

MEDICAL DISCOVERIES INC

Form 10KSB

March 31, 2005

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

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

**For the fiscal period ended December 31, 2004**

**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: (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.   

**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 the last business day of the issuer's most recently completed second fiscal quarter, June 30, 2004, was \$25,523,334.

As of March 16, 2005, the issuer had 105,653,337 shares of Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the issuer's 2005 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.**

**OVERVIEW**

Medical Discoveries, Inc. is a Utah corporation incorporated on November 20, 1991. Our address is 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 safe and effective treatment for bacterial infections, viral infections and fungal infections. 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. We have filed an Investigatory 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 has responded to our IND and we are hopeful that we can satisfactorily answer the FDA's questions and satisfy the FDA's follow-up requests for further animal testing, resulting in the FDA approving the application. If the FDA approves that IND, we will begin human trials at St. Luke's Regional Medical Center in Boise, Idaho using a protocol designed by Dr. Henry Thompson. 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 pre-clinical development.

We recently purchased SaveCream from a German biotechnology company. In a European Union study of SaveCream used by over 100 women diagnosed with Stage 4 breast cancer, a significant number of those women experienced a significant tumor reduction. This study, while preliminary, indicates that SaveCream may be substantially more effective and faster acting than similar drugs already on the market. 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, 2004, we had incurred a cumulative net loss since inception of \$19,353,933.

**RECENT DEVELOPMENTS**

*Savetherapeutics Asset Acquisition.* On March 16, 2005 we announced the completed acquisition of the intellectual property assets of Savetherapeutics AG, a German biotechnology company headquartered in Hamburg. The purchase price was 2,350,000 (approximately \$3.1 million). Savetherapeutics (SaveT) has been developing SaveCream, a topical steroidal form of aromatase inhibitor (AI) for breast cancer.

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 Stage 4 breast cancer received special permission to be treated with SaveCream. A significant number of those women experienced significant tumor reduction. This study indicates substantially improved efficacy in reduction of breast tumors, in shorter time frames than the three approved AIs currently on the market. We are in the process of developing a global commercialization strategy for SaveCream.

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 acquisition.

We expect to perform additional CMC (chemistry manufacturing and control) work and expand the clinical trials over 2005, and believe this will open the door to commercialization opportunities for SaveCream

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by late 2006, which may be quicker than we can commercialize MDI-P. This acquisition also allows us to diversify our product base.

*Cystic Fibrosis IND.* We are continuing to prosecute our IND for Cystic Fibrosis with the FDA. We have agreed with the FDA on a large animal model protocol to establish pharmacological safety with relation to cardio and central nervous system toxicity for this IND. We expect to begin that phase of testing in the very near future and to start Phase I clinical trials on Cystic Fibrosis in Q4 of 2005.

**BUSINESS STRATEGY**

Our highest priorities are to:

gain FDA approval of our IND for Cystic Fibrosis and commence human clinical trials;

file an IND for HIV; and

develop a commercialization strategy for SaveCream.

Our secondary priorities are the completion of a longer-range strategic business plan in which we utilize the intellectual property and analysis that has been developed over the last decade and determine an appropriate direction for future development of the business over the next five 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

Projected long-term financing requirements

**MDI-P: NOVEL ANTI-INFECTIVE TECHNOLOGY**

MDI-P is an anti-effective drug that we believe will be a safe and effective 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 several months 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



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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 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 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

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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.

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

*Overview.* Our pre-clinical 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 pre-clinical analysis. If these results can be replicated in human beings, under appropriate clinical protocols, this therapy 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.

*Existing Therapies for HIV.* There are approximately 83 HIV therapies currently on the market and approved by the FDA with a market value of approximately \$9.5 billion per year. The primary current therapies for HIV are anti-retroviral products falling into four categories: nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, and anti-fusion of HIV-1 with CD4 cells (Fuzeon®, 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®, requires administration with other standard combination antiretroviral therapies, and still exhibits a number of toxicities, including: inflammation/cysts at site of injection (9%/26%), erythema (22%), pruritus (4%), ecchymosis (8%), and on a less frequent basis, rashes, fever, nausea, vomiting, chills, hypotension, increased hepatic enzymes, neutropenia, thrombocytomeia, and renal failure.

*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. MDI-P is very rapid in effect and destroys viruses without destroying host cells.

MDI-P's broad-spectrum antiviral effects appear to make it effective 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.

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*MDI s HIV Protocol.* The HIV virus is known to have a cell replication cycle of approximately 10 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. Since the best-of-breed therapeutics in HIV (e.g., Fuzeon®) establish an ability to bring the HIV RNA cell count below 400 copies per ml for as much as 65% of HIV patients, 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 this level with statistical significance.

In order to expedite MDI 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 pre-clinical 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.

### **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 infection. 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.

*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® (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®. 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®, Singulair®, 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, even with the use of antibiotics, there may be as many as 45% of CF patients with drug-resistant infection that can prove life-threatening. Further, should the more common bacterial infection be complicated through a simultaneous viral infection, the odds of mortality can increase for the infected CF patient. Since CF s build-up of mucus is genetically dependent, and the mucolytic agents and



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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. This risk tends to be compounded with the increasing age of the CF patient. 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 MDI's pre-clinical studies, MDI-P offers CF patients the following:

to serve as a highly effective anti-microbial agent for CF patients with bacterial pulmonary infection, as well as viral pulmonary infection, with little or no 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 benefit of using MDI-P as an adjunct therapy to TOBI 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 through a rebound of the degree of infection with *Pseudomonas aeruginosa* or other bacterial pulmonary infection; and

to lessen the likelihood of adverse events due to endotoxin reaction, due to the unparalleled efficacy of MDI-P in killing pathogens, including *Pseudomonas*.

MDI-P is believed to have the potential, with CF patient compliance, of significantly improving both pulmonary function and longevity of CF patients, due to its unique and potent dual mechanism of action.

*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 3 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 on those indications and may in the future pursue opportunities to commercialize MDI-P as a therapeutic for those indications.

## **SAVECREAM**

*Overview.* MDI acquired substantially all of the assets of a Hamburg, Germany-based biotech company, Savetherapeutics, AG, in March of 2005. The principal assets of Savetherapeutics are its intellectual property, pre-clinical data, and clinical trial data on SaveCream, a novel, topical steroidal form of aromatase inhibitor (AI) indicated for breast cancer. The principal value of SaveCream is its ability to deliver



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substantially more therapeutic drug on the site of the breast tumor, as contrasted with systemic ingestion of competing AIs, thereby promoting 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 Stage 4 breast cancer positive for the estrogen receptor received special permission to be treated with SaveCream. A significant number of those women experienced significant tumor reduction. This study indicates substantially improved efficacy in reduction of breast tumors, in shorter time frames than the three approved AIs currently on the market.

*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 43,000 per year. For the one third of such breast cancers that are positive for human epidermal growth factor receptor-2, the standard treatment therapies are Herceptin®, 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 ), recently achieving an estimated \$2 billion per year in revenues in 2004. The current three approved AIs on the U.S. market are: Novartis' Femara®, AstraZeneca's Arimidex®, and Pfizer's Aromatase®. All are oral in dosage. Because of significantly improved efficacy and reduced toxicity as compared with the former leading first-line ER-positive therapy, Astra Zeneca'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 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. Approximately 70% of women 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. Limiting the amount of estrogen produced means there is less estrogen available to reach cancer cells and make them grow.

In post-menopausal women, estrogen is no longer produced by the ovaries, but is converted from androgen, another hormone. Aromatase inhibitors keep androgen from being converted to estrogen. That means less estrogen in the bloodstream, and less estrogen reaching estrogen receptors to trigger a breast tumor.

In about 70-80% of breast cancer cases, the cancer cells have areas on their surface called receptors to which hormones such as estrogen and progesterone attach, providing fuel for the cells' growth into a tumor. 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.

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.

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 effects 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.

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SaveCream evidenced an average 50%-80% reduction in breast tumor size within two weeks of treatment under its European Union trials, versus 24% over 3-months for the other AI competitor products.

SaveCream appears to offer much less severe, and lower incidence of toxicities (likely due to the limited half-life of the active product). This favorable therapeutic index (efficacy/toxicity ratio) should make the therapeutic amenable to registration with a paper NDA, thereby making the product easier to license. Other AIs are still noted for musculoskeletal complaints and increased risk of osteoporosis and bone fracture, together with mastalgia. Initial clinical experience with SaveCream indicates that these common side-effects of other AIs are largely avoided with this novel AI therapeutic.

SaveCream, because of its higher efficacy and unique mechanism of action, may also prove amenable to:

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

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 supporting chemistry, manufacturing and control (CMC) data supporting SaveCream may need to be expanded and amplified, particularly in reference to the topical vehicle used as the carrier for its therapeutic agent. While undertaking a program to expand SaveCream's CMC data, the Company will also undertake to expand the clinical trial program, including revised protocols. The CMC expansion is expected to require at least 3-6 months, while newly expanded clinical trials may require an additional year of testing.

**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. 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. 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. 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. The duration of this patent is until August 26, 2014, subject to patent term extension for clinical trial time.



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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. 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

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. 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 ascorbic acid (Vitamin C), with or without concurrent colchicine. 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. 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. 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.

***SaveCream and Related Technologies.***

The assets we purchased from Savethearpeutics A.G. included the following patents and patent applications:

Medicament for Preventing and/or Treating a mammary Carcinoma Containing a Steroidal Aromatase Inhibitor

Aromatase Marking

Topical Treatment for Mastalgia

The purchased assets also include U.S. patents on cosmetic products and various international patent applications.

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

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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.

**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.

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**

*Overview.* 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 pre-clinical 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.

*FDA.* 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.

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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.

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



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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 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.

### **RESEARCH AND DEVELOPMENT**

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, 2004, we spent \$550,093 on research and development of MDI-P. During fiscal 2003, we spent \$100,423 on research and development. From inception through December 31, 2004, we have recorded \$3,548,738 in research and development expenses. We are actively pursuing our research efforts of MDI-P and are in the process of establishing a commercialization plan for SaveCream. See Business Strategy above.

### **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 pre-clinical development and all capital resources have been devoted in that direction. At such time as capital resources permit, we will hire a larger 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*

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

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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. In one such action, Dr. Dezube assisted Fuji Immuno Pharmaceuticals, Inc. in receiving the quickest FDA approval for Phase 1 clinical trials ever granted an anti-HIV drug. 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 Capital Group, LLC*

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.

**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 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 and operate the assets and business associated with the Savetherapeutics transaction.

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We file annual, quarterly, and current reports, proxy statements, and other information with the Securities and Exchange Commission. You may read and copy any reports, statements, or other information that we file at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the Public Reference Room. The Commission also maintains an Internet site (<http://www.sec.gov>) that makes available to the public reports, proxy statements, and other information regarding issuers, such as us, that file electronically with the Commission. Reports, proxy statements and other information concerning us can be inspected and copied at the Public Reference Room of the National Association of Securities Dealers, 1735 K Street, N.W., Washington, D.C. 20006. We are not required to deliver annual reports to security holders, but we plan to deliver an annual report to all shareholders this year prior to our annual meeting of shareholders.

**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 AND RELATED STOCKHOLDER MATTERS.****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, 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
<b>Fiscal Year Ended December 31, 2003</b>	<b>High Bid</b>	<b>Low Bid</b>
First Quarter	\$ 0.085	\$ 0.035
Second Quarter	0.090	0.055
Third Quarter	0.075	0.045
Fourth Quarter	0.395	0.060

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

The approximate number of shareholders of record of our common stock as of March 16, 2005 was 1,458. 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, 2004.

Plan Category	Number of Securities	Weighted-Average	Number of Securities Remaining Available for Future Issuance
	to Be Issued upon Exercise of Outstanding Options, Warrants and Rights		under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders			
1993 Incentive Plan	3,483,000	\$ 0.14	-0-
2002 Stock Incentive Plan	16,000,000	\$ 0.02	4,700,000
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>19,483,000</b>	<b>\$ 0.04</b>	<b>4,700,000</b>

**UNREGISTERED SALES OF SECURITIES**

We sold the following unregistered securities in the past three years. None of the sales involved an underwriter. We believe these sales were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 because the sales did not involve a public offering.

On or about March 14, 2005, 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 is 75% 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. 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 common stock of the Company 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 warrants that entitle the holder to purchase up to 1,220,132 shares of common stock of the Company 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 sold 12,000 shares of Preferred Stock and warrants to purchase 4,575,496 shares of common stock for a total offering price of \$1.2 million. Each share of

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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 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 4,575,496 shares of common stock of the Company 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 common stock of the Company on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share.

During 2004 we sold 5,551,011 shares of restricted common stock at \$0.18 per share to various private investors pursuant to a private placement, further terms of which are disclosed in Form D filed with the Commission.

During 2004 we sold 714,286 shares of restricted common stock at \$0.14 per share to various private investors pursuant to a private placement, further terms of which are disclosed in Form D filed with the Commission.

During 2004 we sold 2,272,727 shares of restricted common stock at \$0.11 per share to various private investors pursuant to a private placement, further terms of which are disclosed in Form D filed with the Commission.

During 2004 we sold 11,600,000 shares of restricted common stock at \$0.04 per share to various private investors pursuant to a private placement, further terms of which are disclosed in Form D filed with the Commission.

During 2004 we issued 9,875,951 shares of common stock upon conversion of certain promissory notes with an aggregate outstanding principal and interest amount of \$650,468.

During 2004 we issued 1,189,465 shares of restricted common stock in lieu of cash finders' fees in connection with equity financings.

During the fourth quarter of 2003, we sold 26,862,500 shares of restricted common stock at \$0.04 per share to various private investors pursuant to a private placement, further terms of which are disclosed in Form D filed with the Commission.

\$195,000 secured promissory note dated February 20, 2003, bearing interest at the rate of 12%.

\$25,000 secured promissory note dated October 25, 2002, bearing interest at the rate of 15%, 12% of which is payable in cash and 3% of which is payable in common stock at a rate equal to the 15-day average market price determined at the date of maturity.

\$125,000 secured promissory note dated October 24, 2002, bearing interest at the rate of 15%, 12% of which is payable in cash and 3% of which is payable in common stock at a rate equal to the 15-day average market price determined at the date of maturity. This note has subsequently been retired.

\$50,000 secured promissory note dated October 24, 2002, bearing interest at the rate of 15%, 12% of which is payable in cash and 3% of which is payable in common stock at a rate equal to the 15-day average market price determined at the date of maturity.

\$50,000 unsecured convertible promissory note dated February 8, 2002, bearing interest at the rate of 18%, convertible to common stock of the Company at the rate of \$0.06 per share. This note was subsequently refinanced with a 15% interest rate.

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\$50,000 unsecured convertible promissory note dated April 8, 2002, bearing interest at the rate of 18%, convertible to common stock of the Company at the rate of \$0.06 per share. This note was subsequently refinanced with a 15% interest rate.

\$50,000 unsecured convertible promissory note dated July 12, 2002, bearing interest at the rate of 18%, convertible to common stock of the Company at the rate of \$0.06 per share. This note was subsequently refinanced with a 15% interest rate.

\$50,000 unsecured convertible promissory note dated April 21, 2002, bearing interest at the rate of 18%, convertible to common stock of the Company at the rate of \$0.125 per share. This note was subsequently refinanced with a conversion rate of \$0.06 per share.

\$55,000 unsecured convertible promissory note dated February 22, 2002, bearing interest at the rate of 18%, convertible to common stock of the Company at the rate of \$0.125 per share. This note was subsequently refinanced with a conversion rate of \$0.06 per share.

**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 27 through 43.

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 booked no revenues for the year ended December 31, 2004 or for the prior year ended December 31, 2003. As we continue to pursue pre-clinical and clinical testing of our pharmaceuticals, we do not anticipate booking significant revenues in the near future.

*Operating Expenses and Operating Loss.* We booked \$550,093 in research and development expenses during the year ended December 31, 2004, as compared with \$100,423 in such expenses for the same period in 2003. Our increased research and development activity reflects our success in raising capital to fund pre-clinical studies of MDI-P. We have continued to be successful in raising capital in 2005 and will likely incur substantially higher research and development expenses during 2005. Our general and administrative expenses were \$3,057,429 in 2004, as compared with \$1,206,484 during the year ended December 31, 2003. Of that amount, we recorded non-cash charges of \$1,741,501 for stock and stock options issued for services, expenses and interest. As a result of the foregoing, we sustained an operating loss of \$3,607,522 for the year ended December 31, 2004, as compared with a loss of \$1,306,907 for the same period of 2003.

*Other Income/Expense and Net Loss.* We recorded other income during 2004 in the amount of \$1,408. During 2003, we recorded \$611,558 in other income, \$610,828 of which was on account of writing off certain liabilities from our balance sheet. We incurred interest expenses of \$131,526 in 2004, as compared with \$256,694 in such expenses in 2003. Our interest expenses have decreased as we have paid down or converted to equity relatively short-term, high-interest debt incurred in past periods in order to finance operations, research and development. We also recorded \$6,165 in interest income in 2004. In sum, our net loss available to common stockholders for 2004 was \$4,423,674, or a loss of approximately \$0.05 per fully diluted share. In 2003, we sustained a net loss of \$952,043, or a loss of approximately \$0.02 per fully diluted share.

*Income Taxes.* We have available net operating losses of approximately \$12,830,000 which can be utilized to offset future earnings. See Note C to the Financial Statements for a further explanation of this analysis.

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*Future Commitment and Expectations.* We expect to operate at a loss for several more years while we continue to study, gain regulatory approval of and commercialize our technologies. We will spend more in 2005 in research and development expenses as we continue to implement our commercialization strategy. Similarly, we expect our general and administrative expenses to increase in 2005 as we assimilate the Savetherapeutics assets into our organization and commercialize SaveCream. As a result, we may sustain a greater net loss in 2005, than we have in recent years.

*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 interim and annual periods beginning after June 15, 2005. The Company intends to implement SFAS No. 123 in the third quarter of 2005 and it will not currently have any effect on the Company's financial statements.

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.

**LIQUIDITY AND CAPITAL RESOURCES**

As of December 31, 2004, we had \$1,455,397 in cash and had a working capital deficit of \$1,887,136. Since our inception, we have financed our operations primarily through private sales of equity and the issuance of convertible and non-convertible notes. We will require significant additional 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 issuances of private equity.

We are seeking to raise substantial additional funds in private stock offerings in order to meet our mid-term funding requirements. While we are optimistic that we can raise such funds, we have not always been successful in doing so in recent years. 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.

Pursuant to our commercialization strategy, we estimate we will need to expend an additional \$550,000 in research and development to conduct additional pre-clinical testing and gain acceptance of our IND as a therapy for Cystic Fibrosis. (See Description of Business Commercialization Strategy above.) In addition, we estimate we will need to expend an additional \$300,000 to \$350,000 in debt service and general and administrative costs between now and when we hope to receive acceptance of that IND in Q4 2005. Assuming that IND is accepted, we estimate we will need to expend an additional \$830,000 in conducting Phase I clinical trials (including general and administrative expenses through our projected completion date of such trials in Q1 of 2006). Additionally, upon acceptance of the Cystic Fibrosis IND, we estimate we will need to expend an additional \$300,000 in completing and filing our IND for HIV. Therefore, in total, in order to advance MDI-P through our immediate developmental goals, we estimate to incur expenses of \$1,980,000 to \$2,030,000. As of the date of this report, we nearly have adequate cash for these purposes. However, we have not yet completed our commercialization strategy for SaveCream or our projections of the associated costs. Clearly, therefore, the near-term costs of advancing MDI-P and SaveCream to the next developmental milestones and funding the remaining 1,850,000 of our SaveCream purchase price obligation, when taken together, exceed our current cash.

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Furthermore, we estimate the cost to complete Phase II clinical trials in any one indication to be several million dollars and the cost to complete Phase III testing and obtain approval of an NDA to be in the tens of millions of dollars. While our ability to obtain financing may improve as we continue to advance our technologies, we cannot give assurances that we will have the 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.

**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 Savetherapeutic 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. While our pre-clinical studies of MDI-P and SaveCream to date have been quite favorable, there is no certainty that our drugs will be successful. The results of our pre-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 sales, during commercial use. Even if our drugs do prove to be safe and effective and receive regulatory approvals, we may be unable to successfully.

*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

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approximately \$20,753,510 as of December 31, 2004. Our losses from operations in 2004 were \$3,731,475 and our cumulative losses from operations since inception through December 31, 2004 were \$18,661,734. We will likely continue to experience a net operating 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 Save-Cream 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.

*We May Not Be Able To Raise Sufficient Capital To Meet Present And Future Obligations.* As of December 31, 2004, our current liabilities exceeded our current assets by \$1,887,136 and we had cash of only \$1,455,397. We need substantial additional capital to fund regulatory approvals and to fully commercialize our technologies. We do not anticipate that revenues will satisfy these capital requirements. Furthermore, we may not be able to obtain the amount of additional capital needed or may be forced to pay an extremely high price for capital.

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;

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

the effect of the exercise of outstanding options and warrants exercisable into approximately 58 million shares of common stock.

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.

*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



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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 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.

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.

*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. 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



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patents outside of 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 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 Savethearpeutics A.G. (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.

*We Face Significant Product Liability.* We face an inherent business risk of exposure to product liability and other claims in the event our products results in or is 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.

*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. 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, 2004	\$ 0.260	\$ 0.180
Quarter ended September 30, 2004	0.301	0.150
Quarter ended June 30, 2004	0.300	0.115
Quarter ended March 31, 2004	0.170	0.100

*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;

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

*Obtaining Additional Capital Through 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

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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.

*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 sheet of Medical Discoveries, Inc. and subsidiaries (a development stage company) as of December 31, 2004, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year then ended, and for the period from November 20, 1991 (date of inception of the development stage) through December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. We did not audit the consolidated 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 report, dated February 18, 2004 (except Note K as to which the date is November 15, 2004), 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 audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit and the report of the other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audit 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, 2004, and the results of their operations and their cash flows for the year then ended and for the period from November 20, 1991 through December 31, 2004, 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' deficiency and the operating losses since inception raise substantial doubt about the Company's ability to continue as a going 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 28, 2005

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**INDEPENDENT AUDITORS REPORT**

To the Board of Directors and Stockholders  
Medical Discoveries, Inc. and Subsidiaries  
Boise, Idaho

We have audited the accompanying consolidated statements of operations, changes in stockholders' deficit, and cash flows of Medical Discoveries, Inc. and Subsidiaries (a development stage company) for the year ended December 31, 2003, and for the period from inception (November 20, 1991) to December 31, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to report on these consolidated financial statements based on our audit. The Company's financial statements for the period from inception (November 20, 1991) through December 31, 1999 were audited by other auditors whose report, dated March 20, 2000, expressed an unqualified opinion on those statements. The financial statements for the period from inception (November 20, 1991) through December 31, 1999 reflect total revenues and net loss of \$150,015 and \$9,951,404, respectively, of the related totals. The other auditors' report has been furnished to us, and our report, insofar as it relates to the amounts included for such prior period, is based solely on the report of such other auditors.

We conducted our audit in accordance with U.S. generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. 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 audit provides a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, such consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of Medical Discoveries, Inc. and Subsidiaries for the year ended December 31, 2003, and for the period from inception (November 20, 1991) to December 31, 2003, in conformity with U.S. generally accepted accounting principles.

The accompanying 2003 consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company is a development stage enterprise engaged in developing biopharmaceutical research. As discussed in Note B to the financial statements, the stockholders' deficiency and the operating losses since inception raise substantial doubt about its ability to continue as a going 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/ EIDE BAILLY, LLP (formerly  
BALUKOFF, LINDSTROM & CO., P.A.  
joined Eide Bailly November 1, 2004)

Boise, Idaho

February 18, 2004, except Note K as to which the date is November 15, 2004



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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED BALANCE SHEET**  
**December 31, 2004**

		<b>December 31, 2004</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash	\$	1,455,397
Deposit		51,100
<b>Total current assets</b>		<b>1,506,497</b>
<b>Total assets</b>	\$	<b>1,506,497</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
<b>Current liabilities</b>		
Accounts payable	\$	2,448,454
Accrued interest		415,262
Notes payable		336,717
Convertible notes payable		193,200
<b>Total current liabilities</b>		<b>3,393,633</b>
<b>Stockholders deficit</b>		
Preferred stock, no par value, 50,000 shares authorized Series A, convertible; 12,000 shares issued and outstanding (aggregate liquidation preference of \$1,200,000)		523,334
Common stock, no par value; 250,000 shares authorized; 105,653,335 shares issued and outstanding		14,918,657
Additional paid-in capital		3,424,383
Deficit accumulated prior to the development stage		(1,399,577)
Deficit accumulated during the development stage		(19,353,933)
<b>Total stockholders deficit</b>		<b>(1,887,136)</b>
<b>Total liabilities and stockholders deficit</b>	\$	<b>1,506,497</b>

See Notes to Consolidated Financial Statements

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

**Years Ended December 31, 2004 and 2003, and**  
**Cumulative Amounts Since November 20, 1991 (Date of Inception of the Development Stage)**

	For the Years Ended December 31,		Cumulative Amounts Since November 20, 1991 (Date of Inception of Development Stage)
	2004	2003	
Revenues	\$	\$	\$ 157,044
Cost of revenues			14,564
Gross profit			142,480
Operating expenses:			
Research and development expenses	550,093	100,423	3,548,738
Inventory write-down			96,859
Impairment loss			9,709
License			1,001,500
General and administrative expenses	3,057,429	1,206,484	15,176,970
Operating loss	(3,607,522)	(1,306,907)	(19,691,296)
Other income (expense)			
Interest income	6,165		29,571
Other income	1,408	611,558	881,892
Interest expense	(131,526)	(256,694)	(1,117,437)
Forgiveness of debt			1,235,536
	(123,953)	354,864	1,029,562
Net loss	(3,731,475)	(952,043)	(18,661,734)
Preferred stock dividend from beneficial conversion feature	(692,199)		(692,199)
Net loss applicable to common stockholders	\$ (4,423,674)	\$ (952,043)	\$ (19,353,933)
Basic and diluted loss per share	\$ (0.05)	\$ (0.02)	
Weighted-average shares outstanding	93,947,646	59,302,562	

See Notes to Consolidated Financial Statements



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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, 2004**

	Preferred Stock	Common stock	Additional Paid In Capital	Accumulated Deficit		Escrow/ Subscription Receivables	Total
				Prior to Development Stage	During the Development Stage		
	Shares	Shares	Amount	Amount	Amount	Amount	
Balance at November 20, 1991 (Date of Inception of the 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
1992 \$1.50 per share		40,000	60,000				60,000
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
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
		800,000	400,000				400,000

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1993	\$0.50 per share			
1994	\$1.00 per share	239,675	239,675	239,675
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
Conversion of Debt				
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
Other Issuances				
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 stock from exercise of warrants, \$0.001 per share	200,000	200	200
2000	Reversal of shares issued	(81,538)		

See Notes to Consolidated Financial Statements

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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, 2004**

	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					
Escrow and Subscription Receivables									
1996 Common Stock Canceled per share		\$ .34	(1,400,000)	\$ (472,360)	\$	\$	\$ 472,360	\$	
2000 Issuance for escrow receivable per share		\$ 0.09	5,500,000	500,000			(500,000)		
2000 Write-off of subscription receivable								112,500	112,500
2000 Research and development costs								115,400	115,400
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 \$.14 per share Value of Options exercised for services			170,000	24,000					24,000
1998				2,336,303					2,336,303
1999				196,587					196,587
2001					159,405				159,405

002					124,958			124,9
er								
994	Cash							
Contributed			102,964					102,9
995	Issuance							
of common								
stock option to								
satisfy debt								
structuring			20,000					20,0
loss from								
reception through								
December 31,								
2002						(13,978,216)		(13,978,2
<b>Balance at</b>								
<b>December 31,</b>								
<b>2002</b>		55,598,856	11,713,262	284,363	(1,399,577)	(13,978,216)	(227,300)	(3,607,4
Value of options								
exercised for services				295,000				295,0
Balance of								
common stock								
Cash \$0.04 per								
share		20,162,500	790,300					790,3
services and								
interest								
\$0.06 per share		694,739	43,395					43,3
loss for the								
year ended								
December 31,								
2003						(952,043)		(952,0
<b>Balance at</b>								
<b>December 31,</b>								
<b>2003</b>		76,456,095	12,546,957	579,363	(1,399,577)	(14,930,259)	(227,300)	(3,430,8
Balance and								
extension of								
options for								
services				1,675,000				1,675,0
Termination of								
growth agreement		(2,356,200)	(227,300)				227,300	
Balance of								
preferred stock								
warrants for								
cash (net								
\$10,000,								
common stock								
warrants								
related to								
placement agent)	12,000	523,334	350,000	68,845	477,821			1,070,0
					692,199	(692,199)		

convertible preferred stock								
official version dividend								
balance of common stock								
cash \$0.09 per share		20,138,024	1,813,186					1,813,186
debt and interest		9,875,951	650,468					650,468
services		1,189,465	66,501					66,501
loss for the period ended December 31, 2004						(3,731,475)		(3,731,475)
<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)	\$ (1,887,100)

See Notes to Consolidated Financial Statements



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

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

Years Ended December 31, 2004 and 2003, and

Cumulative Amounts Since November 20, 1991 (Date of Inception of the Development Stage)

	For the Year Ended December 31,		Cumulative Amounts Since November 20, 1991 (Date of Inception of Development Stage)
	2004	2003	
<b>Cash flows from operating activities</b>			
Net loss	\$ (3,731,475)	\$ (952,043)	\$ (18,661,734)
Adjustments to reconcile net loss to net cash from operating activities:			
Common stock options issued for services	1,675,000	295,000	4,811,253
Common stock issued for services, expenses, and litigation	66,501	43,395	4,267,717
Reduction of escrow receivable from research and development			272,700
Reduction of legal costs			(130,000)
Notes payable issued for litigation			385,000
Depreciation			100,271
Write-off of subscription receivables			112,500
Impairment loss on assets			9,709
Loss on disposal of equipment			30,364
Gain on debt restructuring			(1,235,536)
Write-off of receivables			193,965
Changes in assets and liabilities			
Prepaid expenses	11,331	24,929	
Deferred charges	12,077	48,305	
Accounts receivable			(7,529)
Inventory			
Accounts payable	381,727	(211,311)	2,292,545
Accrued expenses	53,934	176,086	599,709
Net cash from operating activities	(1,530,905)	(575,639)	(6,959,066)
<b>Cash flows from investing activities</b>			
Increase in deposit	(51,100)		(51,100)
Purchase of equipment			(132,184)
Payments received on note receivable			130,000
Net cash from investing activities	(51,100)		(53,284)
<b>Cash flows from financing activities</b>			
Contributed equity			131,374

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Issuance of common stock, preferred stock and warrants	2,883,186	790,300	7,027,845
Payments on notes payable	(270,000)	(25,000)	(501,287)
Proceeds from notes payable		220,000	1,336,613
Payments on convertible notes payable			(98,500)
Proceeds from convertible notes payable			571,702
<b>Net cash from financing activities</b>	<b>2,613,186</b>	<b>985,300</b>	<b>8,467,747</b>
<b>Net increase in cash</b>	<b>1,031,181</b>	<b>409,661</b>	<b>1,455,397</b>
<b>Cash, beginning of period</b>	<b>424,216</b>	<b>14,555</b>	
<b>Cash, end of period</b>	<b>\$ 1,455,397</b>	<b>\$ 424,216</b>	<b>\$ 1,455,397</b>
<b>Supplemental disclosure of non-cash activities</b>			
Interest paid	\$ 77,592	\$ 80,608	
<b>Noncash investing and financing activities</b>			
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	\$ 162,746		
Preferred stock dividend as part of beneficial conversion feature	\$ 692,199		

See Notes to Consolidated Financial Statements

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO 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 \$114,564 at December 31, 2004.

**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.

**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 \$550,093 and \$100,423 and \$3,548,738 for the year ended December 31, 2004 and 2003 and for the period November 20, 1991 (date of inception of the development stage) through December 31, 2004, respectively.

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO FINANCIAL STATEMENTS (Continued)**

**Fair Value of Financial Instruments**

The Company estimates that the fair value of all financial instruments, at December 31, 2004, 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.

These accounting policies resulted in the Company recognizing \$1,675,000 and \$295,000 in stock-based compensation cost during the years ended December 31, 2004 and 2003. The effect on net loss and

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

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>2004</b>	<b>2003</b>
Net loss applicable to common stockholders, as reported	\$ (4,423,674)	\$ (952,043)
Add: Stock-based employee compensation expense included in reported net loss	1,675,000	295,000
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards	(1,979,237)	(473,200)
Pro forma net loss applicable to common shareholders	\$ (4,727,911)	\$ (1,130,243)
Basic and diluted loss per share, as reported	\$ (0.05)	\$ (0.02)
Basic and diluted loss per share, pro forma	\$ (0.05)	\$ (0.02)

**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 interim and annual periods beginning after June 15, 2005. The Company intends to implement SFAS No. 123 in the third quarter of 2005 and it will not currently have any effect on the Company's financial statements.

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.

**Reclassifications**

Certain 2003 amounts have been reclassified to conform to the 2004 presentation. These reclassifications had no effect on the previously reported net loss.

**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 \$4,423,674 during the year ended December 31, 2004 and has incurred losses applicable to common shareholders since inception of the development stage of \$19,353,933. The Company 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



**Table of Contents****MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)**

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 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, 2004:

	<b>Years Ended December 31,</b>	
	<b>2004</b>	<b>2003</b>
Federal income tax benefit at statutory rate (34%)	\$ 1,268,000	\$ 327,000
State income tax, net of federal benefit	224,000	38,000
Revaluation and expiration of options	(631,000)	(108,000)
Change in valuation allowance	(861,000)	(257,000)
	\$	\$

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

	<b>2004</b>
Net operating loss carryforward	\$ 5,132,000
Research and development credits	80,000
Stock options	646,000
Accrued compensation	396,000
Valuation allowance	(6,254,000)
Net deferred tax asset	\$

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 \$12,830,000 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 D NOTES PAYABLE**

The Company has the following notes payable at December 31, 2004:

Notes payable to shareholders, which are currently due and in default. Interest is at 12%. The notes are unsecured	\$ 336,717
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**Table of Contents****MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)****NOTES TO FINANCIAL STATEMENTS (Continued)****NOTE E CONVERTIBLE NOTES PAYABLE**

The Company has the following convertible notes payable at December 31, 2004:

Convertible notes payable to a trust, which are currently due and in default. Interest is at 12%.

Each \$1,000 note is convertible into 667 shares of the Company's common stock	\$ 193,200
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**NOTE F STOCKHOLDERS EQUITY****Series A Convertible Preferred Stock**

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 per share. 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 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.

The Series A Convertible Preferred Stock has no dividend or voting rights. In the event of liquidation, the holders are entitled to a liquidating distribution of \$100 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. The Company also entered into a Registration Rights Agreement with Monarch Pointe Fund, Ltd. and Mercator Advisory Group, LLC, requiring the Company to 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.

**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

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

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 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.

**Common Stock and Warrants Issued for Cash**

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.

**Conversion of Notes Payable and Convertible Notes Payable to Common Stock**

During the year ended December 31, 2004, the Company converted \$487,503 of principal and \$162,964 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.

**NOTE G STOCK OPTIONS AND WARRANTS****Stock Options**

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 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. During the year ended December 31, 2003, the Company granted 14,800,000 fully vested stock options to an officer and directors with exercise prices ranging from \$0.01 to \$0.05, the Company recognized stock compensation expense of \$295,000 related to this issuance.

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

The following summarizes option activity for the years ended December 31, 2004 and 2003:

	Number of Options	Option Price per Share
Outstanding at January 1, 2003	4,583,000	\$ 0.01 to 0.50
Granted	14,800,000	0.01 to 0.05
Expired	(600,000)	0.25
Outstanding at December 31, 2003	18,783,000	\$ 0.01 to 0.50
Granted	700,000	0.05
Outstanding at December 31, 2004	19,483,000	\$ 0.01 to 0.50
Exercisable at December 31, 2003	18,783,000	\$ 0.01 to 0.50
Exercisable at December 31, 2004	19,483,000	\$ 0.01 to 0.50

The following table summarizes information about fixed stock options outstanding at December 31, 2004:

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	8.7	\$ 0.02	16,000,000	\$ 0.02
\$0.05	1,500,000	7.1	\$ 0.05	1,500,000	\$ 0.05
\$0.15 to 0.50	1,983,000	7.1	\$ 0.23	1,983,000	\$ 0.23
	19,483,000			19,483,000	

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

	2004	2003
Expected dividend yield		
Risk free interest rate	3.8%	5.0%
Expected volatility	220%	511%
Expected life	7 years	10 years

Weighted average fair value per share	\$	0.10	\$	0.04
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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.

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**Stock Warrants**

The following summarizes warrant activity for the years ended December 31, 2004 and 2003:

	Number of Warrants	Warrant Price per Share
Outstanding at January 1, 2003	3,616,005	\$ 0.10 to 1.00
Outstanding at December 31, 2003	3,616,005	0.10 to 1.00
Granted	12,920,751	0.09 to 0.20
Forfeited	(1,666,005)	0.10 to 0.40
Outstanding at December 31, 2004	14,870,751	\$ 0.09 to 1.00

The following table summarizes information about warrants outstanding at December 31, 2004:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
\$0.09	2,356,200	3.0	\$ 0.09
\$0.18 to 0.20	10,564,551	2.8	\$ 0.19
\$1.00	1,950,000	2.0	\$ 1.00
	14,870,751		

**NOTE H RELATED PARTY TRANSACTIONS**

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

**NOTE I COMMITMENT REGARDING CONSULTING AGREEMENT**

The Company entered into a consulting agreement with Craig R. Palmer (d/b/a Palmer Consulting Group) dated April 7, 2003 and amended as of September 16, 2004, pursuant to which Palmer is to render certain services to the Company relating to the development and commercialization of the Company's technology. Under the agreement, Palmer was paid a consulting fee equal to \$20,000 in cash and 500,000 shares of stock. From October 1, 2004, he also accrues a consulting fee of \$8,000 per month, \$3,500 per month of which is paid monthly and the balance of which is paid in the CEO's discretion as the Company's cash flow permits. The agreement also provides Palmer with the opportunity to earn a contingent fee of 5% of the value of any out-licensing, distribution or co-marketing agreements Palmer secures for the Company and an opportunity to earn 1,500,000 shares of stock upon the successful filing of an investigational new drug application in HIV with the U.S. Food and Drug Administration. The Company has not

recorded a liability for the contingent fees due to the uncertainty that such events will occur.

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

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**NOTE J SUBSEQUENT EVENTS**

**Formation of MDI Oncology, Inc.**

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.

**Savetherapeutics A.G. Asset Acquisition**

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 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 \$3.1 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, as described below. 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.

**Issuance of Series A Preferred Stock**

On or about March 14, 2005, the Company issued 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 is 75% 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. 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 common stock of the Company on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share.

**NOTE K CUMULATIVE NET LOSS**

The Statements of Operations was amended to correct a previously reported error in the cumulative net loss amount since inception through December 31, 2003 (not presented herein). While the Company previously reported the correct cumulative net loss on the Statements of Cash Flows through December 31, 2003 (not presented herein), the same figure as reported on the Statements of Operations through December 31, 2003 (not presented herein) was erroneous based on an apparent incorrect calculation in the 1999 annual report, which error had been carried forward. The previously reported cumulative net loss amount through December 31, 2003 (not presented herein) of \$14,141,763 was corrected to \$14,930,259.

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

None.

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**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.

<b>Number</b>	<b>Exhibit</b>
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. (Exhibits referenced therein will be provided upon request.)*
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).
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.*
4.2	Registration Rights Agreement dated December 3, 2004 among Mercator Momentum Fund, LP, Mercator Momentum Fund III, LP, Mercator Advisory Gropu, LLC and Medical Discoveries, Inc.*
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).
21	Subsidiaries.*



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

\* Filed herewith.

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**ITEM 14. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.* Under the supervision and with the participation of our management, including our principal executive and 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 ), within 90 days of the filing date of this report. Based on this evaluation, our principal executive and financial officer concluded that our disclosure controls and procedures are effective in alerting her on a timely basis to material information relating to our Company (including its consolidated subsidiaries) required to be included in our reports filed or submitted under the Exchange Act.

*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 the preceding paragraph.

**ITEM 15. 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, 2004

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 and Financial Officer)	March 31, 2005
Judy M. Robinett		
/s/ David R. Walker	Chairman of the Board of Directors	March 31, 2005
David R. Walker		
/s/ Larry Anderson	Director	March 31, 2005
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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