No. 333-46872, File No. 333-58096, File No. 333-92603, File No. 333-94257, File No. 333-83195, File No. 333-110092, File No. 333-115678, File No. 333-128155) of our report dated March 17, 2006 relating to the financial statements of The Immune Response Corporation appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2005. Our report contains an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern.

/s/ Levitz, Zacks & Ciceric  
Certified Public Accountants  
San Diego, California  
March 24, 2006

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Immune Response Corporation  
Carlsbad, California

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (File No. 333-101086, File No. 333-64526, File No. 333-81945, File No. 333-106812, File No. 333-103957, File No. 333-116826, File No. 333-116828, File No. 333-126828, File No. 333-126829, File No. 333-130499) and Forms S-3 (File No. 333-101856, File No. 333-46872, File No. 333-58096, File No. 333-92603, File No. 333-94257, File No. 333-83195, File No. 333-110092, File No. 333-115678, File No. 333-128155) of our report dated February 27, 2004 relating to the consolidated financial statements of The Immune Response Corporation appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2005. Our report contains an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern.

/s/ BDO Seidman, LLP  
Certified Public Accountants  
Costa Mesa, California  
March 28, 2006

**Certification of Principal Executive Officer  
Pursuant to Section 302 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(a)**

I, Joseph F. O’Neill, certify that:

1. I have reviewed this annual report on Form 10–K of The Immune Response Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respect the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) for the registrant and we have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 28, 2006

/s/ Joseph F. O’Neill  
Joseph F. O’Neill  
Chief Executive Officer

**Certification of Principal Financial Officer  
Pursuant to Section 302 of the Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(a)**

I, Michael K. Green, certify that:

1. I have reviewed this annual report on Form 10–K of The Immune Response Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respect the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) for the registrant and we have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2006

/s/ Michael K. Green  
Michael K. Green  
Chief Operating Officer and  
Chief Financial Officer

**Certification Pursuant To Section 1350 of Chapter 63 of 18 U.S.C.  
As Adopted Pursuant To Section 906 of The Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(b)**

In connection with the Annual Report of The Immune Response Corporation (the “Company”) on Form 10–K for the period ending December 31, 2005 as filed with the Securities and Exchange Commission, which this written statement accompanies (the “Report”), I, Joseph F. O’Neill, Chief Executive Officer of the Company, certify pursuant to § 1350 of Chapter 63 of 18 U.S.C., as adopted pursuant to § 906 of the Sarbanes–Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2006

/s/ Joseph F. O’Neill  
Joseph F. O’Neill  
Chief Executive Officer



**Certification Pursuant To Section 1350 of Chapter 63 of 18 U.S.C.  
As Adopted Pursuant To Section 906 of The Sarbanes–Oxley Act of 2002/SEC Rule 13a–14(b)**

In connection with the Annual Report of The Immune Response Corporation (the “Company”) on Form 10–K for the period ending December 31, 2005 as filed with the Securities and Exchange Commission, which this written statement accompanies (the “Report”), I, Michael K. Green, Chief Financial Officer of the Company, certify pursuant to § 1350 of Chapter 63 of 18 U.S.C., as adopted pursuant to § 906 of the Sarbanes–Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2006

/s/ Michael K. Green  
Michael K. Green  
Chief Operating Officer and  
Chief Financial Officer

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