

MEDICAL DISCOVERIES INC

Form 10KSB

March 31, 2006

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**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-KSB**

**þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal period ended December 31, 2005**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE EXCHANGE ACT  
For the transition period from to**

**Commission file number 0-12627  
MEDICAL DISCOVERIES, INC.**  
*(Exact name of Small Business Issuer as specified in its charter)*

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

**87-0407858**  
*(I.R.S. Employer  
Identification No.)*

**1338 S. Foothill Drive, #266, Salt Lake City, Utah 84108**  
*(Address of principal executive offices)*  
**(801) 582-9583**

*(Issuer's telephone number, including area code)*

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

**Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, no par value**  
*(Title of Class)*

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

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

**The issuer had no revenues for its most recent fiscal year.**

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, as of March 27, 2006, was \$17,119,390.

As of March 27, 2006, the issuer had 107,992,148 shares of Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the issuer's 2006 Annual Meeting of Shareholders are incorporated by reference in Part III of this Form 10-KSB.

Transitional Small Business Disclosure Format (check one): Yes  No



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**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

**This Report, including the documents incorporated by reference into this Report, contains Forward-Looking Statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding our products still being in the developmental stage, our lack of operating revenues or profits, our dependence on raising significant additional capital, our auditors' expression of substantial doubt as to our ability to continue as a going concern, the government regulation to which we are subject, our exposure to pricing and reimbursement risks, the competition we face, the potential that our intellectual property is not adequately protected, the fact that we may need to litigate to secure certain of our intellectual property rights, our risk of product liability, our stock being thinly traded and subject to manipulation, the volatility of our stock price, the risk that shareholders could suffer substantial dilution, and the fact that we have not paid dividends to date. All statements other than statements of historical fact are Forward-Looking Statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All Forward-Looking Statements included in this document are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any Forward-Looking Statement. In some cases, Forward-Looking Statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, intends, believe, estimates, potential, or continue, or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the Forward-Looking Statements contained herein are reasonable, there can be no assurance that such expectations or any of the Forward-Looking Statements will prove to be correct, and actual results could differ materially from those projected or assumed in the Forward-Looking Statements. Future financial condition and results of operations, as well as any Forward-Looking Statements are subject to inherent risks and uncertainties, including any other factors referred to in the Company's press releases and reports filed with the Securities and Exchange Commission. All subsequent Forward-Looking Statements attributable to the Company or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on the Company's operating results are described under Management's Discussion and Analysis of Financial Condition and Results of Operations Cautionary Statement for Forward-Looking Information and Factors Affecting Future Results and elsewhere in this report.**

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**PART I**

**ITEM 1. DESCRIPTION OF BUSINESS.**

Medical Discoveries, Inc. was incorporated on November 20, 1991 as a Utah corporation and maintains its principal offices at 1338 S. Foothill Drive, #266, Salt Lake City, Utah 84108. Our telephone number is (801) 582-9583 and our web address is www.medicaldiscoveries.com. We are a developmental-stage bio-pharmaceutical company engaged in the research, validation, development and ultimate commercialization of two drugs: MDI-P and SaveCream. MDI-P is an anti-infective drug that we believe will be a useful and well tolerated treatment for bacterial infections, viral infections and fungal infections. We further believe that MDI-P will be a useful therapy for the treatment of cystic fibrosis. SaveCream is a breast cancer medication that is applied topically to reduce breast cancer tumors. Both of these drugs are still in development and have not been approved by the U.S. Food and Drug Administration (FDA).

Our initial target indications for MDI-P are cystic fibrosis and HIV. On November 10, 2004, we filed an Investigational New Drug application (IND) with the FDA seeking permission to begin Phase I human clinical trials of MDI-P as a treatment for cystic fibrosis. The FDA placed the proposed Phase I clinical trials on clinical hold pending additional preclinical testing. The preclinical testing has been completed and no significant toxicities were noted. We have submitted this data to the FDA. If the FDA lifts the clinical hold upon receipt of the amended IND and allows us to proceed with Phase I studies, we will begin human trials at St. Luke's Regional Medical Center in Boise, Idaho using a protocol designed by Dr. Henry Thompson. We hope to commence recruitment for this study in June or July 2006. If our Phase I IND for cystic fibrosis is successful, we intend to file an IND for Phase I testing of MDI-P as a treatment for HIV at Harvard School of Medicine using a protocol designed by Dr. Bruce Dezube. We also expect to add additional indications for the use of MDI-P in the future as we further our preclinical development.

We recently purchased SaveCream from a German biotechnology company. We are in the process of developing a global commercialization strategy for SaveCream.

To date, we have not generated significant revenues from operations or realized a profit. Through December 31, 2005, we had incurred cumulative net losses since inception of \$20,840,714.

***Recent Developments.***

***Cystic Fibrosis IND.*** We are continuing to pursue our IND for cystic fibrosis with the FDA. In 2005 we concluded large animal model testing to establish pharmacological safety with relation to cardiovascular and central nervous system toxicity as well as in-vitro work on genotoxicity for this IND. The preclinical testing has been completed with positive results. We recently submitted the data to the FDA in hopes of being permitted to proceed with Phase I testing. We anticipate that we may be able to start Phase I clinical trials on cystic fibrosis as early as Q2 of 2006. While we believe we have sufficient funds to begin Phase I clinical trials of MDI-P for cystic fibrosis if and when the FDA allows us to begin human trials under an amended IND, we will need to raise additional funds to complete this testing.

More particularly, the clinical hold items established by the FDA to which we responded included:

Use of the same mode of nebulization administration of MDI-P in small and large mammals as proposed for the Phase I cystic fibrosis clinical trial, to develop:

Satisfactory safety pharmacology data from frank toxicity to minimal toxicity for periods mimicking the proposed clinical trial term;

Mouse safety pharmacology on potential central nervous system involvement; and

Dog safety pharmacology on potential cardiovascular system involvement;  
A battery of genotoxicity studies; and

Data to support the safety of the maximum expected human exposure to listed extractables in our prior IND submission.



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We contracted with Ascentia Bio-Medical Technologies for the cGMP, placebo-controlled, multi-dose mouse central nervous system toxicology study. A specialized mouse nebulization system was used, in order to mimic the mode of delivery slated for the Phase I cystic fibrosis trial. We contracted with MPI Research for the cGMP, placebo-controlled, multi-dose dog cardiovascular toxicology study. Again, specialized dog nebulization masks with harnesses were used to mimic the mode of delivery slated for the Phase I cystic fibrosis trial. We contracted with NAMSA for the genotoxicity studies, including a Mouse Peripheral Blood Micronucleus Study, a Dose Range Study in Mouse Peripheral Blood Micronucleus, an In-Vitro Chromosomal Aberration Study in Mammalian Cells, and a Bacterial Reverse Mutation Study. Finally, we contracted with Dr. Robert Mastico for the data submission on the extractables.

SaveCream. On March 16, 2005, Medical Discoveries, Inc. (the Company) completed the purchase of the intellectual property assets (the Assets) of Savetherapeutics AG, a German corporation in liquidation in Hamburg, Germany (SaveT). The Assets consist primarily of patents, patent applications, pre-clinical study data and anecdotal clinical trial data concerning SaveCream, SaveT's developmental topical aromatase inhibitor treatment for breast cancer. The purchase price of the Assets is 2,350,000 (approximately \$2.8 million under current exchange rates) payable as follows: 500,000 at closing, 500,000 upon conclusion of certain pending transfers of patent and patent application rights from SaveT's inventors to the Company, and 1,350,000 upon successful commercialization of the Assets. The Company's source of funds for the acquisition is a \$3 million equity investment by Mercator Momentum Fund LP and Mercator Momentum Fund III LP. Neither SaveT nor any employee of SaveT has a material relationship with the Company or any of its affiliates, any director or officer of the Company or any associate of any such director or officer.

Before it ceased business in 2004, Savetherapeutics (SaveT) had been developing SaveCream, a topical steroidal form of aromatase inhibitor (AI) for breast cancer that never generated revenues for SaveT. This promising cancer therapeutic product has been tested in the European Union under a unique German regulatory scheme that allows patients with limited treatment options to receive novel treatments. In the study, over 100 women diagnosed with breast cancer received special permission to be treated with SaveCream. A significant number of those women experienced a significant reduction in tumor size of fifty percent in two weeks. No follow up data was collected to permit assessment of adverse events or benefits of treatment occurring after the treatment period. We are in the process of developing a global commercialization strategy for SaveCream, to include certain preclinical studies including toxicology and pharmacokinetics, as well as the development of future clinical protocols.

M.A.G. Capital, LLC (formerly Mercator Advisory Group, LLC), through its designated funds, Mercator Momentum Fund, L.P., and Mercator Momentum Fund III, L.P., provided us with \$3 million for the purchase, pursuant to terms described below.

We would like to initiate a preclinical development program for SaveCream, however we do not currently have the funds to do so. Should we be unable to fund preclinical testing necessary to file an IND, we may instead seek a co-development partner or out-licensing opportunities for this product.

We analyzed whether the intellectual property purchased was a business within the contemplation of Regulation S-X, and concluded that no such business had been acquired.

Series A Preferred Stock Financings. On or about March 14, 2005, we closed the second of two rounds of Series A Preferred Stock financing with M.A.G. Capital, LLC (formerly Mercator Advisory Group, LLC). In this round, we sold 30,000 shares of Preferred Stock and warrants to purchase 22,877,478 shares of common stock for a total offering price of \$3 million. Each share of Preferred Stock entitles the holder to convert the share of Preferred Stock into the number of shares of common stock resulting from multiplying \$100 by the conversion price. The conversion price for this round is 75% of the average of the lowest three intra-day trading prices for our common stock during the 10 trading days immediately preceding the conversion date, but the conversion price may not exceed \$0.1967. The number of shares of common stock subject to the warrants and the exercise price are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. The warrants entitle the holder to purchase up to 22,877,478 shares of our common stock on or before the third anniversary of the issuance date of the warrants at \$0.1967 per





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share. The number of shares of common stock subject to the warrants and the exercise price are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. In connection with this financing, we issued to a placement agent warrants that entitle the holder to purchase up to 1,220,132 shares of our common stock on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share.

On or about October 18, 2004, we closed the first of two rounds of Series A Preferred Stock financing with M.A.G. Capital, LLC (formerly Mercator Advisory Group, LLC). In this round, we sold 12,000 shares of Preferred Stock and warrants to purchase 4,575,495 shares of common stock for a total offering price of \$1.2 million. Each share of Preferred Stock entitles the holder to convert the share of Preferred Stock into the number of shares of common stock resulting from multiplying \$100 by the conversion price. The conversion price for this round is 85% of the average of the lowest three intra-day trading prices for our common stock during the 10 trading days immediately preceding the conversion date, but the conversion price may not exceed \$0.1967 or be lower than \$0.05. The number of shares of common stock subject to the warrants and the exercise price are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. The warrants entitle the holder to purchase up to 4,575,495 shares of our common stock on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share. The number of shares of common stock subject to the warrants and the exercise price are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. In connection with this financing, we issued to a placement agent 350,000 shares of restricted common stock and warrants that entitle the holder to purchase up to 488,052 shares of our common stock on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share.

In connection with the Series A Preferred Stock financings, we agreed with the investors to register the shares of common stock into which the Preferred Stock is convertible and the warrants are exercisable.

***Business Strategy.***

Our highest priorities are to:

commence human clinical trials of MDI-P for cystic fibrosis;

file an IND for HIV; and

develop a commercialization strategy for SaveCream.

Our second priorities are the completion of a longer-range strategic business plan in which we utilize the intellectual property that has been developed over the last decade and determine an appropriate direction for future development of the business over the next five to ten years. Some of the issues we will be dealing with will include:

listing the Company's common stock on a stock exchange or NASDAQ;

how to provide shareholders with liquidity, transparency and a return on investment;

a decision on whether or when to relocate the Company or maintain its current location;

a decision as to what staffing requirements the Company will have, when to bring additional permanent staff on board and the best route for recruiting those staff members;

additional target indications and the formulation and development process required for those target indications;

a comprehensive intellectual property strategy;

a potential partnering strategy; and

projected long-term financing requirements.



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***MDI-P: Novel Anti-Infective Technology.***

MDI-P is an anti-infective drug that we believe will be useful treatment for bacterial infections, viral infections and fungal infections. MDI-P appears to work by virtue of the direct virus-, bacteria- and fungus-killing effect of several of the powerful oxidants present in the MDI-P solution. The MDI-P solution contains oxidants such as various hypochlorous acid chains, ozone and dilute hydrogen peroxide. These oxidants, traditionally believed to have a very short half-life in their natural state, seem to exhibit stability of one month or longer in MDI-P.

During the past nine years, we have conducted a variety of cell line testing at the following university and medical research institutions, among others:

Stratton V.A. Medical Center, Albany, New York  
Albany Medical College, Albany, New York  
Indiana University School Of Medicine And Dentistry  
University of California, Los Angeles  
Baylor College of Medicine and Dentistry, Dallas, Texas  
Dana-Farber Cancer Institute, Boston, Massachusetts  
University of Washington Medical School

Highlights from those tests include the following:

In 1998, we initiated *in vitro* testing, conducted at the Dana-Farber Cancer Institute in Boston, Massachusetts, a major teaching affiliate of the Harvard Medical School. The results of this independent testing confirmed that MDI-P achieved destruction of more than 90% of the HIV virus in cell cultures, with no toxicity to the cells.

In 2000, data and results published by Dr. Aldonna Baltch, M.D., of the Stratton V.A. Medical Center and Albany Medical College, Albany NY, indicated that MDI-P is a potent antibacterial and anti-fungal agent. Dr. Baltch's work demonstrated that MDI-P was effective in destroying the fungi *Candida albicans* and *Legionella pneumophillia* (Legionnaire's Disease) within 60 seconds of exposure to the fungi with no evidence of cell toxicity. This work was published in The American Journal of Infection Control in 2000 and as abstracts of the American Society of Microbiology meetings in 1997 and 1998.

Toxicity tests completed in 2001 by WIL Research Laboratories demonstrated that various strengths of MDI-P (up to a 50% solution strength) produced no systemic toxicity in laboratory animal tests used to assess potential problems for human application. These preclinical studies were conducted following FDA guidelines and have helped establish that MDI-P is reasonably safe for human clinical trials.

In 2004, Dr. Emil Chi, Chairman of the Department of Histopathology at the University of Washington Medical School, conducted a mouse study focused on MDI-P as a potential therapeutic agent for the treatment of sepsis. The results reaffirmed the anti-infective strength and low toxicity profile in preclinical models of MDI-P.

In 2004, we also commissioned a mouse study by Dr. Chi focused on MDI-P as a potential therapeutic agent for the treatment of the symptoms of asthma. In the study, 36 female mice were examined in a chronic asthma model, using various doses of MDI-P as a therapeutic agent as measured against a saline control. Samples of bronchial lavage lung fluid and tissue were taken from all mice, with assays performed in airway mucus build-up and eosinophil infiltration, a prime blood cell measure of asthmatic attacks. More than 70% of the MDI-P treated mice exhibited no increase in mucus secretions, comparable with saline control animals, with a marked reduction in eosinophil infiltration. Untreated asthmatic mice, in contrast, had more than a nine-fold increase in mucus build-up as compared with saline controls. Further, no toxicity was found in the MDI-P treated mice.

On July 15, 2004, we announced our receipt from Clagett Consulting of a large mammal toxicity report for MDI-P. The study found no sign of any toxicity from MDI-P in the anatomy, behavior, clinical chemical, hematological, or histopathological measures of adverse events. The study was conducted in



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a rabbit species (New Zealand white rabbits) because of their acknowledged hyper-reactivity to toxicity in drugs. These results, when combined with our prior toxicological work, suggest that MDI-P should not cause toxic events in humans. Also included in the Clagett Consulting report was a further genomic analysis for toxicology of MDI-P. This genomics analysis indicated that MDI-P had no effect on any of the following: bone marrow function, hematocrit levels in peripheral blood, serum levels for alanine aminotransferase levels and aspartate aminotransferase levels, both of which provide sensitive measures of hepatic toxicity, serum protein and albumin levels, bound urinary nitrogen levels, serum calcium levels or blood glucose levels. In addition, this genomics analysis provided confirmation that various measures of impact on the hundreds of genes controlling toxicity as well as the immuno-regulatory system were neither up-or-down regulated by MDI-P.

In 2004 Dr. Chi also studied MDI-P as a potential therapeutic agent for the treatment of the symptoms of cystic fibrosis. In this study of 48 mice, it was found that MDI-P is a useful agent to reduce primary measures of disease in cystic fibrosis, including bacterial infection, mucus secretion, cellular infiltration, lung edema (swelling with excess fluid), lung hemorrhage, and lung infiltration by neutrophils and eosinophils, the principal white blood cells responding to allergic and infectious pathogens. Excessive presence of neutrophils and eosinophils can lead to cell death in surrounding tissues, causing serious health problems from their over-expression. No overt signs of toxicity were found in the primary organs (lungs, liver, spleen, kidneys, brain) of mice treated with MDI-P.

In 2004 we conducted a chronic toxicity study of MDI-P. The study involved the weekly injection of MDI-P into the body cavity of test mice for six-months. No statistically relevant changes in body weight, or morphometry or histopathology of vital organs were observed, when compared with mice receiving saline control injections or with untreated animals. The study resulted in no dose-dependency and no toxic effects.

In 2005 and 2006 we conducted a battery of tests in response to the FDA's clinical hold items for our cystic fibrosis IND. Those studies included a mouse central nervous system toxicity study conducted by Ascentia Bio-Medical Technologies, a dog cardiovascular toxicity study conducted by MPI Research, and the following genotoxicity studies conducted by NAMSA: Mouse Peripheral Blood Micronucleus Study, Dose Range Study in Mouse Peripheral Blood Micronucleus, In-Vitro Chromosomal Aberration Study in Mammalian Cells, and Bacterial Reverse Mutation Study. No adverse events were discovered in these studies.

***Application of MDI-P to HIV.***

***Overview.*** Our preclinical research has demonstrated that MDI-P is capable of rapidly killing HIV upon direct contact and preventing infection of cells in a cell culture. MDI-P has also shown it is capable of rapidly killing the HIV virus in an acutely infected cell line. Furthermore, the destruction of the HIV virus by MDI-P in a cell culture or a cell line does not require any additional combination of drugs, and appears to have a low toxicity profile in preclinical analysis. If these results can be replicated in human beings, under appropriate clinical protocols, this compound may represent a significant clinical advance over existing therapies.

***Background of HIV/AIDS.*** HIV is a retrovirus whose genetic information is encoded by ribonucleic acid (RNA) instead of deoxyribonucleic acid (DNA). It spreads through the body by invading host cells and using the human cells' own protein synthesis process to replicate itself. As the virus replicates, it slowly destroys the immune system by infecting and killing T lymphocytes, so-called "T cells", which are critical for the function of the human immune system. The most recent estimates of the World Health Organization report that in 2003, between thirty-five and forty-two million people were infected with the HIV virus worldwide.

***Existing Therapies for HIV.*** There are approximately 24 HIV therapies currently on the market and approved by the FDA with a market value in 2004 of approximately \$6 billion per year and a projected annual growth rate of five and a half to six percent over the next ten years. The current U.S. market is valued in excess of \$3 billion annually. The primary current therapies for HIV are anti-retroviral products falling into four categories: nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors,

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protease inhibitors, and anti-fusion of HIV-1 with CD4 cells (Fuzeon<sup>®</sup>, or enfuvirtide). These therapies are typically taken in combination under a protocol called Highly Active Antiretroviral Therapy (HAART). HAART is effective in controlling the levels of virus and in increasing the number of T cells. However, these combination therapies are also associated with significant toxicity and viral resistance. As a result, current therapy management is characterized by a set of complex issues: when to initiate therapy, what regimen to use, which drugs within each class to use, and when to change therapies. Due to limitations of chronic use of anti-retroviral drug therapies, guidelines issued by the National Institutes of Health suggest starting these therapies later in the disease. Therefore, a need exists for therapies that are useful early in the disease process, that are non-toxic, that are active against resistant strains and that do not give rise to rapid resistance. Even the new best-of-breed therapeutic, Fuzeon<sup>®</sup>, requires administration with other standard combination antiretroviral therapies, and exhibits a number of toxicities, including: injection site reactions in approximately 98% of patients treated, and on a less frequent basis, pneumonia, diarrhea, nausea, fatigue, fever, increased hepatic enzymes, neutropenia, thrombocytopenia, and renal failure.

***Potential Benefits of MDI-P.*** MDI-P appears to have several important characteristics that could provide benefits to both patients and providers alike:

MDI-P's mechanism of action is not accomplished by enzyme or nucleic acid inhibition, but rather by direct intra-cellular effects. In preliminary testing, MDI-P has been shown to be very rapid in effect and to destroy viruses without destroying host cells.

MDI-P's broad-spectrum antiviral effects appear to make it active against even highly resistant viral strains and not subject to rapid resistance.

The destruction of bacterial organisms by exposure to MDI-P does not appear to produce any potential harmful effects.

MDI-P appears to have a low toxicity profile and therefore may be better tolerated by patients.

***MDI-P's HIV Protocol.*** The HIV virus is known to have a cell replication cycle of approximately ten days to two weeks. For this reason, the Phase I protocol designed by Dr. Bruce Dezube planned at Harvard Medical School will use daily infusions over fourteen-day infusion cycles of MDI-P, followed by a rest period, followed by subsequent two-week infusions. The selection of the appropriate human dosing regimen will be based upon the dose curve data currently being established at the University of Washington Medical School. The Harvard Phase I studies will be examining toxicity, together with early signs of efficacy in bringing HIV RNA cell copies in blood tests down to or below the 400 copies/mL level experienced by at least 34% of treatment-experienced patients in trials of the best of breed therapeutics in HIV (e.g. Fuzeon<sup>®</sup>).

In order to expedite MDI-P's IND for HIV, the Company may pursue an adjunct therapy program for its therapeutic, as in joint dosing with an approved HAART HIV therapeutic with MDI-P as an adjunct therapy to clinically manage the effects of fungal infections which frequently plague HIV patients. Specific preclinical studies in common fungi associated with HIV patients would be undertaken to support such a filing, together with the improved toxicity profile for MDI-P currently being established for the cystic fibrosis indication. Some of our toxicity work for cystic fibrosis (specifically, cardiovascular involvement in dogs and central nervous system involvement in mice) may need to be repeated via an infusion mode of delivery for HIV prior to filing an IND for HIV.

***Application of MDI-P to Cystic Fibrosis.***

***Overview.*** Cystic fibrosis (CF) is a recessive genetic disease that manifests itself in multiple systems of the body. Individuals who suffer from CF produce excessive amounts of thick, sticky mucus that obstructs the airways of the CF patient. If mucus is not reduced in the CF patient, then respiratory failure can occur. Due to the fact that mucus serves as a medium for the growth of bacteria, the CF patient faces a high risk of morbidity and mortality due to frequent pulmonary infections. Currently, there are no FDA approved CF therapeutics that provide a statistically significant mucus-clearing effect. The prospective ability of MDI-P to remove CF patient mucus accumulation may, in fact, provide a significant extension of life for CF patients.





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*Background of Existing Therapies.* With CF being a genetically-determined illness, there is presently no known cure for CF. Current treatment standards, which may entail 3-4 hours of treatment per day for the CF patient, include:

Dietary control to lessen the build-up of fats, proteins (and to a lesser extent, carbohydrates) which can not be readily absorbed and metabolized. Typically, such dietary control is augmented with oral pancreatic enzymes to assist in fat metabolism.

Treatment of bacterial infection with erythromycin, Tobramycin<sup>®</sup> (TOBI), and in severe infection cases, vancomycin to eradicate or control the infection. In some cases, daily use of oral antibiotics may be prescribed due to the high frequency of lung infection in CF patients and its risk of mortality.

Frequent use of mucolytic agents such as N-acetylcysteine and bronchodilator therapy with Pulmozyme<sup>®</sup>. Clinical response may further indicate bronchial drainage through recombinant human Dnase or flutter devices to assist in mucus airway clearance, together with clapping of the chest to dislodge mucus. In extreme cases, broncho-alveolar lavage may be used, and if necessary, lung transplantation.

Periodic corticosteroid tablets and inhaled anti-asthma medications (e.g., Advair<sup>®</sup>, Singulair<sup>®</sup>, etc.) to combat lung inflammation (frequently resulting from the presence of infection), together with high doses of ibuprofen for its anti-inflammatory effect.

In addition, the CF patient may have insulin prescribed for CF-related diabetes, as well as medications for CF-associated liver disease, supplements of vitamins A and D, and medication to treat constipation. Oxygen therapy may also be prescribed.

At present, current therapies tend to be more effective in controlling pulmonary infection than in clearance of mucus. However, the increasing use of antibiotics to treat CF patients has lead to an increased number of CF patients with drug-resistant infection that can prove life-threatening. Since CF's build-up of mucus is genetically dependent, and the mucolytic agents and therapies limited in total mucus-clearing effect, the CF patient lives with a serious threat of respiratory failure from any of the various frequent pulmonary infections. Even with the use of all such therapies administered through approved CF disease centers, the common prognosis for life expectancy of a CF patient is currently 31-32 years.

*Prospective Benefits of MDI-P.* New anti-microbial therapies that would reduce continued mucus build-up would be beneficial to the CF patient to help prevent airway obstruction and frequent pulmonary infection. Should such new anti-microbial therapies also prove less susceptible to drug resistance, together with efficacy on viruses, their value in extending the quality of life and life span of CF patients would be substantial.

Based upon preliminary evidence from MDI's pre-clinical studies, we are hopeful that MDI-P may offer CF patients the following:

to serve as a highly active anti-microbial agent for CF patients with bacterial pulmonary infection, as well as viral pulmonary infection, with low drug resistance probability; and

to serve as the best-of-breed mucolytic agent in clearing the continuous mucus build-up in CF, when applied by nebulization into the lungs, as an adjunct therapy to TOBI.

The potential benefits of using MDI-P as an adjunct therapy to TOBI, based on preliminary data from our pre-clinical studies, are as follows:

to avoid the possibility of significant clinical risk of adverse events with CF patients that a lengthy drug-clearance period might introduce if TOBI was discontinued and MDI-P used alone; and

to lessen the likelihood of adverse events due to endotoxin reaction, due to the high level of activity MDI-P may exhibit in killing pathogens.

We are hopeful that MDI-P may, with CF patient compliance, significantly improve both pulmonary function and longevity of CF patients, due to its unique dual mechanism of action.

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***MDI's CF Protocols.*** MDI has established its planned Phase I CF trials at St. Luke's Regional Medical Center, Boise, Idaho), under the supervision of Dr. Henry Thompson, Principal Investigator, who is Director of the Idaho CF Clinic. The Phase I trial is planned on adult CF patients in the latter term of life expectancy (age 21+). There are two arms to the study:

*Arm I-a:* a clinical trial will be conducted on a healthy normal adult population consisting of 10-15 individuals to establish the safety of MDI-P as a prospective adjunct therapy,

*Arm I-b:* a clinical trial will be conducted on a TOBI-dependent adult CF population consisting of 30 individuals, in which MDI-P is used as an adjunct therapy during TOBI's 28-day rest period on a dose-rising regimen. Fifteen of the 30 patients will undergo each dose regimen, to determine if greater efficacy is achieved on the higher dose of MDI-P.

Nebulization of MDI-P through Pari Research Institute's new FDA-approved e-Flow device is planned. All patients will be hospitalized during the initial 24-hour start of nebulization, to allow monitoring for endotoxic reactions. Patients will then self-nebulize three times daily at home, and will come into the CF clinic for weekly physicals, blood tests, pulmonary function tests, and the like.

***Other Indications for MDI-P.***

Our preclinical testing has also shown efficacy of MDI-P in treating sepsis and asthma. We have filed patent applications for those indications and may in the future pursue opportunities to commercialize MDI-P as a therapeutic for those indications.

***SaveCream Overview.***

MDI purchased intellectual property assets from the liquidation estate of Savetherapeutics AG in March of 2005. The assets related to SaveCream, a novel, topical steroidal form of aromatase inhibitor (AI) indicated for breast cancer. Because it is applied topically, SaveCream may be shown to deliver substantially more therapeutic drug on the site of the breast tumor, as contrasted with systemic ingestion of competing AIs. If clinical research confirms the early evidence, SaveCream may be found to promote faster and greater breast tumor reduction with fewer side effects.

This promising cancer therapeutic product has been tested in the European Union under a unique German regulatory scheme that allows terminal patients to receive novel treatments. In the study, over 100 women diagnosed with breast cancer received special permission to be treated with SaveCream. Patients in this preliminary study experienced an average reduction in tumor size of fifty percent with two weeks' treatment. No follow-up data was collected to permit assessment of adverse events or benefits of treatment occurring after the treatment period. If these preliminary results are confirmed in further clinical testing, this compound may be a useful neoadjuvant therapy for reducing tumor size to increase the potential for breast-saving surgery in place of mastectomy.

***Background on the Breast Cancer Market.*** Breast cancer is one of the leading cancer indications, with an annual incidence in the U.S. of 211,000 new cases per year, with annual mortality of 40,000 per year. For the 25 percent of such breast cancers that are positive for human epidermal growth factor receptor-2, the standard treatment therapies are Herceptin<sup>®</sup>, followed by doxorubicin or epirubicin.

For the remaining two thirds of breast cancers which are positive for the estrogen receptor ( ER ), the leading therapies over the past several years have become the aromatase inhibitors ( AIs ), achieving \$1.1 billion per year in revenues in 2004, with an estimated annual growth rate of 4%. The current three approved AIs on the U.S. market are: Novartis' Femara<sup>®</sup>, AstraZeneca's Arimide<sup>®</sup>, and Pfizer's Aromatas<sup>®</sup>. All are oral in dosage. Because of significantly improved efficacy and reduced toxicity as compared with the former leading first-line ER-positive therapy, AstraZeneca's Tamoxifen, the AIs became the preferred first-line therapy for most breast cancers in the fall of 2004.

***Background on Aromatase Inhibitors.*** An aromatase inhibitor is an anti-estrogen therapy, blocking estrogen's ability to activate cancer cells. Aromatase is the enzyme that converts other naturally occurring

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hormones (such as androgen) into estrogen. The way aromatase inhibitors work is to limit the production of estrogen by blocking its catalysis from other hormones. Testing at the time breast cancer is diagnosed can determine whether the cancer cells are sensitive to estrogen or progesterone. Neither Tamoxifen® nor AIs are effective in treating breast cancer that is not hormone sensitive, that is, cancer that does not use hormones to help the tumor grow. Approximately 70% of women with breast cancer test positive for estrogen receptors (ER) or progesterone receptors (PR) to which estrogen can dock, activating cancer cells. For this 70% ER/ PR positive patient grouping, the results of anti-estrogen therapy through AIs is strongest.

Aromatase inhibitors represent a preferred approach to anti-estrogen therapy by lowering the amount of estrogen being produced by the body. This method contrasts with that of Tamoxifen and related therapies, which block estrogen's ability to turn on cancer cells.

While Tamoxifen® and AIs both interfere with cancer cells' use of hormones to help them grow, but the drugs work in different ways. Tamoxifen® interferes directly with cancer cells' ability to use estrogen for fuel. AIs block the action of a substance called aromatase, which helps the body to produce estrogen. Limiting the amount of estrogen produced means there is less estrogen available to reach cancer cells and make them grow.

Following reduction in tumor size by AI treatment, current treatment regimens usually proscribe surgery to remove the tumor(s), which, if tumor size reduction has been substantial, may obviate the need for a mastectomy.

*Potential Benefits of SaveCream in Treating ER-Positive Breast Cancers.* SaveT has formulated its AI therapeutic in a topical steroidal cream (SaveCream), applied twice daily, unlike the current AI oral formulations. By local administration on the breast, SaveCream may affect a stronger down-regulation of estrogen in the local breast tissue now believed to be key to reduction in ER-positive breast tumors—as contrasted with oral forms, which are constrained to systemic blood levels of active product under recommended dosing.

In our preliminary European Union studies of SaveCream, we observed an average fifty to eighty percent reduction in breast tumor size within two weeks of treatment. If these preliminary results are realized in further clinical testing, this compound may be a useful neoadjuvant therapy for reducing tumor size, increasing the potential for breast-saving surgery in place of mastectomy. SaveCream was well tolerated in our limited clinical studies, suggesting that it may offer a lower incidence of toxicities that are less severe than those reported for oral aromatase inhibitors. Other AIs are noted for musculoskeletal complaints and increased risk of osteoporosis and bone fracture, together with mastalgia. In our initial, limited clinical experience with SaveCream, these common side-effects of other AIs were not observed. Furthermore, the limited half-life of the active product suggests that SaveCream may be shown to have an improved side effect profile over existing oral formulations. The safety and efficacy of SaveCream will require further clinical evaluation, as the patients in the European Union studies were not followed for collection of safety and efficacy data beyond the treatment period.

The aromatase inhibitor in SaveCream is a known therapeutic compound, for which we believe substantial published safety and efficacy data are already available. The Food, Drug and Cosmetic Act and its implementing regulations provide for the filing of a paper NDA for certain products that are similar to approved products, including those utilizing a new route of administration of the approved product. An applicant filing a paper NDA may rely upon the agency's finding of safety and efficacy for the approved product, as well as on published data, to show safety and efficacy, eliminating much of the clinical testing required in a full NDA. Some clinical data is required for a paper NDA submission, however, including clinical data analyzing any differences between the known or approved product and the new product. While we have not confirmed that sufficient data is available to support a paper NDA for SaveCream, we believe this abbreviated filing procedure may be available. If this procedure can be utilized, the costs of clinical development will be reduced and the product may be easier to license.

SaveCream's unique mechanism of action suggests the product may be shown to be useful in treating:

pre-menopausal breast cancer patients, thereby expanding the targeted breast cancer indication substantially;

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other cancer indications, including ovarian, uterine, endometrial and skin cancers; and

osteoporosis, effectively turning the therapeutic into a technology platform for drug development.

*MDI's Commercialization Program for SaveCream.* MDI believes that the existing chemistry, manufacturing and control (CMC) data supporting SaveCream will be sufficient, however additional preclinical data will need to be obtained, including toxicology and pharmacokinetic testing. While the Company plans to undertake a program to expand SaveCream's preclinical data and expand the clinical trial program, including revised protocols, additional funds will need to be raised before this work can proceed. The preclinical testing will likely take an additional three to six months once it has begun, and expanded clinical trials will likely take an additional year of work.

***Patents: MDI-P and Related Technologies.***

We hold eight United States Patents, two Japanese patents and a Mexican patent covering various applications for MDI-P, the machinery that manufactures it and the method by which it is manufactured. We believe that these patents, in combination with our pending applications for patents covering additional uses of MDI-P are sufficient to protect our proposed indications for use, however additional patents may be sought if we pursue additional uses for this product. The U.S. Patents are as follows:

*Patent No. 5,334,383:* Electrically Hydrolyzed Salines as In Vivo Microbicides for the Treatment of Cardiomyopathy and Multiple Sclerosis

This patent covers a method of treating antigen related infections related to cardiomyopathy and multiple sclerosis in humans and other warm blooded animals. It does not cover the MDI-P Substance itself, but covers a particular use of the substance. This method of treatment includes the use of an electrolyzed saline solution in conjunction with one or more modulating agents such as ascorbic acid (Vitamin C), with or without concurrent colchicine, to mimic or enhance the body's naturally occurring immune response to bacterial, viral or fungal infection. The duration of this patent is until August 2, 2011, subject to patent term extension for clinical trial time.

*Patent No. 5,507,932:* Apparatus for Electrolyzing Fluids

This patent covers equipment that exposes a liquid solution to an electrical current, creating an electrolyzed solution. This equipment may be used to produce an electrolyzed saline solution, capable of killing bacterial, viral and fungal agents, for use in medical applications such as the treatment of antigen related infections in humans and other warm blooded animals. This patent covers the equipment used to produce MDI-P, not the substance itself. The duration of this patent is until August 26, 2014.

*Patent No. 5,560,816:* Method for Electrolyzing Fluids

This patent covers a method for electrolyzing fluids, by using specialized equipment to expose liquid solutions to an electrical current. Saline, for example, may be treated by this process to yield an electrolyzed saline solution, capable of killing bacterial, viral and fungal agents, for the treatment of antigen related infection in humans and other warm blooded animals. This patent covers the method by which MDI-P is produced, not the substance itself. The duration of this patent is until August 26, 2014, subject to patent term extension for clinical trial time.

*Patent No. 5,622,848:* Electrically Hydrolyzed Saline Solution as Microbicides for In Vitro Treatment of Contaminated Fluids Containing Blood

This patent covers a method of treating whole blood and other blood products with an electrolyzed saline solution to reduce infection with bacterial, viral and fungal agents. This patent covers a particular use of MDI-P, not substance itself. The duration of this patent is until April 22, 2014, subject to patent term extension for clinical trial time.

*Patent No. 5,674,537:* An Electrolyzed Saline Solution Containing Concentrated Amount of Ozone and Chlorine Species

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This patent covers a specific electrolyzed saline solution containing a regulated amount of microbicidal agents including ozone and active chlorine species. This solution is intended for use in the treatment of infections in the body of humans and other warm blooded animals, or in blood or blood products. This patent covers the MDI-P substance. The duration of this patent is until October 7, 2014, subject to patent term extension for clinical trial time.

*Patent No. 5,731,008: Electrically Hydrolyzed Salines as Microbicides*

This patent covers a method of using a specific electrolyzed saline solution containing a regulated amount of microbicidal agents including ozone and active chlorine species for the treatment of microbial infections, including HIV infection. The method includes intravenous administration of the solution along with one or more modulating agents such as ascorbic acid (Vitamin C), with or without concurrent colchicine. This patent covers a method for using MDI-P, not the substance itself. The duration of this patent is until May 23, 2010, subject to patent term extension for clinical trial time.

*Patent No. 6,007,686: System for Electrolyzing Fluids for Use as Antimicrobial Agents*

This patent covers a system for electrolyzing fluids, such as a saline solution, for use in sterilizing dental and medical instruments and other health care equipment. The patent covers the necessary equipment for generating and circulating the electrolyzed saline solution around the instruments to be sterilized, and includes specific claims for equipment designed for use with dental drill handpieces and flexible tubing. This patent covers a process by which MDI-P may be made for a particular use, not the substance itself. The duration of this patent is until August 26, 2014.

*Patent No. 6,117,285: System for Carrying Out Sterilization of Equipment*

This patent covers a system for cleaning and sterilizing medical and dental instruments to prevent the spread of infection from one patient to another. The covered system bathes the instrument in an electrolyzed saline solution and causes the solution to flow into and sterilize any openings in the equipment. It includes specific claims for systems designed specifically for the sterilization of dental drills and flexible tubing. This patent covers a particular use of MDI-P, not the substance itself. The duration of this patent is until August 26, 2014.

The Japanese and Mexican patents provide coverage in those countries for various of the U.S. patents. We also have pending applications with the US Patent and Trademark Office for patents on MDI-P as a pharmaceutical treatment for cystic fibrosis, sepsis and asthma. These include:

A patent application for the use of MDI-P in the treatment of sepsis. This patent, if it is ultimately granted, would cover a particular use of the MDI-P substance, not the substance itself.

A provisional patent application for the use of MDI-P in the treatment of sepsis. A provisional patent application is an abbreviated application intended to establish a priority filing date for this technology. A full patent application will be required before this patent application is reviewed by the U.S. Patent and Trademark Office. This patent, if it is ultimately granted, would cover a particular use of the MDI-P substance, not the substance itself.

A provisional patent application for the use of MDI-P in the treatment of asthma. A provisional patent application is an abbreviated application intended to establish a priority filing date for this technology. A full patent application will be required before this patent application is reviewed by the U.S. Patent and Trademark Office. This patent, if it is ultimately granted, would cover a particular use of the MDI-P substance, not the substance itself.

As existing patents and pending patent applications are method patents covering the use of MDI-P for particular indications, we believe they are adequate to protect the proposed indications for use.

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***Patents: SaveCream and Related Technologies.***

The intellectual property assets we purchased from the liquidation estate of Savetherapeutics A.G. include the following four patent families:

*Substances and Agents for Positively Influencing Collagen.* This includes an EU patent application and a Canadian patent. This patent covers the use of a substance such as an aromatase inhibitor to inhibit the local formation of estrogen to stabilize, multiply and/or restore collagen in the skin for cosmetic purposes. It does not cover the SaveCream substance itself.

*Topical Treatment for Mastalgia.* This includes U.S. patent application 10/416,096 filed October 30, 2001. A European Union patent application has been filed as well. This patent application seeks to cover a substance containing an aromatase inhibitor for topical administration for medicinal treatment, including prevention and treatment of mastalgia.

*Medicament for Preventing and/or Treating a Mammary Carcinoma Containing a Steroidal Aromatase Inhibitor.* This includes a U.S. patent application, No. 09/646,355, filed November 16, 2000 and divisional and continuation applications based upon the initial application. These applications seek to cover a method or prevention or treatment of breast cancer involving the local, topical application of an aromatase inhibitor. These applications seek to cover a particular use of the SaveCream substance, not the substance itself.

*Aromatase Marking.* This includes a U.S. Patent application, No. 10/487,953, filed August 28, 2002, as well as a European Union patent application. These patents seek to cover a group of compounds that exhibit an inhibitory action toward the enzyme aromatase, permitting them to be used for the medical diagnosis and treatment of tumor diseases including breast cancer.

We believe that these patents, if granted, will sufficiently protect our proposed indications for use. We may, however, seek additional patents to cover new uses of SaveCream that may be discovered during the product's development.

We are in the process of transferring the patents and applications to MDI's subsidiary. At the time we purchased SaveCream and the other intellectual property assets from SaveT, SaveT had not yet obtained and filed with the appropriate patent offices assignments of the various inventors' rights to the underlying inventions. Each of those inventors has agreed and is contractually bound to assign such rights. We are currently in the process of securing the applicable assignments. However, we may need to initiate litigation against the inventors to secure such assignments. See "Risk Factors - We May Need to Litigate to Secure Our Rights to SaveCream and Related Assets."

***Competition.***

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technologies and intense competition. Our competitors include major pharmaceutical, and specialized biotechnology companies, many of which have financial, technical, and marketing resources significantly greater than ours. Fully integrated pharmaceutical companies, due to their expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing, as well as their substantially greater financial and other resources, may be our most formidable competitors. In addition, acquisitions by such pharmaceutical companies could enhance the financial and marketing resources of smaller competitors. Furthermore, colleges, universities, governmental agencies, and other public and private research organizations will continue to conduct research and possibly market competitive commercial products on their own or through joint ventures. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. These institutions also will compete with us in recruiting and retaining highly qualified scientific personnel.

In particular, we face competition from the manufacturers of products that would compete with MDI-P and SaveCream should they be commercialized. Manufacturers of products currently available for the treatment of HIV and cystic fibrosis would be among our most significant competitors in the market for MDI-

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P. While there are 24 HIV therapies currently on the market (commonly used in three- or four-drug combinations), the primary therapies currently in use are produced by Pfizer, Bristol-Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline, Gilead Sciences, Hoffman-La Roche, Merck, Abbott Laboratories, Agouron Pharmaceuticals, and Trimeris. Currently available anti-infectives commonly used in the treatment of cystic fibrosis are manufactured by Bayer Corporation, the maker of Cipro; Pfizer, the maker of Zithromax; and Chiron, the maker of tobramycin solution (TOBI); Bayer and Pfizer would compete with us in the cystic fibrosis market, while MDI-P is being studied as an adjunct to treatment with TOBI; thus we would be unlikely to compete directly with Chiron. Producers of aromatase inhibitors and other breast cancer treatments would compete with SaveCream should we be able to commercialize this product. These companies include Astra-Zeneca, the maker of both Tamoxifen and Arimidex; Novartis, the maker of Femara; and Pfizer, the maker of Aromasin.

If and when we obtain regulatory approval for any of the potential uses of our technology which require them, we must then compete for acceptance in the marketplace. Given that such regulatory approval, especially in the United States, may take a number of years, the timing of the introduction of our technology and other products to the market is critical. Other safe and effective drugs and treatments may be introduced into the market prior to the time that we are able to obtain approval for the commercialization of our technology. In addition, even after such regulatory approval is obtained, competition among products approved for sale may be affected by, among other things, product efficacy, safety, reliability, availability, price, and patent position. There can be no assurance that our technology will be competitive if and when introduced into the marketplace for any of its possible uses.

***Government Regulations.***

Our use of MDI-P and SaveCream as pharmaceuticals is subject to extensive regulation by United States and foreign governmental authorities. In particular, pharmaceutical treatments are subject to rigorous preclinical and clinical testing and other approval requirements by the FDA in the United States under the federal Food, Drug and Cosmetic Act and by comparable agencies in most foreign countries. Various federal, state and foreign statutes also govern or influence the manufacture, labeling, storage, record keeping, and marketing of such products. Pharmaceutical manufacturing facilities are also regulated by state, local, and other authorities. Obtaining approval from the FDA and other regulatory authorities for a new drug or treatment may take several years and involve substantial expenditures. Moreover, ongoing compliance with these requirements can require the expenditure of substantial resources. Difficulties or unanticipated costs may be encountered by us in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing MDI-P or SaveCream.

The FDA imposes substantial requirements upon and conditions precedent to the introduction of therapeutic drug products, such as MDI-P or SaveCream, through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time consuming procedures to demonstrate that such products are both safe and effective in treating the indications for which approval is sought. After testing in animals, an Investigational New Drug, or IND, application must be filed with the FDA to obtain authorization for human testing. When the clinical testing has been completed and analyzed, final manufacturing processes and procedures are in place, and certain other required information is available to the manufacturer, a manufacturer may submit a new drug application, or NDA, to the FDA. No action can be taken to market any therapeutic drug product in the United States until an NDA has been approved by the FDA.

The IND process in the United States is governed by regulations established by the FDA which strictly control the use and distribution of investigational drugs in the United States. The guidelines require that an application contain sufficient information to justify administering the drug to humans, that the application include relevant information on the chemistry, pharmacology and toxicology of the drug derived from chemical, laboratory and animal or *in vitro* testing, and that a protocol be provided for the initial study of the new drug to be conducted on humans.



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In order to conduct a clinical trial of a new drug in humans, a sponsor must prepare and submit to the FDA a comprehensive IND. The focal point of the IND is a description of the overall plan for investigating the drug product and a comprehensive protocol for each planned study. The plan is carried out in three phases: Phase I clinical trials, which involve the administration of the drug to a small number of healthy subjects to determine safety, tolerance, absorption and metabolism characteristics; Phase II clinical trials, which involve the administration of the drug to a limited number of patients for a specific disease to determine dose response, efficacy and safety; and Phase III clinical trials, which involve the study of the drug to gain confirmatory evidence of efficacy and safety from a wide base of investigators and patients.

Phase I testing typically takes at least one year, Phase II trials typically take from 1<sup>1/2</sup> to 2<sup>1/2</sup> years, and Phase III trials generally take from 2 to 5 years to complete. Should the FDA grant fast-track status to MDI-P based upon its safety profile and early signs of efficacy in Phase I clinical trials, the overall timeline for completion of Phase II-III clinical trials can be compacted to as little as 2-3 years. We can give no assurance that Phase I, Phase II or Phase III testing for MDI-P or SaveCream will be completed successfully within any specified time period, if at all. While we are hopeful that fast-track status might be provided MDI-P, there is no assurance that such status will, in fact, be provided. Furthermore, the FDA may suspend clinical trials at any time if the patients are believed to be exposed to a significant health risk.

An investigator's brochure must be included in the IND and the IND must commit the sponsor to obtain initial and continual review and approval of the clinical investigation. A section describing the composition, manufacture and control of the drug substance and the drug product is included in the IND. Sufficient information is required to be submitted to assure the proper identification, quality, purity and strength of the investigational drug. A description of the drug substance, including its physical, chemical, and biological characteristics, must also be included in the IND. The general method of preparation of the drug substance must be included. A list of all components including inactive ingredients must also be submitted. There must be adequate information about pharmacological and toxicological studies of the drug involving laboratory animals and *in vitro* tests on the basis of which the sponsor has concluded that it is reasonably safe to conduct the proposed clinical investigation. Where there has been widespread use of the drug outside of the United States or otherwise, it is possible in some limited circumstances to use well documented clinical experience as a substitute for other pre-clinical work.

The FDA typically takes several months to consider and act on an IND application. We can give no assurance that our IND application will be approved or, if approved following comments or subject to modifications, the length of FDA approval time.

After the FDA approves the IND, the investigation is permitted to proceed, during which the sponsor must keep the FDA informed of new studies, including animal studies, make progress reports on the study or studies covered by the IND, and also be responsible for alerting FDA and clinical investigators immediately of unforeseen serious side effects or injuries.

When all clinical testing has been completed and analyzed, final manufacturing processes and procedures are in place, and certain other required information is available to the manufacturer, a manufacturer may submit an NDA to the FDA. An NDA must be approved by the FDA covering the drug before its manufacturer can commence commercial distribution of the drug. The NDA contains a section describing the clinical investigations of the drug which section includes, among other things, the following: a description and analysis of each clinical pharmacology study of the drug; a description and analysis of each controlled clinical study pertinent to a proposed use of the drug; a description of each uncontrolled clinical study including a summary of the results and a brief statement explaining why the study is classified as uncontrolled; and a description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source foreign or domestic. The NDA also includes an integrated summary of all available information about the safety of the drug product including pertinent animal and other laboratory data, demonstrated or potential adverse effects of the drug, including clinically significant potential adverse effects of administration of the drug contemporaneously with the administration of other drugs and other related drugs. A section is included describing the



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statistical controlled clinical study and the documentation and supporting statistical analysis used in evaluating the controlled clinical studies.

Another section of the NDA describes the data concerning the action of a drug in the human body over a period of time and data concerning the extent of drug absorption in the human body or information supporting a waiver of the submission of such data. Also included in the NDA is a section describing the composition, manufacture and specification of the drug substance including the following: a full description of the drug substance, its physical and chemical characteristics; its stability; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality and purity of the drug substance as well as the availability of the drug products made from the substance. NDAs contain lists of all components used in the manufacture of the drug product and a statement of the specifications and analytical methods for each component. Also included are studies of the toxicological actions of the drug as they relate to the drug's intended uses.

The data in the NDA must establish that the drug has been shown to be safe for use under its proposed labeling conditions and that there is substantial evidence that the drug is effective for its proposed use(s). Substantial evidence is defined by statute and FDA regulation to mean evidence consisting of adequate and well-controlled investigations, including clinical investigations by experts qualified by scientific training and experience, to evaluate the effectiveness of the drug involved. We can give no assurance that even if we complete clinical testing that our NDA will be approved.

***Raw Materials.***

The components of both MDI-P and SaveCream are readily available from a number of sources. Therefore, once we are in the production stage with respect to these drugs, we do not anticipate raw materials acquisition difficulties or supplier identification or relations problems.

***Research and Development Expenditures.***

Our research and development efforts to date have consisted primarily of pre-clinical development of and preparing applications for regulatory approvals for MDI-P for our initial target indications, HIV and cystic fibrosis. Our research and development is accomplished by outside scientific researchers under the coordination of Craig Palmer, Ph.D. During the fiscal year ended December 31, 2005, we spent \$2,172,461 on research and development of MDI-P. During fiscal year 2004, we spent \$550,093 on research and development. From inception through December 31, 2005, we have recorded \$5,721,199 in research and development expenses including expenditures relating to the purchase of the SaveCream intellectual property. We are actively pursuing our research efforts of MDI-P and are in the process of establishing a commercialization plan for SaveCream.

***Employees.***

We currently have two employees, our President and CEO, Judy M. Robinett, and our controller. We have engagements with a number of consultants for communications, investor relations, website development, accounting and other services. Over the past several years, our priority has been the advancement of our therapeutic technology through preclinical development and all capital resources have been devoted in that direction. At such time as capital resources permit, we will hire a full-time staff of employees.

***Scientific Advisory Board.***

We have a scientific advisory board consisting of the following individuals:

*Bruce I. Dezube, M.D.*

*Director of AIDS Oncology, Beth Israel Deaconess Medical Center, Boston*

*Associate Professor of Medicine, Harvard Medical School*

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We retained Dr. Dezube to oversee medical testing, FDA protocol alignment and approvals planning for MDI-P. Dr. Dezube will be the principal investigator for our IND in HIV. Dr. Dezube is a member of the AIDS Clinical Trial Group (ACTG) where he is principal investigator in more than seven studies involving the testing and evaluation of interferon and newer anti-HIV agents. Additionally, Dr. Dezube has been involved in industry-sponsored studies of other anti-HIV agents, assisting with required FDA approvals. Dr. Dezube received his M.A. from Harvard University and his M.D. from Tufts University. Dr. Dezube was a research fellow in hematology and oncology and is board certified in internal medicine, hematology, and oncology.

*Robert A. Mastico, Ph.D.*

*Physical Chemist, Independent Consultant*

Dr. Mastico specializes in the chemistry, manufacturing and control of new drug substances required for FDA approval. He has experience submitting INDs to the FDA, handling the manufacturing and analytical data (CMC section) for investigational therapeutics. We have retained Dr. Mastico to determine the chemical characterization requirements for MDI-P, and for planning and compliance with all FDA and other required certifications involving chemical analyses. Dr. Mastico received his Ph.D. from the University of Leeds in genetic biochemistry and has fifteen years experience in the fields of biotherapeutics and pharmaceutical production.

*Craig R. Palmer, Ph.D.*

*Principal, Palmer Consulting Group*

Dr. Palmer has served over the past twenty years as a strategic financial advisor to a wide variety of technology platform and biotech companies in their capital formation, management and product licensing arenas. We have retained Dr. Palmer to assist us in managing the pre-clinical and clinical development of MDI-P as well as commercialization. He serves as a director on several biotech and biomedical companies, and has successfully licensed major ethical drugs and biomedical devices. Prior to his involvement as a Principal in Palmer Capital Group LLC, and its predecessor The Palmer Group, he served as a manager and principal in the consulting operations of Ernst & Young (10 years), followed by a brief stint as a VP of Investments for a regional bank and its SBIC. Dr. Palmer has assisted a number of his clients in securing underwriters for their IPOs or secondary offerings. He has also assisted several clients in establishing major strategic partnerships for product development. Dr. Palmer received his Ph.D. from the University of Washington.

*Dr. Henry R. Thompson, M.D.*

*Director, Cystic Fibrosis Program Therapeutics Center, St. Luke's Health Center, Boise, Idaho*

On September 23, 2004, Dr. Thompson agreed to serve as Project Manager and Principal Investigator for MDI's Phase I trials in late-term adult Cystic Fibrosis (CF) patients. Dr. Thompson is a gastroenterologist, and received his M.D. from Oregon Health Sciences University. He held a Fellowship in pediatric gastroenterology at Children's Hospital in Denver, at the University of Colorado Health Sciences unit, where he also participated in clinical studies. Dr. Thompson has been an Assistant Professor at the University of Utah's Medical School, and is a Board certified Fellow in the American Association of Pediatrics. He has previously received grants from both the Cystic Fibrosis Foundation and the NIH.

***Organizational History.***

Medical Discoveries, Inc. was incorporated under the laws of the State of Utah on November 20, 1991. Effective as of August 6, 1992, the Company merged with and into WPI Pharmaceutical, Inc., a Utah corporation (WPI), pursuant to which WPI was the surviving corporation. Pursuant to the MDI-WPI merger, the name of the surviving corporation was changed to Medical Discoveries, Inc. WPI was incorporated under the laws of the State of Utah on February 22, 1984 under the name Westport Pharmaceutical, Inc. Effective as of May 8, 1984, Westport Pharmaceutical, Inc. merged with and into Euripides Technology, Inc., a Utah corporation (Euripides), pursuant to which Euripides was the surviving corporation. Pursuant to the

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Westport-Euripides merger, the name of the surviving corporation was changed to Westport Pharmaceutical, Inc. Westport Pharmaceutical, Inc. subsequently changed its name to WPI Pharmaceutical, Inc. Euripides was incorporated under the laws of the State of Utah on November 9, 1983.

On July 6, 1998, we incorporated a wholly-owned subsidiary, Regenere, Inc., in the State of Nevada. On October 2, 1998, we incorporated another wholly-owned subsidiary, MDI Healthcare Systems, Inc., in the State of Nevada. Both subsidiaries were incorporated to undertake special purposes, neither of which were pursued by us in recent years. As of December 31, 2003, we dissolved those subsidiaries.

On March 22, 2005, we formed MDI Oncology, Inc., a Delaware corporation, as a wholly-owned subsidiary to acquire certain intellectual property assets from the liquidation estate of Savetherapeutics, A.G.

**ITEM 2. DESCRIPTION OF PROPERTY.**

We do not currently own or lease any real property. Currently, we operate out of the President and CEO's home office. We do not pay any rent to the President and CEO. Over the past several years, our priority has been the advancement of our therapeutic technology through pre-clinical development and all capital resources have been devoted in that direction. At such time as capital resources permit, we will lease dedicated office and laboratory space.

**ITEM 3. LEGAL PROCEEDINGS.**

None.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

**PART II****ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES.****MARKET INFORMATION**

Our common stock is traded on the NASD OTC Bulletin Board under the symbol MLSC. The following table sets forth the range of bid quotations for our common stock for the quarters indicated according to data provided by The NASDAQ Stock Market, Inc. Such quotations reflect inter-dealer prices, without retail mark-ups, markdowns or commissions, and may not represent actual transactions.

<b>Fiscal Year Ended December 31, 2005</b>	<b>High Bid</b>	<b>Low Bid</b>
First Quarter	\$ 0.220	\$ 0.130
Second Quarter	0.170	0.082
Third Quarter	0.180	0.080
Fourth Quarter	0.135	0.090

<b>Fiscal Year Ended December 31, 2004</b>	<b>High Bid</b>	<b>Low Bid</b>
First Quarter	\$ 0.170	\$ 0.100
Second Quarter	0.300	0.115
Third Quarter	0.301	0.150
Fourth Quarter	0.260	0.180

**Table of Contents****SHAREHOLDERS**

The approximate number of shareholders of record of our common stock as of March 27, 2006 was 1500. This number does not include shareholders whose shares are held in securities position listings.

**DIVIDENDS**

We have never paid any cash dividends on our common stock and do not anticipate paying dividends in the foreseeable future. We presently intend to retain any future earnings for financing our growth and expansion.

**SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS**

The following table contains information regarding our equity compensation plans as of December 31, 2005.

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)</b>
Equity compensation plans approved by security holders			
1993 Incentive Plan	3,483,000	\$ 0.11	-0-
2002 Stock Incentive Plan	16,000,000	\$ 0.02	4,000,000
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>19,483,000</b>	<b>\$ 0.04</b>	<b>4,000,000</b>

**ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The purpose of this section is to discuss and analyze our consolidated financial condition, liquidity and capital resources, and results of operations. This analysis should be read in conjunction with the financial statements and notes thereto at pages 30 through 50.

This section contains certain forward-looking statements that involve risks and uncertainties, including statements regarding our plans, objectives, goals, strategies and financial performance. Our actual results could differ materially from the results anticipated in these forward-looking statements as a result of factors set forth under Cautionary Statement for Forward-Looking Information and Factors Affecting Future Results below and elsewhere in this report.

**RESULTS OF OPERATIONS**

*Revenues and Gross Profit.* We did not book any revenue for the year ended December 31, 2005. As we continue to pursue preclinical and clinical testing of our pharmaceuticals, we may not book significant revenues in the near future.

*Operating Expenses and Operating Loss.* We incurred \$2,172,461 in research and development expenses for the year ended December 31, 2005, \$1,345,000 of which is related to our acquiring the patents and patent rights relating

to SaveCream. We incurred \$550,093 in research and development expenses for the same period of 2004. Our general and administrative expenses were \$1,878,027 during the year ended

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December 31, 2005, as compared to \$3,057,429 during the year ended December 31, 2004. As a result of the foregoing, we sustained an operating loss of \$4,050,488 for the year ended December 31, 2005, as compared with an operating loss of \$3,607,522 for the same period of 2004.

*Other Income/ Expense and Net Loss.* We booked \$25,727 in interest income and incurred interest expense of \$38,264 for the year ended December 31, 2005, as compared with interest income of \$6,165 and \$131,526 in interest expenses during 2004. During the year ended December 31, 2005, we also booked foreign currency gain of \$56,480. We had no foreign currency risk in 2004. We recorded \$2,300,191 as unrealized gain on financial instrument to record the accounting of warrants resulting from the issuance of the Series A Convertible Preferred Stock entered into in October 2004 and March 2005. We also recorded \$196,353 in gain on forgiveness of debt. There was no gain on forgiveness of debt during 2004. In sum, our net loss applicable to common shareholders for the year ended 2005 was \$1,486,781 or a loss of \$0.01 per fully diluted share. For the year ended December 31, 2004 we incurred a net loss applicable to common shareholders of \$4,423,674, making a loss of \$0.05 per fully diluted share.

*Future Expectations.* We may operate at a loss for several more years while we continue to research, gain regulatory approval of, and commercialize our technologies. We will spend more in 2006 in research and development expenses than we did over the prior year as we continue to implement our commercialization strategy. Similarly, we expect our general and administrative expenses to continue to increase during 2006 as we continue to expand the scope of our operations. As a result, we may sustain a greater net loss in 2006 than we have in recent years.

**LIQUIDITY AND CAPITAL RESOURCES**

As of December 31, 2005, we had \$654,438 in cash and had a working capital deficit of \$5,893,077. Since our inception, we have financed our operations primarily through private sales of equity and the issuance of convertible and non-convertible notes. We continue to require significant supplementary funding to continue to develop, research, and seek regulatory approval of our technologies. We do not currently generate any cash from operations and have no credit facilities in place or available. Currently, we are funding operations through private issuances of equity.

Given that we are still in an early development stage and do not have revenues from operations, raising equity financing is difficult. In addition, any additional equity financing will have a substantial dilutive effect to our current shareholders.

We have entered into fixed price contracts for all of the services we expect will be required in connection with our cystic fibrosis Phase I testing should the FDA allow us to proceed to clinical trials. We have budgeted for these costs and believe we have sufficient funds to initiate this trials. However we will need to raise additional capital to complete Phase I.

We have insufficient capital to file our IND for HIV. Once an IND application for HIV is submitted, and assuming it is approved, we also will need additional capital to initiate Phase I clinical trials. We estimate the cost to complete Phase I and Phase II clinical trials to be several million dollars per indication and the cost to complete Phase III testing and obtain approval of an NDA to be in the tens of millions of dollars per indication. While our ability to obtain financing may improve in the event our IND application is approved, we cannot give assurances that we will have access to the significant capital required to take a drug through regulatory approvals and to market. We may seek a partner in the global pharmaceutical industry to help us co-develop, license, or even purchase some or all of our technologies.



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**OFF-BALANCE SHEET ARRANGEMENTS**

We have no off-balance sheet arrangements as defined in Item 303(c) of Regulation S-B.

**FOREIGN CURRENCY RISK**

The Company bears foreign currency exchange risk because our remaining purchase price obligation for the Savetherapeutics assets is stated in Euros.

**CAUTIONARY STATEMENT FOR FORWARD LOOKING INFORMATION  
AND FACTORS AFFECTING FUTURE RESULTS**

Certain information set forth in this report contains forward-looking statements within the meaning of federal securities laws. Forward looking statements include statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, and financing needs and other information that is not historical information. When used in this report, the words estimates, expects, anticipates, forecasts, plans, believes and variations of such words or similar expressions are intended to identify forward-looking statements. Additional forward-looking statements may be made by us from time to time. All such subsequent forward-looking statements, whether written or oral and whether made by us or on our behalf, are also expressly qualified by these cautionary statements.

Our forward-looking statements are based upon our current expectations and various assumptions. Our expectations, beliefs and projections are expressed in good faith and are believed by us to have a reasonable basis, including without limitation, our examination of historical operating trends, data contained in our records and other data available from third parties, but there can be no assurance that our expectations, beliefs and projections will result or be achieved or accomplished. Our forward-looking statements apply only as of the date made. We undertake no obligation to publicly update or revise forward-looking statements which may be made to reflect events or circumstances after the date made or to reflect the occurrence of unanticipated events. There are a number of risks and uncertainties that could cause actual results to differ materially from those set forth in, contemplated by, or underlying the forward-looking statements contained in this report. In addition to the other factors and matters discussed elsewhere in this report, the following factors are among the factors that could cause actual results to differ materially from the forward-looking statements. Any forward-looking statements made by us or on our behalf should be considered in light of these factors.

*We Are A Development-Stage Company That Has Not Yet Commercialized A Product.* We have not commercialized MDI-P, SaveCream or any other product and our failure to commercialize our drugs would likely cause us to cease operations. While we believe MDI-P and SaveCream may have very broad commercial applications, we do not have any other products under development, nor do we have scientific personnel on staff to develop any further technologies. The results of our preclinical and anecdotal clinical studies may not be indicative of future clinical trials. Moreover, unacceptable side effects could occur at any time in the course of human trials or, if our drugs are approved for sale, during commercial use. Even if our drugs do prove to be safe and effective and receive regulatory approvals, we may be unable to successfully commercialize them.

*We Have Incurred Substantial Losses Since Our Inception And May Continue To Operate At A Loss.* We have experienced net losses in each twelve-month period since inception, with a retained deficit of approximately \$22,240,291 as of December 31, 2005. Our net losses were \$1,486,781 for the fiscal year ended December 31, 2005, and \$20,840,714 from inception through December 31, 2005. We will likely continue to experience a net loss until, and if, we can fully commercialize our technologies, which may not be for several years. We are presently investing all of our resources in the testing, development and commercialization of MDI-P and Save-Cream. If MDI-P and SaveCream do not generate revenues or if the revenues do not exceed the costs of research, development, testing, regulatory approval and other costs, then we may never realize a profit from operations.

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*We May Not Be Able To Raise Sufficient Capital To Meet Present And Future Obligations* As of December 31, 2005, we had \$654,438 in cash and a working capital deficit of \$5,893,077. We need additional capital in order to satisfy our current liabilities. However, because many of our creditors have foreborne (including our CEO who we owed \$877,636 in back compensation as of December 31, 2005), we believe we have sufficient funds to achieve our next developmental milestone for MDI-P, that being commencing Phase I clinical trials for cystic fibrosis.

More specifically, we believe we have sufficient capital on hand to pay for the additional preclinical testing requested by the FDA before it will remove the clinical hold on our IND and permit us to begin Phase I clinical testing. That preclinical testing has been completed. We entered into fixed price contracts for each of the planned preclinical tests, totaling \$907,939. \$865,311 of these contract charges have been paid with \$42,628 in preclinical testing fees outstanding pending receipt of the preclinical study reports. We have sufficient funds to make these payments and to fund overhead expenses in the near term. While we believe we have sufficient funds to begin Phase I clinical trials of MDI-P for cystic fibrosis if and when the FDA allows use to begin human trials under an amended IND, we may need to raise additional funds to complete this testing. Should the FDA request further preclinical testing beyond our current expectations, we will need to expend additional funds beyond what is budgeted for our MDI-P development activities. This could impact our ability to commercialize this product.

We believe we have insufficient capital to file our IND for HIV. In addition, once an IND application for HIV is submitted, and assuming it is approved, we will need additional capital to initiate Phase I clinical trials.

We estimate the cost to complete Phase I and Phase II clinical trials to be several million dollars per indication and the cost to complete Phase III testing and obtain approval of a New Drug Application to be in the tens of millions of dollars per indication. While our ability to obtain financing may improve in the event our IND application is approved, we cannot give assurances that we will have access to the significant capital required to take a drug through regulatory approvals and to market.

We do not currently have revenues that could be used to satisfy our capital requirements. We may seek to obtain revenues at any time, however, by partnering with another company to help us co-develop, license, or even purchase some or all of our technologies. Most likely, we will seek to raise additional capital through equity and/or debt financings.

The timing and amount of our future capital requirements will depend on many factors, including, without limitation the following:

our ability to raise additional funding and the amounts raised, if any;

the time and costs involved in obtaining regulatory approvals;

the results of pre-clinical studies and clinical trials;

the cost of manufacturing scale-up;

competing technological and market developments;

the costs of filing, prosecuting and enforcing patent claims; and

the effectiveness of our commercialization activities.

Factors affecting the availability and price of capital may include, without limitation, the following:

market factors affecting the availability and cost of capital generally;

our performance;

the size of our capital needs;

the market's perception and acceptance of our technologies; and

the price, volatility and trading volume of our common shares.

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If we are unable to obtain sufficient capital or are forced to pay a high price for capital, we may be unable to complete testing, regulatory approval and commercialization of our technologies and may never achieve consistent revenues or profitability. In addition, because of their size, resources and other factors, our competitors may have better access to capital than we do and, as a result, may be able to exploit opportunities more rapidly, easily or thoroughly than we can.

*Obtaining Additional Capital Though The Sale Of Common Stock Will Result In Dilution Of Stockholder Interests.* We plan to raise additional funds in the future by issuing additional shares of common stock, or securities such as convertible notes, options, warrants or preferred stock that are convertible into common stock. Any such sale of common stock or other securities will lead to further dilution of the equity ownership of existing holders of our common stock. Additionally, the existing options, warrants and conversion rights, detailed in Part III of this report, may hinder future equity offerings, and the exercise of those options, warrants and conversion rights may have an adverse effect on the value of our stock. In particular, we have 19,483,000 options outstanding with exercise prices ranging from \$0.01 to \$0.50 and a weighted average exercise price of \$0.04 per share; 40,923,861 warrants outstanding with exercise prices ranging from \$0.09 to \$1.00 and a weighted average exercise price of \$0.23 per share; and 41,800 shares of Series A convertible preferred stock outstanding, 11,800 of which can be exercised into as many as 23,600,000 shares of common stock at the exercise price of \$0.05 per share and 30,000 of which can be exercised into a theoretically unlimited number of shares of common stock without a floor on the exercise price. If any such options, warrants or conversion rights are exercised at a price below the current market price of our shares, then the market as a whole will experience dilution. Further, if any such options, warrants or conversion rights are exercised at a price below the price at which any particular shareholder purchased shares, then that particular shareholder will experience dilution in his or her investment.

*Selling Pressure From Our Series A Convertible Preferred Shareholders May Negatively Impact Our Stock Price, Our Market Value, And Our Ability To Raise Additional Capital.* Because the conversion price of much of the Series A convertible preferred stock has no floor, coupled with the fact that the conversion price is at a discount to market, the holders of those shares could realize a profit on selling common stock no matter what price our common stock is trading at in the market at the time. Because our trading volume is limited and our stock price is subject to fluctuation, the market price of our stock could decrease dramatically if the holders of those shares decide to liquidate all or even some of their position. Even if the Series A stockholders liquidate their position slowly over time, because the overall number of shares into which they could exercise is so large as a proportion to our shares outstanding, the result could be a sustained market price for our stock that is much lower than it would otherwise be without such sustained selling pressure. If our stock price does suffer due to this type of selling pressure, our market value will be lower and our ability to raise much needed additional capital will be negatively impacted. If the Series A shareholders decide to liquidate their position in a market with very little purchaser demand, the result could be to eliminate substantially all of our market value, resulting in no meaningful opportunity whatsoever to obtain additional financing that we need to continue to develop our development-stage products.

*Our Independent Auditors Have Expressed Substantial Doubt As To Our Ability To Continue As A Going Concern.* Our auditors have expressed substantial doubt about our ability to continue as a going concern because of our recurring losses from our development-stage activities in current and prior years. We have not generated any significant revenues to date. We expect to continue to incur substantial net operating losses over the next several years. We may not be able to generate sufficient revenues to become profitable and do not expect to generate any revenues for several years. We struggle with operating and liquidity issues due to our negative cash flows from operations and we have had difficulty in the past with raising capital. As a result of these and other factors, our independent auditors have expressed substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

*Our Operations Are And Will Be Subject To Extensive Regulation.* Our use of MDI-P and SaveCream in the treatment of humans is subject to extensive regulation by United States and foreign governmental authorities. In particular, pharmaceutical treatments are subject to rigorous pre-clinical and clinical testing and other approval requirements by the FDA in the United States under the federal Food, Drug and Cosmetic



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Act and by comparable agencies in most foreign countries. Various federal, state and foreign statutes also govern or influence the manufacture, labeling, storage, record keeping, and marketing of such products. Pharmaceutical manufacturing facilities are also regulated by state, local, and other authorities. Obtaining approval from the FDA and other regulatory authorities for a new drug or treatment may take several years and involve substantial expenditures. Moreover, ongoing compliance with these requirements can require the expenditure of substantial resources. Difficulties or unanticipated costs may be encountered by us in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

*Our Products Will Be Exposed To Pricing And Reimbursement Risks.* Our ability to earn revenue will depend in part on the extent to which reimbursement for the costs of the products and related treatments will be available from government health administration authorities, private health coverage and managed care organizations. Third-party payers are increasingly challenging the prices of drugs and medical services. If purchasers or users of MDI-P or SaveCream are not able to obtain adequate reimbursement, they may forego or reduce their use.

*We Face Intense Competition And Competing Products.* Competition in the markets for MDI-P and SaveCream is intense and will likely further intensify. The biotechnology and pharmaceutical industries are characterized by rapidly evolving technologies and intense competition. Our competitors include major pharmaceutical, and specialized biotechnology companies, many of which have financial, technical, and marketing resources significantly greater than ours. Fully integrated pharmaceutical companies, due to their expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing, as well as their substantially greater financial and other resources, may be our most formidable competitors. In addition, acquisitions by such pharmaceutical companies could enhance the financial and marketing resources of smaller competitors. Furthermore, colleges, universities, governmental agencies, and other public and private research organizations will continue to conduct research and possibly market competitive commercial products on their own or through joint ventures. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. These institutions also will compete with us in recruiting and retaining highly qualified scientific personnel.

In particular, we face competition from the manufacturers of products that would compete with MDI-P and SaveCream should they be commercialized. Manufacturers of products currently available for the treatment of HIV and cystic fibrosis would be among our most significant competitors in the market for MDI-P. While there are 24 HIV therapies currently on the market (commonly used in three- or four-drug combinations), the primary therapies currently in use are produced by Pfizer, Bristol-Myers Squibb, Boehringer Ingelheim, GlaxoSmithKline, Gilead Sciences, Hoffman-La Roche, Merck, Abbott Laboratories, Agouron Pharmaceuticals, and Trimeris. Currently available anti-infectives commonly used in the treatment of cystic fibrosis are manufactured by Bayer Corporation, the maker of Cipro; Pfizer, the maker of Zithromax; and Chiron, the maker of tobramycin solution (TOBI). Bayer and Pfizer would compete with us in the cystic fibrosis market, while MDI-P is being studied as an adjunct to treatment with TOBI; thus we would be unlikely to compete directly with Chiron. Producers of aromatase inhibitors and other breast cancer treatments would compete with SaveCream should we be able to commercialize this product. These companies include Astra-Zeneca, the maker of both Tamoxifen and Arimidex; Novartis, the maker of Femara; and Pfizer, the maker of Aromasin.

If and when we obtain regulatory approval for any of the potential uses of our technology which require them, we must then compete for acceptance in the marketplace. While we believe that both MDI-P and SaveCream will be shown to be at least as effective as existing therapies with more favorable risk profiles, as described more fully in the Description of Business section, clinical trials have not been conducted to prove these potential competitive advantages. Additionally, given that regulatory approval, especially in the United States, may take a number of years, the timing of the introduction of our technology and other products to the market is critical. Other safe and effective drugs and treatments may be introduced into the market prior to the time that we are able to obtain approval for the commercialization of our technology. In addition, even after such regulatory approval is obtained, competition among products approved for sale may be affected by, among other things, product efficacy, safety, reliability, availability, price, and patent position.



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The extensive financial and other resources of the major pharmaceutical manufacturers who are our most likely competitors may make it unlikely that we can successfully compete in the HIV, cystic fibrosis or breast cancer markets on our own. As a result, we may seek a development partner or pursue licensing opportunities for these technologies.

*Our Intellectual Property May Not Be Adequately Protected.* We rely heavily on our patent protection to prevent others from using the human therapeutic applications of our technology. It is our policy to protect our intellectual property and proprietary technologies by, among other means, filing patent applications to protect technology that we consider important to the development of our business.

We also rely on trade secrets and improvements, unpatented know how, and continuing technological innovation to develop and maintain our competitive position. Despite our policy to seek patent protection wherever appropriate, we cannot be sure that our patent applications will result in further patents being issued or that, if issued, the patents will afford protection against competitors with similar technology. We are unaware of any current or past infringement of our patented technologies; however, if such infringement were to occur, sufficient funds may not be available to adequately pursue an action for infringement. While we have obtained several United States patents, persons in jurisdictions outside of the United States in which no application has been filed or which do not honor United States patents may develop and market infringing technologies. Also, the cost of enforcing patents outside North America as well as other obstacles, may limit our ability to enforce any patents outside of the United States. Finally, our products and processes may infringe on patents of others. 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 claims, or be required to obtain licenses or redesign our products or processes to avoid infringement.

We currently hold eight U.S. patents, two Japanese patents and one Mexican patent related to MDI-P. These patents, detailed in the Description of Business section, cover a specific solution, methods of using this solution as an anti-infective, and the equipment and processes necessary to produce it. The durations of these patents range from May 2010 to August 2014. We also have three pending U.S. patent applications relating to methods of using MDI-P to treat cystic fibrosis, sepsis and asthma. The intellectual property assets purchased from Savetherapeutics include the intellectual property rights in four patent families related to SaveCream. These patents and the related international patents and patent applications are detailed in the Description of Business section.

*We May Need to Litigate to Secure Our Rights to SaveCream And Related Assets.* At the time we purchased SaveCream and the other intellectual property assets from Savetherapeutics A.G. (SaveT), SaveT had not yet obtained and filed with the appropriate patent offices assignments of the inventors' rights to the underlying inventions. As a result, at the time the SaveT assets were obtained, the two inventors of SaveCream, Heinrich Wieland and Alfred Schmidt, were the record holders of the U.S. patent rights related to this product. Each of those inventors has agreed and is contractually bound to assign such rights to SaveT. As of September 25, 2005, Heinrich Wieland has executed assignments of his interests in the SaveCream patents to Savetherapeutics and has provided us with a declaration to the U.S. Patent and Trademark Office detailing the agreements by which he and Mr. Schmidt, upon receipt of consideration from SaveT, agreed and intended to transfer these rights to SaveT. Those assignments, along with assignments of Savetherapeutics' rights in the patents to us, have been filed with the U.S. Patent and Trademark Office.

Despite his prior written agreements to do so, Mr. Schmidt has refused to execute assignments of his rights in the SaveCream patents. To our knowledge, Mr. Schmidt's refusal to undertake his contractual obligation to assign the SaveCream patents has no basis in law. It may be necessary, however, to litigate against Mr. Schmidt in all countries in which patents are filed in order to obtain the assignment of these rights. These countries include the U.S., Germany, Canada, France, Great Britain, Italy, the Netherlands, Switzerland and Spain. We may not have the funds necessary to effectively pursue these claims.

Should we fail to obtain the assignment of Mr. Schmidt's rights in the SaveCream patents, it may be more difficult to commercialize SaveCream should FDA approval for such commercialization be granted. While the product would remain subject to patent protection and we could pursue our development and commercialization activities based upon Dr. Wieland's assignment, Mr. Schmidt, as a co-inventor, may be





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able to independently exploit his rights in the SaveCream patents and could enter into competition with us or license his rights to third parties. This would effectively preclude us from pursuing an exclusive licensing or co-development opportunity, and would, therefore substantially reduce the value of this intellectual property to us.

*We Face Significant Product Liability.* We face an inherent business risk of exposure to product liability and other claims in the event our products result in or are alleged to result in harmful effects. We may not be able to avoid significant liability exposure. We may not have or be able to obtain or maintain sufficient insurance coverage at a reasonable cost. An inability to obtain sufficient insurance coverage at a reasonable cost could prevent or inhibit the commercialization of our technology. Even if we avoid liability exposure, we could incur significant costs that hurt our financial performance. We currently do not have and have not applied for product liability insurance. We intend to purchase product liability insurance prior to commencing clinical trials, and have incorporated the costs of insurance coverage into our budget for the trials.

*The Market For Our Stock Is Thin And Subject To Manipulation.* Our common stock is traded on the NASD OTC Bulletin Board under the symbol MLSC. Since our inception, trading in our stock has been sporadic. During the three months ended February 28, 2006, the daily trading volume of our stock averaged 40,496 shares per day. This thin trading market increases the volatility of our stock price and allows trades of even small blocks of stock to have a significant impact on our stock price. Our thin trading market also increases the risk of illegal naked short selling which may cause the stock price to decrease to as low as \$0.001 and shareholders to lose essentially all value in their stock. The following table sets forth the range of bid quotations for our common stock for the quarters indicated according to data provided by The NASDAQ Stock Market, Inc. Such quotations reflect inter-dealer prices, without retail mark-ups, markdowns or commissions, and may not represent actual transactions.

<b>Period</b>	<b>High Bid</b>	<b>Low Bid</b>
Quarter ended December 31, 2005	0.135	0.090
Quarter ended September 30, 2005	0.180	0.080
Quarter ended June 30, 2005	0.170	0.082
Quarter ended March 31, 2005	\$ 0.220	\$ 0.130

*The Market Price For Our Common Stock Will Likely Be Volatile And May Change Dramatically At Any Time.* The market price of our common stock, like that of the securities of other early-stage companies, may be highly volatile. Our stock price may change dramatically as the result of announcements of our quarterly results, the execution or termination of significant customer contracts, significant litigation or other factors or events that would be expected to affect our business or financial condition, results of operations and other factors specific to our business and future prospects. In addition, the market price for our common stock may be affected by various factors not directly related to our business, including the following:

intentional manipulation of our stock price by existing or future stockholders;

short selling of our common stock or related derivative securities;

the interest, or lack of interest, of the market in our business sector, without regard to our financial condition or results of operations;

the adoption of governmental regulations and similar developments in the United States or abroad that may affect our ability to develop our products or affect our cost structure; and

economic and other external market factors, such as poor economic indicators or investor distrust.

*Penny stock rules may make buying or selling our securities difficult which may make our stock less liquid and make it harder for investors to buy and sell our shares.* Trading in our securities is subject to the SEC's penny stock

rules and it is anticipated that trading in our securities will continue to be subject to the penny stock rules for the foreseeable future. The SEC has adopted regulations that generally define a penny stock to be any equity security that has a market price of less than \$4.00 per share, subject to certain exceptions. These rules require that any broker-dealer who recommends our securities to persons other than

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prior customers and accredited investors must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser's written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities.

*We Are Unlikely To Pay Dividends On Our Common Stock In the Foreseeable Future.* We have never declared or paid dividends on our stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business. We do not anticipate paying any cash dividends in the foreseeable future, and it is unlikely that investors will derive any current income from ownership of our stock. This means that your potential for economic gain from ownership of our stock depends on appreciation of our stock price and will only be realized by a sale of the stock at a price higher than your purchase price.

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**ITEM 7. FINANCIAL STATEMENTS.**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders  
Medical Discoveries, Inc.

We have audited the accompanying consolidated balance sheets of Medical Discoveries, Inc. and subsidiaries (a development stage company) as of December 31, 2005 and 2004, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the years then ended, and for the period from November 20, 1991 (date of inception of the development stage) through December 31, 2005. These consolidated 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 did not audit the financial statements of the Company from November 20, 1991 through December 31, 2003, which statements reflect total revenues and deficit accumulated during the development stage of \$157,044 and \$14,930,259, respectively. Those statements were audited by other auditors whose reports, dated February 18, 2004 (except Note K, not included herein, as to which the date is November 15, 2004) and March 20, 2000, included an explanatory paragraph stating there was substantial doubt regarding the Company's ability to continue as a going concern. Our opinion, insofar as it relates to the consolidated financial statements for the period from November 20, 1991 through December 31, 2003, is based solely on the report of the other auditors.

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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Medical Discoveries, Inc. and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for the years then ended and for the period from November 20, 1991 through December 31, 2005, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company is a development stage enterprise engaged in developing bio-pharmaceutical research. As discussed in Note B to the financial statements, the stockholders' deficit and the operating losses since inception raise substantial doubt about the Company's ability to continue as a going

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concern. Management's plans concerning these matters are also described in Note B. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

/s/ **HANSEN, BARNETT & MAXWELL**

Salt Lake City, Utah  
March 3, 2006

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED BALANCE SHEETS**

	December 31, 2005	December 31, 2004
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash	\$ 654,438	\$ 1,455,397
Deposits		51,100
<b>Total Current Assets</b>	<b>654,438</b>	<b>1,506,497</b>
Note receivable	296,050	
Property and equipment, net	80,635	
<b>TOTAL ASSETS</b>	<b>\$ 1,031,123</b>	<b>\$ 1,506,497</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 2,608,783	\$ 2,448,454
Accrued interest payable	237,836	415,262
Notes payable	56,000	336,717
Convertible notes payable	193,200	193,200
Research and development obligation	592,100	
Financial instrument	2,859,596	
<b>Total Current Liabilities</b>	<b>6,547,515</b>	<b>3,393,633</b>
<b>TOTAL LIABILITIES</b>	<b>6,547,515</b>	<b>3,393,633</b>
<b>STOCKHOLDERS DEFICIT</b>		
Preferred Stock undesignated, Series A, convertible; no par value; 50,000 shares authorized; 42,000 and 12,000 shares issued and outstanding, respectively; (aggregate liquidation preference of \$4,200,000 and \$1,200,000, respectively)	523,334	523,334
Common stock, no par value; 250,000,000 shares authorized; 107,679,724 and 105,653,335 shares issued and outstanding, respectively	15,211,895	14,918,657
Additional paid-in capital	988,670	3,424,383
Deficit accumulated prior to the development stage	(1,399,577)	(1,399,577)
Deficit accumulated during the development stage	(20,840,714)	(19,353,933)
<b>Total Stockholders Deficit</b>	<b>(5,516,392)</b>	<b>(1,887,136)</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT</b>	<b>\$ 1,031,123</b>	<b>\$ 1,506,497</b>





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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Years Ended December 31, 2005 and 2004, and**  
**Cumulative Amounts Since November 20, 1991 (Date of Inception)**

	For the Years Ended		From Inception of the Development Stage on November 20, 1991 through December 31, 2005
	December 31,		
	2005	2004	
REVENUES	\$	\$	\$ 157,044
COST OF GOODS SOLD			14,564
<b>GROSS PROFIT</b>			<b>142,480</b>
<b>OPERATING EXPENSES</b>			
General and administrative	1,878,027	3,057,429	17,054,997
Research and development	2,172,461	550,093	5,721,199
Inventory write-down			96,859
Impairment loss			9,709
License fees			1,001,500
Total Expenses	4,050,488	3,607,522	23,884,264
<b>LOSS FROM OPERATIONS</b>	<b>(4,050,488)</b>	<b>(3,607,522)</b>	<b>(23,741,784)</b>
<b>OTHER INCOME (EXPENSES)</b>			
Unrealized gain on financial instrument	2,300,191		2,300,191
Interest income	25,727	6,165	55,298
Interest expense	(38,264)	(131,526)	(1,155,701)
Foreign currency transaction gain	56,480		56,480
Gain on forgiveness of debt	196,353		1,431,889
Other income	23,220	1,408	905,112
Total Other Income (Expenses)	2,563,707	(123,953)	3,593,269
<b>NET LOSS</b>	<b>(1,486,781)</b>	<b>(3,731,475)</b>	<b>(20,148,515)</b>
Preferred stock dividend from beneficial conversion feature		(692,199)	(692,199)
<b>NET LOSS APPLICABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (1,486,781)</b>	<b>\$ (4,423,674)</b>	<b>\$ (20,840,714)</b>
	<b>\$ (0.01)</b>	<b>\$ (0.05)</b>	

**BASIC AND DILUTED LOSS PER COMMON  
SHARE**

WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	107,398,164	93,947,646
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**MEDICAL DISCOVERIES INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT**  
**Period From November 20, 1991 (Date of Inception of the Development Stage) through**  
**December 31, 2005**

	Preferred Stock	Common Stock		Additional Paid in Capital	Accumulated Deficit Prior to Development Stage	Accumulated Deficit During the Development Stage	Escrow/ Subscription Receivables	Total
	Shares Amount	Shares	Amount	Capital	Stage	Stage	Receivables	Total
Balance at October 31, 1991		1,750,000	\$ 252,997	\$	\$ (1,482,514)	\$	\$	\$ (1,229,517)
Restatement for reverse acquisition of WPI Pharmaceutical, Inc. by Medical Discoveries, Inc.			(252,997)		252,997			
Shares issued in merger of WPI Pharmaceutical, Inc. Medical Discoveries, Inc., \$0.01 per share		10,000,000	135,000		(170,060)			(35,060)
Balance at November 20, 1991 (Date of Inception of Development Stage)		11,750,000	135,000		(1,399,577)			(1,264,577)
Issuance of common stock for:								
Cash								
1992 \$0.50 per share		200,000	100,000					100,000
		40,000	60,000					60,000

1992 \$1.50 per share				
1993 \$0.97 per share	542,917	528,500		528,500
1994 \$1.20 per share	617,237	739,500		739,500
1995 \$0.67 per share	424,732	283,200		283,200
1996 \$0.66 per share	962,868	635,000	(60,000)	575,000
1997 \$0.43 per share	311,538	135,000	60,000	195,000
1998 \$0.29 per share	2,236,928	650,000		650,000
1999 \$0.15 per share	13,334	2,000		2,000
2001 \$0.15 per share	660,000	99,000		99,000
2003 \$0.04 per share	20,162,500	790,300		790,300
Services and Interest				
1992 \$0.50 per share	500,000	250,000		250,000
1993 \$0.51 per share	251,450	127,900		127,900
1993 \$0.50 per share	800,000	400,000		400,000
1994 \$1.00 per share	239,675	239,675		239,675

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**MEDICAL DISCOVERIES INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT (Continued)**  
**Period From November 20, 1991 (Date of Inception of the Development Stage) through**  
**December 31, 2005**

	Preferred Stock	Common Stock	Additional Paid in Capital	Accumulated Deficit Prior to Development Stage	Accumulated Deficit During the Development Stage	Escrow/Subscription Receivables	Total
	Share Amount	Shares	Amount	Capital Stage	Stage	Receivables	Total
1995	\$0.39 per share	4,333,547	1,683,846			(584,860)	1,098,986
1996	\$0.65 per share	156,539	101,550				101,550
1997	\$0.29 per share	12,500	3,625				3,625
1998	\$0.16 per share	683,000	110,750				110,750
1999	\$0.30 per share	100,000	30,000				30,000
2001	\$0.14 per share	1,971,496	284,689				284,689
2002	\$0.11 per share	2,956,733	332,236				332,236
2003	\$0.06 per share	694,739	43,395				43,395
<b>Conversion of Debt</b>							
1996	\$0.78 per share	239,458	186,958				186,958
1997	\$0.25 per share	100,000	25,000				25,000
1998	\$0.20 per share	283,400	56,680				56,680
2002	Debt \$0.03 per share	17,935,206	583,500				583,500
<b>Other Issuances</b>							
1993	License \$0.50 share	2,000,000	1,000,000				1,000,000
1997	Settlement of contract	800,000	200,000				200,000
1998	Issuance of common	200,000	200				200

stock from exercise of warrants, \$0.001 per share				
2000 Reversal of shares issued	(81,538)			
Escrow and Subscription Receivables				
1996 Common stock canceled \$0.34 per share	(1,400,000)	(472,360)		472,360
2000 Issuance for escrow receivable \$0.09 per share	5,500,000	500,000		(500,000)
2000 Write-off of subscription receivable				112,500
2000 Research and development costs				112,500
				115,400
				115,400

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**MEDICAL DISCOVERIES INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT (Continued)**  
**Period From November 20, 1991 (Date of Inception of the Development Stage)through**  
**December 31, 2005**

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit Prior to Development Stage	Deficit Accumulated During the Development Stage	Escrow/ Subscription Receivables	Total
	Shares	Amount	Shares	Amount					
2001 Research and development costs								132,300	132,300
2001 Operating expenses								25,000	25,000
Exercise of Options and Warrants									
1997 \$0.25 per share			87,836	21,959					21,959
1999 Waived option price \$0.14 per share			170,000	24,000					24,000
Value of Issued for Services									
1998				2,336,303					2,336,303
1999				196,587					196,587
2001					159,405				159,405
2002					124,958				124,958
2003					295,000				295,000
Other									
1994 Cash contributed				102,964					102,964
1995 Issuance of common stock option to satisfy debt restructuring				20,000					20,000
							(14,930,259)		(14,930,259)



Net loss from inception through December 31, 2003								
<b>Balance at December 31, 2003</b>		76,456,095	12,546,957	579,363	(1,399,577)	(14,930,259)	(227,300)	(3,430,816)
Extension of options for services				1,675,000				1,675,000
Termination of escrow agreement		(2,356,200)	(227,300)				227,300	
Issuance of preferred stock and warrants for cash (net \$130,000, common stock and warrants issued to placement agent)	12,000	523,334	350,000	68,845	477,821			1,070,000
Convertible preferred stock beneficial conversion dividend					692,199	(692,199)		
Issuance of common stock for:								
Cash \$0.09 per share		20,138,024	1,813,186					1,813,186
Debt and interest \$0.07 per share		9,875,951	650,468					650,468
Services \$0.06 per share		1,189,465	66,501					66,501
Net loss for the year ended December 31, 2004						(3,731,475)		(3,731,475)



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**MEDICAL DISCOVERIES INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS DEFICIT (Continued)**  
**Period From November 20, 1991 (Date of Inception of the Development Stage) through**  
**December 31, 2005**

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit Prior to Development Stage	Deficit Accumulated During the Escrow/ Development Stage	Subscription Receivables	Total
	Shares	Amount	Shares	Amount					
<b>Balance at December 31, 2004</b>	12,000	523,334	105,653,335	14,918,657	3,424,383	(1,399,577)	(19,353,933)		(1,887,136)
Issuance of common stock for services			104,167	11,312					11,312
Issuance of common stock for cash at \$0.18 per share			1,922,222	281,926					281,926
Issuance of preferred stock and warrants for cash (net \$340,000, entire amount was reclassified to financial instrument liability)	30,000								
Reclassification of warrants to a financial instrument liability						(2,435,713)			(2,435,713)
Net loss for the year ended December 31, 2005							(1,486,781)		(1,486,781)
<b>Balance at December 31, 2005</b>	42,000	\$ 523,334	107,679,724	\$ 15,211,895	\$ 988,670	\$ (1,399,577)	\$ (20,840,714)	\$	\$ (5,516,392)



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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A Development Stage Company)**  
**Consolidated Statements of Cash Flows**

	For the Year Ended		From Inception of
	December 31,		the
	2005	2004	Development Stage
			on
			November 20, 1991
			through Dec. 30,
			2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net Loss	\$ (1,486,781)	\$ (3,731,475)	\$ (20,148,515)
Adjustments to reconcile net loss to net cash used by operating activities:			
Foreign currency transaction gain	(56,480)		(56,480)
Gain on debt restructuring	(196,353)		(1,431,889)
Common stock issued for services, expenses, and litigation		66,501	4,267,717
Commitment for research and development obligation	665,700		665,700
Depreciation	8,515		108,786
Reduction of escrow receivable from research and development			272,700
Unrealized gain on financial instrument	(2,300,191)		(2,300,191)
Stock options and warrants granted for services		1,675,000	4,811,253
Reduction of legal costs			(130,000)
Write-off of subscriptions receivable			112,500
Impairment of loss on assets			9,709
Loss on disposal of equipment			30,364
Write-off of receivable	51,100		245,065
Note payable issued for litigation			385,000
Changes in operating assets and liabilities			
Increase in accounts receivable			(7,529)
Decrease in prepaid expenses		11,331	
Decrease in deferred charges		12,077	
Increase in accounts payable	171,641	381,727	2,464,186
Increase in accrued expenses	38,210	53,934	637,919
Net Cash Used by Operating Activities	(3,104,639)	(1,530,905)	(10,063,705)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Increase in deposits		(51,100)	(51,100)
Purchase of equipment	(89,150)		(221,334)
Issuance of note receivable	(313,170)		(313,170)
Payments received on note receivable			130,000
Net Cash Used by Investing Activities	(402,320)	(51,100)	(455,604)

**CASH FLOWS FROM FINANCING ACTIVITIES**

Issuance of common stock, preferred stock and warrants for cash	3,006,000	2,883,186	10,033,845
Contributed equity			131,374
Proceeds from notes payable			1,336,613
Payments on notes payable	(300,000)	(270,000)	(801,287)
Proceeds from convertible notes payable			571,702
Payments on convertible notes payable			(98,500)
Net Cash Provided by Financing Activities	2,706,000	2,613,186	11,173,747
NET INCREASE (DECREASE) IN CASH	(800,959)	1,031,181	654,438
CASH AT BEGINNING OF PERIOD	1,455,397	424,216	
CASH AT END OF PERIOD	\$ 654,438	\$ 1,455,397	\$ 654,438

**SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION**

Interest paid	\$ 19,283	\$ 77,592
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**NONCASH INVESTING AND FINANCING ACTIVITIES**

Retirement of notes payable and interest through issuance of common stock	\$	\$ 650,468
Release of shares as part of Perrigrine settlement	\$	\$ 227,300
Common stock and warrants issued to placement agent	\$ 11,312	\$ 162,746
Preferred stock dividend as part of beneficial conversion feature	\$	\$ 692,199

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**NOTE A SIGNIFICANT ACCOUNTING POLICIES**

Medical Discoveries, Inc. ( MDI or the Company ) was incorporated under the laws of the State of Utah on November 20, 1991. Effective as of August 6, 1992, the Company merged with and into WPI Pharmaceutical, Inc., a Utah corporation ( WPI ), pursuant to which WPI was the surviving corporation. Pursuant to the MDI-WPI merger, the name of the surviving corporation was changed to Medical Discoveries, Inc.

On July 6, 1998, the Company incorporated a wholly owned subsidiary, Regenere, Inc., in the State of Nevada. On October 2, 1998, the Company incorporated another wholly owned subsidiary, MDI Healthcare Systems, Inc., in the State of Nevada. As of December 31, 2003, the Company dissolved those subsidiaries.

On March 22, 2005, the Company formed MDI Oncology, Inc., a Delaware corporation, as a wholly-owned subsidiary to acquire and operate the assets and business associated with the Savetherapeutics transaction, discussed further in Note J.

**Principles of Consolidation**

The consolidated financial statements include the accounts of Medical Discoveries, Inc. and subsidiaries. All significant intercompany transactions have been eliminated in consolidation.

**Development Stage Company**

The Company has not generated any significant revenue and is, therefore, considered a development stage company as defined in the Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 7. The Company has, at the present time, not paid any dividends. Any dividends that may be paid in the future will depend upon the financial requirements of the Company. The primary purpose of the business is the research and development of pharmaceuticals.

**Cash and Cash Equivalents**

For purposes of the statement of cash flows, the Company considers all highly liquid debt instruments maturing in three months or less to be cash equivalents. At year end, the Company has cash deposits in excess of federally insured limits. The Company had an insured bank balance of \$113,752 at December 31, 2005.

**Property and Equipment**

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated lives of the related assets. Estimated useful lives are 5 years.

Normal maintenance and repair items are charged to costs and expensed as incurred. The cost and accumulated depreciation of property and equipment sold or otherwise retired are removed from the accounts and gain or loss on disposition is reflected in net income.

**Income Taxes**

The Company utilizes the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and the carryforward of operating losses and tax credits and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. An allowance against deferred tax assets is recorded when it is more likely than not that such tax benefits will not be realized. Research tax credits are recognized as utilized.

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
Notes to Consolidated Financial Statements (Continued)**

**Research and Development**

Research and development has been the principal function of the Company. Expenses in the accompanying financial statements include certain costs which are directly associated with the Company's research and development of the Company's anti-infective pharmaceutical, MDI-P. These costs, which consist primarily of pre-clinical testing activities, amounted to \$2,172,461 and \$550,093 and \$5,721,199 for the year ended December 31, 2005 and 2004 and for the period November 20, 1991 (date of inception of the development stage) through December 31, 2005, respectively.

**Fair Value of Financial Instruments**

The Company estimates that the fair value of all financial instruments, at December 31, 2005, do not differ materially from the aggregate carrying values of its financial instruments recorded in the accompanying balance sheet. The estimated fair value amounts have been determined by the Company using available market information and appropriate valuation methodologies. Considerable judgment is required in interpreting market data to develop the estimates of fair value, and accordingly, the estimates are not necessarily indicative of the amounts that the Company could realize in a current market exchange.

**Estimates**

Management uses estimates and assumptions in preparing financial statements. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and reported revenues and expenses. Significant estimates used in preparing these financial statements include those assumed in determining the valuation of common stock and stock options. It is at least reasonably possible that the significant estimates used will change within the next year.

**Basic and Diluted Loss per Share**

Basic loss per share is computed on the basis of the weighted-average number of common shares outstanding during the year. Diluted loss per share is computed on the basis of the weighted-average number of common shares and all dilutive potentially issuable common shares outstanding during the year. Common stock equivalents, stock options and stock warrants have not been included as they are anti-dilutive.

**Concentration of Credit**

The Company has no significant revenues and, therefore, no significant trade receivables or extensions of credit.

**Stock Based Compensation**

The Company accounts for its stock-based compensation issued to non-employees using the fair value method in accordance with SFAS No. 123, Accounting for Stock-Based Compensation. Under SFAS No. 123, stock-based compensation is determined as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The measurement date for these issuances is the earlier of the date at which a commitment for performance is reached or the date at which the recipient's performance is complete.

The Company accounts for employee stock option and award plans under the recognition method and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and the related Interpretations. Under APB Opinion No. 25, compensation related to stock options, if any, is recorded if an option's exercise price on the measurement date is below the fair value of the Company's common stock. The compensation is amortized to expense over the vesting period.



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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements (Continued)**

These accounting policies resulted in the Company recognizing \$0 and \$1,675,000 in stock-based compensation cost during the years ended December 31, 2005 and 2004, respectively. The effect on net loss and net loss per common share if the Company had applied the fair value recognition provisions of SFAS No. 123 to employee stock-based compensation is as follows:

	<b>Fiscal Year Ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
Net loss applicable to common stockholders, as reported	\$ (1,486,781)	\$ (4,423,674)
Add: Stock-based employee compensation expense included in reported net loss		1,675,000
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards		(1,979,237)
Pro forma net loss applicable to common shareholders	\$ (1,486,781)	\$ (4,727,911)
Basic and diluted loss per share, as reported	\$ (0.01)	\$ (0.05)
Basic and diluted loss per share, pro forma	\$ (0.01)	\$ (0.05)

**Recently Issued Accounting Statements**

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is an amendment to SFAS No. 123, *Accounting for Stock-Based Compensation*. This new standard eliminates the ability to account for share-based compensation transactions using Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees* (APB 25) and requires such transactions to be accounted for using a fair-value-based method and the resulting cost recognized in the Company's financial statements. This new standard is effective for annual periods beginning after June 15, 2005, and will require the Company to record as an expense all stock option grants issued to employees after January 1, 2006.

In December 2004, the FASB issued SFAS Statement No. 153, *Exchanges of Non-monetary Assets* an amendment of APB Opinion No. 29. This Statement amends APB Opinion 29 to eliminate the exception for non-monetary exchanges of similar productive assets and replaces it with a general exception for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Statement will be effective in January 2006. The Company does not expect that the adoption of SFAS No. 153 will have a material impact on its Consolidated Financial Statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections - a replacement of APB Opinion No. 20 and FASB Statement No. 3*. SFAS No. 154 applies to all voluntary changes in accounting principle or when an accounting pronouncement does not include specific transition provisions and changes the requirements for the accounting for and reporting of a change in accounting principle. This statement requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period specific effects or the cumulative effect of the change. The Company implemented this standard on January 1, 2006 and will not have a material impact to the company.

**NOTE B BASIS OF PRESENTATION AND GOING CONCERN**

As shown in the accompanying financial statements, the Company incurred a net loss applicable to common shareholders of \$1,486,781 during the year ended December 31, 2005 and has incurred losses applicable to common shareholders since inception of the development stage of \$20,840,714. The Company

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A Development Stage Company)**

**Notes to Consolidated Financial Statements (Continued)**

has not had significant revenues and is still in the process of testing and commercializing its technologies. The Company is hopeful, but there is no assurance, that the current product development and research will be economically viable. Those factors raise substantial doubt about the Company's ability to continue as a going concern.

Management plans to meet its cash needs through the issuance of equity or debt securities and the potential licensure of its technologies. The ability of the Company to continue as a going concern is dependent on that plan's success. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

**NOTE C PROPERTY AND EQUIPMENT**

Property and equipment as of December 31, 2005 and 2004 are detailed below:

	2005	2004
Equipment	\$ 168,468	\$ 79,318
Accumulated depreciation	(87,833)	(79,318)
	\$ 80,635	\$

Depreciation expense was \$8,515 and \$0 for the years ended December 31, 2005 and 2004, respectively.

**NOTE D INCOME TAXES**

Income taxes are provided for temporary differences between financial and tax basis income. The following is a reconciliation of the amount of benefit that would result from applying the federal statutory rate to pretax loss with the benefit from income taxes for the year ended December 31, 2005:

	Years Ended December 31,	
	2005	2004
Federal income tax benefit at statutory rate (34%)	\$ 506,000	\$ 1,268,000
State income tax, net of federal benefit	89,000	224,000
Unrealized gain on financial instrument	920,000	
Revaluation and expiration of options		(631,000)
Change in valuation allowance	(1,515,000)	(861,000)
	\$	\$

The components of net deferred taxes are as follows at December 31 using a combined deferred tax rate of 40%:

	December 31,	
	2005	2004
Net operating loss carryforward	\$ 6,663,000	\$ 5,132,000
Research and development credits	80,000	80,000
Stock options	646,000	646,000

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Accrued compensation	380,000	396,000
Valuation allowance	(7,769,000)	(6,254,000)
Net deferred tax asset	\$	\$

**Table of Contents****MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)****Notes to Consolidated Financial Statements (Continued)**

Inasmuch as it is not possible to determine when or if the net operating losses will be utilized, a valuation allowance has been established to offset the benefit of the utilization of the net operating losses.

The Company has available net operating losses of approximately \$16,700,000 which can be utilized to offset future earnings of the Company. The Company also has available approximately \$80,000 in research and development credits which expire in 2008. The utilization of the net operating losses and research and development credits are dependent upon the tax laws in effect at the time such losses can be utilized. The losses begin to expire between the years 2007 and 2023. Should the Company experience a change of ownership the utilization of net operating losses could be reduced.

**NOTE E NOTES PAYABLE**

The Company has the following notes payable at December 31, 2005:

	2005	2004
Notes payable to shareholders, which are currently due and in default. Interest is at 12%	\$ 56,000	\$ 336,717

On April 1, 2005, the Company negotiated a settlement regarding notes payable totaling \$280,717 and accrued interest of \$215,636, by payment of \$300,000 in cash. The Company recognized a gain on settlement of debt totaling \$196,353.

**NOTE F CONVERTIBLE NOTES PAYABLE**

The Company has the following convertible notes payable at December 31, 2005:

	2005	2004
Convertible notes payable to a trust, which is currently due and in default. Interest is at 12%. Each \$1,000 note is convertible into 667 shares of Company's common stock	\$ 193,200	\$ 193,200

**NOTE G STOCKHOLDERS EQUITY*****Common Stock***

During the year ended December 31, 2005, the Company issued 2,026,389 shares of restricted common stock, 104,167 of which were issued to satisfy accrued liabilities valued at \$11,312 and 1,922,222 of which were issued for cash totaling \$346,000. In connection with the sales for cash, the Company also issued warrants to purchase 1,922,222 shares of restricted common stock at \$0.18 per share, expiring 3 years from the date of issuance.

During 2004, as part of a private placement offering, the Company issued 5,551,011 shares of common stock for \$0.18 per share or \$999,180. In conjunction with the private placement, the Company issued to these investors warrants to purchase 5,551,011 shares of common stock at \$0.18 per share. These warrants expire three years from the date of issuance.

During the year ended December 31, 2004, the Company converted \$487,503 of principal and \$162,965 of interest related to notes payable and convertible notes payable into 9,875,951 shares of common stock. The conversion prices ranged from \$0.06 to \$0.21 per share.

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
Notes to Consolidated Financial Statements (Continued)**

**Preferred Stock and Warrants**

**2005**

During the year ended December 31, 2005, the Company issued 30,000 shares of Series A Convertible Preferred Stock and warrants to purchase 22,877,478 shares of common stock for a total offering price of \$3.0 million. The Company incurred \$340,000 of offering costs and issued to the placement agent warrants to purchase 1,220,132 shares of common stock exercisable at \$0.1967 per share which are exercisable for a period of three years.

Each share of Preferred Stock entitles the holder to convert the share of Preferred Stock into the number of shares of common stock resulting from multiplying \$100 by the conversion price. The conversion price is 75% of the average of the three lowest intra-day trading prices for the Company's common stock during the 10 trading days immediately preceding the conversion date. The conversion price may not exceed \$0.1967. The warrants are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. The warrants entitle the holder to purchase up to 22,877,478 shares of common stock of the Company at \$0.1967 per share. The warrants expire three years after the date of issuance.

The Series A Convertible Preferred Stock has no voting rights. In the event of liquidation, the holders are entitled to a liquidating distribution of \$100 per share. The Company also entered into a Registration Rights Agreement with the investors requiring the Company to use its best efforts to timely file a registration statement with the Securities and Exchange Commission registering the shares of common stock issuable upon conversion of the Preferred Stock and exercise of the warrants. There are no significant liquidation damages in the event the Company is unable to file its registration statement.

The conversion feature of the Series A Convertible Preferred Stock has more of the attributes of an equity instrument than a liability instrument, and thus not considered a derivative. However, the Company is unable to guarantee that there will be enough shares of stock to settle other freestanding instruments. Accordingly, the warrants attached to the convertible preferred stock are measured at their fair value and classified as liability in the financial statements. The fair value of the warrants was \$3,844,116 on the date of issuance computed using the Black Scholes model with the following assumptions: volatility of 170%, risk-free interest rate of 3.9%, and an expected life of three years. The fair value of the warrants exceeded the proceeds received by \$1,184,116, which was recorded as an expense on the statement of operations. Due to the fact that the value of the warrants exceeded the proceeds received, no value was assigned to the preferred stock.

**2004**

On October 18, 2004, the Company issued 12,000 shares of Series A Convertible Preferred Stock and warrants to purchase 4,575,495 shares of common stock for a total offering price of \$1.2 million. The Company incurred \$130,000 of offering costs and issued to the placement agent 350,000 shares of common stock (valued at \$0.20 per share) and warrants to purchase 488,052 shares of common stock exercisable at \$0.1967 per share which are exercisable for a period of three years. The Company valued these warrants at \$0.19 per share using a Black Scholes option pricing model with the following assumptions: risk free rate 2.82%, volatility of 171% and an expected life of three years.

Each share of Preferred Stock entitles the holder to convert the share of Preferred Stock into the number of shares of common stock resulting from multiplying \$100 by the conversion price. The conversion price is 85% of the average of the lowest three intra-day trading prices for the Company's common stock during the 10 trading days immediately preceding the conversion date, but the conversion price may not exceed \$0.1967 or be lower than \$0.05. The warrants are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. The warrants entitle the holder to purchase up to 4,575,495 shares of common

**Table of Contents****MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)****Notes to Consolidated Financial Statements (Continued)**

stock of the Company on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share.

The Company has allocated the proceeds from the issuance of the Series A Convertible Preferred Stock and warrants, based on their relative fair values on the date of issuance which are as follows: \$1,200,000 to the Series A Convertible Preferred and \$880,325 to the warrants. The warrants were valued using the Black Scholes Pricing model using the following assumptions: volatility of 171%, risk-free interest rate of 2.82% and a term of three years. The allocation of the net proceeds resulted in \$523,334 being allocated to the Series A Convertible Preferred Stock and \$383,920 being allocated to the warrants. The Company recognized a beneficial conversion dividend of \$692,199 on the date of issuance equal to the value allocated to the Series A Convertible Preferred Stock (before offering costs). The actual value of the beneficial conversion option was \$719,177, but the dividend was limited to the amount of gross proceeds allocated to the Series A Convertible Preferred Stock.

**Financial Instrument**

As noted above, all warrants and options outstanding on March 11, 2005 (with the exception of stock options issued to employees) were measured at their fair value and reclassified as a liability in the financial statements. There were 16,215,100 warrants issued prior to March 11, 2005 had a fair value of \$2,435,713. The value of the warrants was computed using the Black Scholes model with the following assumptions: volatility of 170%, risk-free interest rate of 3.9%, and an expected life of three years. As a result of the reclassification, stockholders' equity was decreased by the fair value of the liability.

Subsequent to March 11, 2005, 611,110 warrants were issued as part of common stock offerings of 611,110 shares. The warrants have a fair value of \$64,074 and are classified as a liability on the financial statements. The value of the warrants was computed using the Black Scholes model with the following weighted assumptions: volatility of 165%, risk-free interest rate of 3.8%, and an expected life of three years. The proceeds received from this issuance exceeded the value of the warrants by \$45,926, which was attributed to the common stock.

The Company adjusted to market value the outstanding warrants as of December 31, 2005. The fair value of the financial instrument was \$2,859,596. The Company used the Black-Scholes model in calculating fair value with the following assumptions: volatility of 152%, risk free interest rate of 4.41% and an expected life of two years. The changes in fair market value have been recorded as adjustments in the line "Unrealized gain on financial instrument" in the statement of operations for all periods presented.

**Commitment Regarding Peregrine Stock**

Peregrine Properties, LLC, a Utah limited liability company ( "Peregrine" ), has entered into an agreement to provide \$500,000 to the Company to fund testing and research steps necessary to continue development of MDI-P. The studies are funded through an escrow agent. As of December 31, 2000, the Company had deposited in escrow a single certificate for 5.5 million shares of common stock for these purposes. Through December 31, 2003, Peregrine had funded \$275,800 to the escrow, of which \$272,700 had been disbursed and recorded as research and development expense on the financial statements of the Company. The remaining \$227,300 to be expended under the agreement was recorded in equity under the caption escrow receivable. As expenditures are made from the escrow for research and development, the expenses are recorded by the Company with a corresponding reduction in the escrow receivable. Under the original agreement, upon completion of the studies, the escrow agent was to disburse the 5.5 million shares to Peregrine and to disburse the research results to the Company. On March 22, 2002, the parties entered into an agreement to partially close the escrow agreement to the extent of Peregrine's funding to date. On that date, 3,143,800 shares were distributed to Peregrine and all research conducted to date was disbursed to the

**Table of Contents****MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)****Notes to Consolidated Financial Statements (Continued)**

Company. As of February 20, 2004, the Company held Peregrine in breach with respect to its remaining funding obligation and terminated the Peregrine research agreement. The Company and Peregrine resolved the matter during 2004 by the Company agreeing to grant Peregrine a warrant to purchase 2,356,200 shares of restricted common stock at an exercise price of \$0.09 per share, exercisable at any time within 3 years. The exchange of the escrow receivable for the warrants was considered a financing transaction, with no additional expense being recorded. The Company reversed the \$227,300 escrow receivable and cancelled the remaining 2,356,200 shares held in escrow.

**NOTE H STOCK OPTIONS AND WARRANTS**

The Company has two incentive stock option plans wherein 24,000,000 shares of the Company's common stock are reserved for issuance thereunder. The Company did not grant any options during 2005 and granted 700,000 fully vested stock options during the year ended December 31, 2004 to consultants with an exercise price of \$0.05. These options were valued at \$98,000 using the Black Scholes pricing model using the following weighted average assumptions: risk free interest of 3.8%, expected dividend yield of 0%, volatility of 220% and an expected life of 7 years.

The following summarizes the option activity for the years ended December 31, 2005 and 2004:

	2005		2004	
	Options	Weighted-Average Exercise Price	Options	Weighted-Average Exercise Price
Outstanding at beginning of year	19,483,000	\$ 0.04	18,783,000	\$ 0.04
Issued			700,000	0.05
Forfeited				
Outstanding at end of year	19,483,000	0.04	19,483,000	0.04
Exercisable at end of year	19,483,000	\$ 0.04	19,483,000	\$ 0.04
Weighted average fair value of options granted during the year		\$		\$ 0.14

The following table summarizes information about fixed options outstanding at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.01 to 0.02	16,000,000	7.6	\$ 0.02	16,000,000	\$ 0.02
\$0.05	1,500,000	6.1	\$ 0.05	1,500,000	\$ 0.05



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\$0.15 to 0.50	1,983,000	6.1	\$ 0.02	1,983,000	\$ 0.02
	19,483,000			19,483,000	

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements (Continued)**

Assumptions used to calculate the impact of stock options granted as if the Company had adopted FAS 123 were as follows:

	2005	2004
Expected dividend yield		
Risk free interest rate		3.8%
Expected volatility		220%
Expected life		7 years
Weighted average fair value per share	\$	\$ 0.10

During 2004, the Company extended the expiration date of options to purchase an aggregate amount of 18,603,000 shares of stock. As a result of such extension, such options expire from between 2011 to 2013. These options are subject to a one-time remeasurement of the options as if they were newly granted. The expense associated with the change in expiration date was \$1,577,000.

**Stock Warrants**

The following summarizes warrant activity for the years ended December 31, 2005 and 2004:

	2005		2004	
	Warrants	Weighted-Average Exercise Price	Warrants	Weighted-Average Exercise Price
Outstanding at beginning of year	14,904,029	\$ 0.28	3,616,005	\$ 0.61
Issued	26,019,832	0.20	12,954,029	0.17
Expired			(1,666,005)	0.16
Exercised				
Outstanding at end of year	40,923,861	\$ 0.23	14,904,029	\$ 0.28

The following table summarizes information about warrants outstanding at December 31, 2005:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
\$0.09	2,356,700	1.5	\$ 0.09
\$0.18 to 0.20	36,617,161	2.1	0.19
\$1.00	1,950,000	1.0	1.00

40,923,861                      2.0                      \$   0.23

**NOTE I   RELATED PARTY TRANSACTIONS**

At December 31, 2005 and 2004 the Company had accounts payable to current and former officers and directors totaling \$1,550,898 and \$1,491,586, respectively, for services performed and costs incurred in behalf of the Company, including \$877,636 and \$902,636, respectively, payable to the Company's President and CEO. Also at December 31, 2005 and 2004, the Company had accounts payable to its controller of \$73,000 and \$87,444, respectively.

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**Table of Contents****MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)****Notes to Consolidated Financial Statements (Continued)**

On July 15, 2005, the Company entered into an agreement to grant a consultant a non-interest bearing loan in the amount of 500,000 (approximately \$592,000 under current exchange rates) in exchange for the transfer of certain patents in relation to Savetherapeutics AG, and the performance of certain research activities. The loan is payable as follows, 100,000 upon closing, 150,000 after signature of consent to the transfer of patents, and 250,000 after performance and acceptance of certain research activities. As of December 31, 2005, the amount of the loan was 250,000 (approximately \$296,000 under current exchange rates). Settlement of the loan shall take place by offsetting against profit claims, which accrue to the consultant from his stake in the Company.

Subsequent to the transfer of the industrial property rights and applications, the Company shall grant to the aforementioned consultant a 6% stake in MDI Oncology, Inc. and assign to him 6% of the shares. The Company deemed these shares to have no value because it is a start-up company, and its success is contingent on several different factors. The Company also entered into an employment contract with the consultant for a period of 24 months. The consultant will receive a fee of 120,000 per annum (approximately \$142,000 using current exchange rates.)

**NOTE J OTHER SIGNIFICANT TRANSACTIONS****SaveCream Asset Purchase**

On March 16, 2005, the Company completed the purchase of the intellectual property assets (the Assets) of Savetherapeutics AG, a German corporation in liquidation in Hamburg, Germany ( SaveT ). The Assets consist primarily of patents, patent applications, pre-clinical study data and clinical trial data concerning SaveCream, SaveT s developmental-stage topical aromatase inhibitor treatment for breast cancer. SaveCream never generated revenues for SaveT. The Company s analysis as to whether the intellectual property purchased constituted a business resulted in the conclusion that no such business had been acquired.

The purchase price of the Assets was 2,350,000 (approximately \$2.8 million under current exchange rates), payable as follows: 500,000 at closing, 500,000 (approximately \$665,700 on the date of transaction, \$592,000 using the December 31, 2005 exchange rates) upon conclusion of certain pending transfers of patent and patent application rights from SaveT s inventors to the Company, and the remaining 1,350,000 (approximately \$1.6 million at current exchange rates) upon successful commercialization of the Assets. The Company s source of funds for the acquisition was a \$3 million investment in the Company s Series A Preferred Stock by an unrelated third party, as described in Note G.

SaveT inventors have yet to assign the patent and application rights to the Company, management has deemed the assignment of the rights to be reasonably likely because the inventors are contractually bound to execute and deliver the assignments; therefore, the Company has recorded the second 500,000 payment as a current liability in these financial statements. At present it is undeterminable whether the intellectual property will ever be commercialized; therefore, the final 1,350,000 under this acquisition has not been accrued as a liability as of December 31, 2005. The Company determined the intellectual property purchased should be expensed as research and development costs

**Formation of MDI Oncology, Inc.**

On March 22, 2005, the Company formed MDI Oncology, Inc., a Delaware Corporation, as a wholly-owned subsidiary for the purpose of acquiring and operating the assets and associated business ventures associated with the SaveCream purchase.

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE K - SUBSEQUENT EVENTS**

**Exercise of Series A Convertible Preferred Stock**

During the first quarter of 2006, Monarch Pointe Fund, Ltd. converted 200 shares of Series A Convertible Preferred Stock into 242,424 shares of common stock.

**Re-Grant of Stock Option**

During the first quarter of 2006, the Company re-granted a stock option to a former insider that had expired. The option is for 500,000 shares exercisable at \$0.25 per share through December 31, 2012. Because the prior option had expired prior to the re-grant, the Company has treated this as a new option grant. The Company will record the fair value of the option grant as part of operations during the first quarter of 2006.

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**ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 8A. CONTROLS AND PROCEDURES.**

*Evaluation of Disclosure Controls and Procedures.* Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act ), as of December 31, 2005. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2005.

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

**PART III**

**ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT.**

The information required by this Item is incorporated by reference to the section entitled Election of Directors in our definitive proxy statement to be filed with the Commission.

**ITEM 10. EXECUTIVE COMPENSATION.**

The information required by this Item is incorporated by reference to the section entitled Executive Compensation in our definitive proxy statement to be filed with the Commission.

**ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required by this Item is incorporated by reference to the section entitled Security Ownership of Certain Beneficial Owners and Management in our definitive proxy statement to be filed with the Commission.

**ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.**

The information required by this Item is incorporated by reference to the section entitled Certain Relationships and Related Transactions in our definitive proxy statement to be filed with the Commission.

**ITEM 13. EXHIBITS.**

The following documents are furnished as exhibits to this Form 10-KSB. Exhibits marked with an asterisk are filed herewith. The remainder of the exhibits previously have been filed with the Commission and are incorporated herein by reference.

Number	Exhibit
2.1	Sale and Purchase Agreement between Attorney Hinnerk-Joachim Müller as liquidator of Savetherapeutics AG i.L. and Medical Discoveries, Inc. regarding the purchase of the essential assets of Savetherapeutics AG i.L. (filed as Exhibit 2.1 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004, and incorporated herein by reference).
3.1	Amended and Restated Articles of Incorporation of the Company (filed as Exhibit 3.1 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1994, and incorporated herein by reference).

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<b>Number</b>	<b>Exhibit</b>
3.2	Amended Bylaws of the Company (filed as Exhibit 3.2 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1994, and incorporated herein by reference).
4.1	Registration Rights Agreement dated October 18, 2004 among Monarch Pointe Fund, Ltd., Mercator Advisory Group, LLC and Medical Discoveries, Inc. (filed as Exhibit 4.1 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004, and incorporated herein by reference).
4.2	Registration Rights Agreement dated December 3, 2004 among Mercator Momentum Fund, LP, Mercator Momentum Fund III, LP, Mercator Advisory Group, LLC and Medical Discoveries, Inc. (filed as Exhibit 4.2 to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004, and incorporated herein by reference).
4.3	Certificate of Designations of Preferences and Rights of Series A Convertible Preferred Stock of Medical Discoveries, Inc. (filed as Exhibit 4.1 to Registration Statement No. 333-121635 filed on Form SB-2 on December 23, 2004, and incorporated herein by reference).
4.4	Amendment to Certificate of Designations of Preferences and Rights of Series A Convertible Preferred Stock of Medical Discoveries, Inc. (filed as Exhibit 4.2 to Registration Statement No. 333-121635 filed on Form SB-2 on December 23, 2004, and incorporated herein by reference).
10.1	2002 Stock Incentive Plan adopted by the Board of Directors as of July 11, 2002 (filed as Exhibit 10.5 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2002, and incorporated herein by reference).
10.2	Subscription Agreement dated October 18, 2004 among Monarch Pointe Fund, Ltd., Mercator Advisory Group, LLC, and Medical Discoveries, Inc. (filed as Exhibit 10.2 to Amendment No. 2 to Registration Statement No. 333-121635 filed on Form SB-2 on June 2, 2005, and incorporated herein by reference).
10.3	Subscription Agreement dated December 3, 2004 among Mercator Momentum Fund, LP, Mercator Momentum Fund III, LP, Mercator Advisory Group, LLC, and Medical Discoveries, Inc. (filed as Exhibit 10.3 to Amendment No. 2 to Registration Statement No. 333-121635 filed on Form SB-2 on June 2, 2005, and incorporated herein by reference).
10.4	Employment Agreement dated as of March 1, 2005 between Medical Discoveries, Inc. and Judy M. Robinett (filed as Exhibit 10.4 to Amendment No. 3 to Registration Statement No. 333-121635 filed on Form SB-2 on October 13, 2005, and incorporated herein by reference).
21	Subsidiaries.*

- 31.1 Rule 13a-14(a) Certification, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Rule 13a-14(a) Certification, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

\* Filed herewith.

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

The information required by this Item is incorporated by reference to the section entitled Principal Accountant Fees and Services in our definitive proxy statement to be filed with the Commission.



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**SIGNATURES**

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDICAL DISCOVERIES, INC.

/s/ Judy M. Robinett

Judy M. Robinett  
President and Chief Executive Officer

Date: March 31, 2006

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Judy M. Robinett _____	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2006
Judy M. Robinett		
/s/ Deirdra J. Burgess _____	Controller (Principal Financial Officer)	March 31, 2006
Deirdra J. Burgess		
/s/ David R. Walker _____	Chairman of the Board of Directors	March 31, 2006
David R. Walker		
/s/ Larry Anderson _____	Director	March 31, 2006
Larry Anderson		

Fuzeon is a registered trademark of Roche Laboratories, Inc. and Timeris Inc.  
 Tobramycin is a registered trademark of Chiron Corporation or its subsidiaries.  
 Pulmozyme is a registered trademark of Genetech, Inc.  
 Advair is a registered trademark of GlaxoSmithKline.  
 Singulair is a registered trademark of Merck & Co., Inc.  
 Herceptin is a registered trademark of Genetech, Inc.  
 Femara is a registered trademark of Novartis Pharma AG.  
 Arimidex is a registered trademark of AstraZeneca Pharmaceuticals LP.  
 Aromasin is a registered trademark of Pfizer, Inc.

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**INDEX TO EXHIBITS**

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10.3	Subscription Agreement dated December 3, 2004 among Mercator Momentum Fund, LP, Mercator Momentum Fund III, LP, Mercator Advisory Group, LLC, and Medical

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Discoveries, Inc. (filed as Exhibit 10.3 to Amendment No. 2 to Registration Statement No. 333-121635 filed on Form SB-2 on June 2, 2005, and incorporated herein by reference).

- 10.4 Employment Agreement dated as of March 1, 2005 between Medical Discoveries, Inc. and Judy M. Robinett (filed as Exhibit 10.4 to Amendment No. 3 to Registration Statement No. 333-121635 filed on Form SB-2 on October 13, 2005, and incorporated herein by reference).
- 21 Subsidiaries.\*
- 31.1 Rule 13a-14(a) Certification, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Rule 13a-14(a) Certification, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

\* Filed herewith.