MEDICAL DISCOVERIES INC
Form 10KSB
March 30, 2004

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

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

For the fiscal period ended December 31, 2003

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

For the transition period from to

Commission file number 0-12627

Medical Discoveries, Inc.

(Exact name of Small Business Issuer as specified in its charter)

Utah	**87-0407858**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

738 Aspenwood Lane, Twin Falls, Idaho 83301

(Address of principal executive offices)

(208) 736-1799

(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. þ Yes o 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. þ

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, 2003, was $3,040,627.

As of March 5, 2004, the issuer had 83,629,077 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the issuer s 2004 Annual Meeting of Shareholders are incorporated by reference in Part III of this Form 10-KSB.

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

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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 dependence on a single product, 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 unproven state of our technologies, the competition we face, the potential that our intellectual property is not adequately protected, our risk of product liability, and the risk that shareholders could suffer substantial dilution. 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, believes, estimates, potential, or continue, or the negative thereof or other comparable terminology. Althou 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 and other factors referred to in the Company s press releases and reports filed with the Securities and Exchange Commission (the SEC). 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.

PART I

Item 1. ***Description of Business***

OVERVIEW

We are a development-stage bio-pharmaceutical company engaged in the research, validation, development and ultimate commercialization of a patented anti-infective technology. Our electrolyzed solution of free radicals represents a novel approach to treating our initial target indication, HIV. We plan in the near future to conclude our pre-clinical work and enter the clinic in our initial target indication. If our HIV clinical trials are successful, we plan to develop this therapy for additional target indications.

Our product, called MDI-P, appears to have the ability to destroy certain viruses, bacteria and fungi without any associated toxicity both in animals and in cell-based assays. We are committed to the development of MDI-P as an anti-infective therapeutic product for in-vitro and in-vivo applications. Our highest priority is to develop and commercialize MDI-P as a pharmaceutical for the treatment of HIV. We are in the process of completing pre-clinical development and plan to file an Investigative New Drug application (IND) with the Food and Drug Administration (FDA) for MDI-P as an HIV treatment. If the FDA approves the IND, we will begin a Phase I clinical test at the Harvard School of Medicine using a protocol designed by Dr. Bruce Dezube. We expect to add additional indications for the use of MDI-P in the future as we complete our pre-clinical development.

To date, we have not generated significant revenues from operations or realized a profit. Through December 31, 2003, we had incurred a cumulative net loss since inception of $14,141,763. We are currently attempting to secure capital commitments to finance the completion of our pre-clinical analysis, file our IND for MDI-P as an HIV therapeutic, determine additional potential indications for MDI-P, and to otherwise

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continue research and testing of our technologies in order to secure required approvals to bring products to market. In that we are a development stage company, we will increasingly require additional funding to continue the development of our technology and to finance submittal of our testing and trials to the appropriate regulatory agencies in order to secure approvals for product development and sales.

RECENT DEVELOPMENTS

Sepsis Study Reaffirms Anti-Infective Strength and Low Toxicity of MDI-P. In March, 2004, we received a study on sepsis that reaffirms the anti-infective strength and low toxicity profile in pre-clinical mouse models of MDI-P. In the MDI-sponsored study, the goal was to test the efficacy of MDI-P in inhibiting inflammatory responses in mice, induced by bacteria that cause sepsis, a severe illness caused by infection of the bloodstream by toxin-producing bacteria. The study used 25%, 50% and 100% MDI-P solutions to inhibit inflammatory processes that generally lead to septic shock. MDI-P was evaluated against both a saline control group of mice and a positive control group that had been given Gentamicin, an established antibiotic treatment for sepsis. The study confirmed that 100% dose strength of MDI-P offered substantial benefit to the mice when compared to both the placebo and to Gentamicin, but without the apparent toxicity profile that Gentamicin exhibits.

While HIV is our initial target indication, this report is significant. In the US, sepsis is the leading cause of death in noncoronary ICU patients, and recent 1998 data from the Centers for Disease Control show that it is the 11th leading cause of death overall. Despite enormous investments in intensive care, sepsis has been associated with mortality rates ranging from 28% to 50%. It is estimated that more than 700,000 cases of severe sepsis occur in the US each year, resulting in more than 200,000 deaths. Extrapolated to a global population, this represents several million cases of severe sepsis annually worldwide with a mortality of up to 1 million cases.

This research is one of several studies on pre-clinical models of infectious diseases that mimic human disease, being conducted by Dr. Emil Chi, Director of the University of Washington Medical School s Department of Histopathology. This and Dr. Chi s other studies will help support our IND for HIV.

Retirement of Secured Note. In March, 2004, we negotiated an arrangement whereby we converted an outstanding, secured promissory note to common stock. The total obligation outstanding on the note was approximately $130,000 and was converted at an effective rate of approximately 8 cents per share.

Old Debt Reduction. In February, 2004, we wrote off $610,828 in liabilities from our balance sheet after we received approvals from our legal counsel to do so. The extinguished liabilities were either determined to be uncollectible by the creditor for a variety of reasons or were determined to be inaccurately booked. All of the written off liabilities were booked prior to 2000.

Private Placement. In January, 2004 we announced the closure of a $1.1 million private placement of restricted common stock at the price of $0.04 per share. The funds will be used primarily to complete the needed pre-clinical work (in-vivo animal models of infectious diseases) and Chemistry, Manufacturing and Control (CMC) work to support the filing of our IND for HIV.

Engagement of C.K. Cooper & Company. In December 2003, we engaged C.K. Cooper & Company to serve as our investment banker and advise us on completing our restructuring process, achieving milestones, and developing future capital. C.K. Cooper & Company is a specialty, full service investment banking/brokerage firm that provides a high level of customer service to its clients and institutional investors, focusing on private, small and micro cap growth companies in the life sciences, oil & gas and technology industries.

BUSINESS STRATEGY

Our highest priority is to complete our pre-clinical development, file an IND and begin the clinical development of MDI-P as a therapeutic regimen for the treatment of HIV. We have completed much of the preliminary pre-clinical work necessary for an IND application, including testing in chemistry and composition, microbiology, efficacy in cell lines, and toxicity and efficacy in animals. Prior to submitting the IND application, we intend to conduct additional toxicity and efficacy testing in animals, establish the chemistry,

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manufacturing and control (CMC) production of MDI-P, and establish current Good Manufacturing Practices (cGMP), as outlined by the FDA.

Our second priority is 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 a proprietary electrolyzed solution of free radicals which has been proven in cell lines and in live animal tests to have significant anti-infective effects. MDI-P appears to work by virtue of the direct virus-, bacteria-and parasite-killing effect of several of the powerful oxidants present in the MDI-P solution, including various hypochlorous acid chains, ozone and dilute hydrogen peroxide. Most such 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:

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

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 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

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guidelines and have helped establish that MDI-P is reasonably safe for human clinical trials. This toxicity data is being amended by inclusion of 100% strength MDI-P in our ongoing mouse and rabbit studies.

Several months ago, we initiated a new series of live animal tests of MDI-P at the University of Washington Medical School, including a cystic fibrosis mouse model and a mouse ozone model. All of these tests may indicate MDI-P is a technology with a broad spectrum of anti-infective applications with limited cell-based toxicities.

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 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 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%), proritus (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.

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

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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.

PATENTS

Our patents and resulting intellectual properties now span more than a decade of research and development. We hold eight United States Patents, two Japanese patents and a Mexican patent on our core technologies. The US Patents are identified and have been awarded by the U.S. Patent Office under the following Notifications:

Patent No. 5,334,383
Electrically Hydrolyzed Salines As In Vivo Microbicides For Treatment Of Cardiomyopathy And Multiple Sclerosis,

Patent No. 5,507,932
Apparatus For Electrolyzing Fluids,

Patent No. 5,560,816
Method For Electrolyzing Fluids,

Patent No. 5,622,848
Electrically Hydrolyzed Saline Solutions As Microbicides For In Vitro Treatment Of Contaminated Fluids Containing Blood,

Patent No. 5,674,537
An Electrolyzed Saline Solution Containing Concentrated Amounts Of Ozone And Chlorine Species,

Patent No. 5,731,008
Electrically Hydrolyzed Salines As Microbicides,

Patent No. 6,007,686
System For Electrolyzing Fluids For Use As Antimicrobial Agents,

Patent No. 6,117,285
System For Carrying Out Sterilization Of Equipment,

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

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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.

COMPETITIVE BUSINESS POSITION

We are aware of other companies who may be developing similar technologies and products for markets in which we may pursue product development and revenue. We are continuing to monitor and learn about these companies and technologies, in that they may provide opportunities to develop key relationships that will enhance our understanding and development of these technologies and assist us to enter worldwide markets in the future, either separately or in strategic alliance with these companies. None of these companies is seen as an immediate competitive threat to our stated strategy.

The HIV market, our initial targeted application, is intensely competitive and rapidly changing. There are approximately 83 drugs currently approved by the FDA for the treatment of HIV. In addition, a number of companies are pursuing the development of novel pharmaceutical products for HIV treatment. Although we believe there is a significant future market for HIV therapies and we believe MDI-P offers competitive advantages over existing therapies, even if MDI-P is approved for sales, we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. There can be no assurance that existing products or new products for HIV treatment developed by our largest competitors, principally including Roche, Pfizer, GlaxoSmithKline, Merck & Co., Bristol-Myers Squibb and Abbott Laboratories, will not be more effective or more effectively marketed and sold than our technology.

GOVERNMENT REGULATIONS

Overview. Our use of MDI-P in the treatment of HIV and for other human or non-human uses 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.

FDA. The FDA imposes substantial requirements upon and conditions precedent to the introduction of therapeutic drug products, such as MDI-P, 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 MDI-P, or any therapeutic drug product, in the United States until an NDA has been approved by the FDA.

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

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

Phase I testing typically takes at least one year, Phase II trials typically take from 1 1/2 to 2 1/2 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 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. If no agency comment is provided on the IND application within one month, we will be allowed to begin recruiting patients for our Phase I clinical trial. We can give no assurance that our IND application will be approved or, if approved following comments or subject to modifications, the length of FDA approval time.

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

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

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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.

Currently, we have not completed all testing required to prepare and submit an IND to the FDA and we do not have the financial resources necessary to do so.

Other Regulations. Other product applications which may be developed for MDI-P could require regulatory approvals from other governmental agencies, such as the Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, and other present and potential federal, state and local regulations. These approvals can involve considerable money, time and effort and do not, in and of themselves, guarantee any commercial success for the product applications approved.

RESEARCH AND DEVELOPMENT

Our research and development efforts consist primarily of pre-clinical development of and preparing applications for regulatory approvals for MDI-P for our primary indication, HIV. 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, 2003, we spent $100,423 on research and development of MDI-P. During fiscal 2002, we had no research and development expenditures due to lack of funds. From inception through December 31, 2003, we have recorded $2,622,164 in research and development expenses. We are actively pursuing our research efforts of MDI-P. See Business Strategy above.

EMPLOYEES

We currently have no employees. Judy M. Robinett, MDI s President and CEO, is an independent contractor. 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 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 successfully submits at least three new INDs to the FDA each year, 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, where he was an NDEA Title IV fellow.

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, 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. Both subsidiaries were incorporated to undertake special purposes, neither of which were pursued by the Company in recent years. As of December 31, 2003, we dissolved both subsidiaries.

The Company files annual, quarterly, and current reports, proxy statements, and other information with the Commission. You may read and copy any reports, statements, or other information that the Company files 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

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statements, and other information regarding issuers, such as the Company, that file electronically with the Commission. Reports, proxy statements and other information concerning the Company 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 as our address of record. 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.

Fiscal Year Ended December 31, 2003	High Bid	Low Bid
First Quarter	$0.085	$0.035
Second Quarter	0.090	0.055
Third Quarter	0.075	0.045
Fourth Quarter	0.395	0.060

Fiscal Year Ended December 31, 2002	High Bid	Low Bid
First Quarter	$0.250	$0.095
Second Quarter	0.450	0.075
Third Quarter	0.105	0.035
Fourth Quarter	0.075	0.045

SHAREHOLDERS

The approximate number of shareholders of record of our common stock as of March 5, 2004 was 1,388. 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.

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SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information regarding our equity compensation plans as of December 31, 2003.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders(1)	3,283,000	$0.13	-0-
Equity compensation plans not approved by security holders(2)	15,300,000	$0.02	4,700,000
Total	18,583,000	$0.04	4,700,000

(1) Consists of the 1993 Incentive Plan.

(2) Consists of the 2002 Stock Incentive Plan, which was adopted by the Board of Directors as of July 11, 2002. It has not been approved by our stockholders. A maximum of 20,000,000 shares of our common stock are authorized to be issued under the plan. This number is subject to adjustment in the case of certain changes in our capital structure. Moreover, shares subject to expired, terminated or canceled options or performance-based awards and shares forfeited to or repurchased by us will again be available for issuance under the plan. The plan is administered by the Board of Directors.

The plan provides for grants of incentive stock options, nonstatutory stock options, stock bonuses, restricted stock and performance-based awards to selected employees, officers, directors, non-employee agents, consultants and independent contractors of the Company or any parent or subsidiary of the Company. The plan will remain in effect until all shares available for issuance under the plan have been issued and all restrictions on outstanding shares have lapsed. The Board of Directors may suspend or terminate the plan early, however, except with respect to outstanding options, restricted stock and performance-based awards.

Options awarded under the plan are subject to vesting requirements. Generally, options awarded under the plan have a term of ten years, subject to acceleration in the event of termination, death or disability or a change of control of the Company, and the exercise price is equal to the fair market value on the date of grant. Shares of restricted stock are also subject to vesting requirements. Performance-based awards are intended to qualify as qualified performance-based compensation under Section 162(m) of the Internal Revenue Code.

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 October 8, 2003 through January 26, 2004, 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.

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$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.

$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.

On December 20, 2001, the Company sold 160,000 shares of common stock to Ferret Resources at $0.15 per share for total proceeds of $24,000.

On August 30, 2001, the Company sold 500,000 shares of common stock to Ferret Resources at $0.15 per share for total proceeds of $75,000.

$50,000 unsecured convertible promissory note dated August 1, 2001, bearing interest at the rate of 18%, convertible to common stock of the Company at the rate of $0.06 per share.

$50,000 unsecured convertible promissory note dated May 28, 2001, bearing interest at the rate of 12%, convertible to common stock of the Company at the 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 20 through 33.

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, 2003. By comparison, in 2002, we booked revenues of $3,108 from isolated sales of past inventory of skin care products we are no longer selling. Because we wrote off the remaining value of our skin care product inventory as impaired in 2000, we booked no cost of goods sold against our 2002 revenues. Therefore, our gross profit on these sales for fiscal 2002 was $3,108.

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As we continue to pursue pre-clinical and clinical testing of MDI-P as a pharmaceutical for the treatment of HIV as well as other pre-commercialization testing of our technologies, we do not anticipate booking significant revenues in the near future.

Operating Expenses and Operating Loss. We booked $100,423 in research and development expenses during the year ended December 31, 2003, as compared with no such expenses for the same period in 2002. Our increased research and development activity reflects our success is raising capital to fund pre-clinical studies of MDI-P. We have continued to be successful in raising capital in 2004 and will incur substantially higher research and development expenses during 2004. Our general and administrative expenses were $1,206,484 in 2003, as compared with $1,217,634 during the year ended December 31, 2002. Of that amount, we recorded non-cash charges of $338,395 for stock and stock options issued for services, expenses and interest. As a result of the foregoing, we sustained an operating loss of $1,306,907 for the year ended December 31, 2003, as compared with a loss of $1,214,526 for the same period of 2002.

Other Income/ Expense and Net Loss. We recorded other income during 2003 in the amount of $611,558, $610,828 of which was on account of writing off certain liabilities from our balance sheet. The extinguished liabilities were either determined to be uncollectible by the creditor for a variety of reasons or were determined to be inaccurately booked. All of the written off liabilities were booked prior to 2000. We incurred interest expenses of $256,694 in 2003, as compared with $212,365 in such expenses in 2002. Our interest expenses have increased and continue to be high as we have continue to carry relatively short-term, high-interest debt incurred in past periods in order to finance operations, research and development. In sum, our net loss for 2003 was $952,043, or a loss of approximately $0.02 per fully diluted share. In 2002, we sustained a net loss of $1,426,891, or a loss of approximately $0.04 per fully diluted share.

Income Taxes. We have a net operating loss carryforward of approximately $10,880,000. Due to our operating condition, the net operating loss has been fully offset with a valuation allowance resulting in no deferred tax asset. See Note E to the Financial Statements for a further explanation of this analysis.

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 2004 in research and development expenses as we continue to implement our commercialization strategy. Similarly, we expect our general and administrative expenses to increase in 2004 as we seek patent protection relating to our pre-clinical progress on MDI-P. As a result, we expect to sustain a greater net loss in 2004, than we have in recent years.

Recently Issued Accounting Statements

In June 2002, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS 146 changed the accounting for costs associated with exit or disposal activities. The Company adopted SFAS No. 146 in fiscal year ended December 31, 2003. During that period, the Company dissolved its wholly owned subsidiaries Regenere, Inc., and MDI Healthcare Systems, Inc., The subsidiaries were inactive and costs associated with dissolving these entities were minimal and did not have a material impact on the results of operations and financial position of the Company.

In January 2003, the FASB issued FASB Interpretation Number, or FIN, 46, Consolidation of Variable Interest Entities, an interpretation of ARB 51. FIN 46 addresses consolidation of variable interest entities, which are entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for variable interest entities created after January 31, 2003, and for variable interest entities in which an enterprise obtains an interest after that date. In October 2003, the FASB deferred to the fourth quarter of 2003 from the third quarter the implementation date of FIN 46 with respect to variable interest entities in which a variable interest was acquired before February 1, 2003. In December 2003, the FASB issued a revision to FIN 46, known as FIN 46R, to clarify certain provisions and exempt certain entities from its requirements. In addition, FIN 46R deferred to the first quarter of 2004 application of its provisions to certain entities in which a variable interest was acquired prior to February 1, 2003. FIN 46 may be applied prospectively with a cumulative effect adjustment as of the date on which it is first applied or by restating previously issued financial statements with a cumulative effect

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adjustment as of the beginning of the first year restated. Since we do not have any variable interest entities, the adoption of FIN 46 and FIN 46R will not have an impact on our financial position or results of operations.

In April 2003, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities, which is effective for contracts entered into or modified after June 30, 2003. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The adoption of SFAS No. 149 did not have an impact on our financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity, which is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the first interim period beginning after June 15, 2003. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The adoption of SFAS No. 150 did not have an impact on our financial position or results of operations.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2003, we had only $424,216 in cash and had a working capital deficit of $3,430,816. 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. In addition, we cannot survive, even in the near term, without immediate additional funding for operations. 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 and short-term loans from shareholders and others.

We are seeking to raise substantial additional funds in private stock offerings in order to meet our near-term and 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 $500,000 in research and development to file an IND application with the FDA for MDI-P as an HIV therapy. (See Description of Business Commercialization Strategy above.) In addition, we estimate we will need to expend an additional $300,000 to $475,000 in debt service and general and administrative costs between now and when we hope to file the IND in Q4 2004 or Q1 2005. As of the date of this report, we have approximately $600,000 in cash. Therefore, we are between $200,000 and $375,000 short to advance our highest priority target, HIV, to the next development milestone.

Once our IND application is submitted, and assuming it is approved, we will need additional capital to initiate Phase I clinical trials and progress through FDA clinical testing toward the end of a drug that is approved for marketing and sales. We estimate the cost to complete Phase I and Phase II clinical trials 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 in the event our IND application is approved, 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.

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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, intends, 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 Dependent on a Single Product, the Failure of Which Would Likely Cause Us to Cease Operations. We are entirely dependent on our ability to develop MDI-P, which is our sole product. We have not commercialized MDI-P or any other product and our failure to commercialize MDI-O would likely cause us to cease operations. While we believe MDI-P may have very broad commercial applications and is not tied to any one indication, 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 to date have been quite favorable in terms of high efficacy as an anti-infective with a low toxicity profile, there is no certainly that MDI-P will be successful. The results of our pre-clinical studies may not be indicative of future clinical trials. Moreover, unacceptable toxicity could occur at any time in the course of human trials or, if MDI-P is approved for sales, during commercial use. Even if MDI-P does prove to be safe and effective and receives regulatory approvals, we may be unable to successfully commercialize it or any other product.

We Have Not Generated Significant Operating Revenues or Any Profits and May Continue to Operate at a Loss. We are a development stage company. To date, we have not generated significant revenues from operations or realized a profit. We have experienced a loss from operations in every fiscal year since our inception. Our losses from operations in 2003 were $1,306,907 and our cumulative losses from operations since inception through December 31, 2003 were $15,390,319. We will likely continue to experience a net operating loss until, and if, we can fully commercialize our technologies, which will not be for several years. We are presently investing all of our resources in the testing, development and commercialization of MDI-P and our other technologies. There can be no assurance that MDI-P, our other technologies, or any other project undertaken by us will ever enable us to generate consistent revenues from operations. Even if our technologies begin generating revenues, the revenues may not exceed the costs of research, development, testing, regulatory approval and other costs. Accordingly, we may not ever realize a profit from operations.

We May Not Be Able to Raise Sufficient Capital to Meet Present and Future Obligations. As of December 31, 2003, our current liabilities exceeded our current assets by $3,430,816 and we had cash of only $424,216. We need additional capital by Q3 2004 in order to satisfy current liabilities and meet basic operational needs. We also will 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 to be able to obtain the amount of additional capital needed or may be forced to pay an extremely high price for capital.

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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;

the effect of the exercise of outstanding options and warrants exercisable into approximately 23.1 million shares of common stock; and

the effect of the conversion of notes that are convertible into approximately 7.5 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. As of December 31, 2003, we had a consolidated accumulated deficit of $15,390,319. 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, Balukoff Lindstrom & Co, P.A., have expressed substantial doubt about our ability to continue as a going concern.

Our Operations Are and Will Be Subject to Extensive Government Regulation. As more fully discussed in Description of Business Government Regulations above, before MDI-P can be used as drugs or in other human applications in the United States, we will need to obtain approval from the Food and Drug Administration. Similar approval is also required in most other countries. FDA approval and the prerequisite testing is time consuming and expensive. There can be no assurance that we will attract sufficient capital to complete the regulatory approval process. Even if we do attract sufficient capital, we can make no assurance that we will be successful in achieving approval or, if we do achieve approval, that future revenues will be sufficient to justify the expense of the regulatory approval process. In addition, a marketed product is subject to continual FDA scrutiny. Post-clinical discovery of problems or failure to comply with Good Manufacturing Practices or other FDA requirements may result in restrictions on or discontinuance of marketing of a product, as well as expose the Company to potential civil and criminal sanctions.

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

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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 are not able to obtain adequate reimbursement, they may forego or reduce their use.

Our Technologies Are Unproven. While we have received positive results from preliminary studies of MDI-P, more studies are necessary in order for us to accurately predict the ultimate effectiveness of our technologies as anti-viral, anti-bacterial and anti-fungal agents. Furthermore, we cannot as of yet be sure that MDI-P is safe to humans when used as intended. Extensive additional research and testing will be necessary before we can fully commercialize our technologies. If our technologies are ultimately deemed unsafe or ineffective, then we will not likely be able to recoup our substantial investment in research and development.

We Face Intense Competition and Competing Products. As more fully discussed in Description of Business Competition above, competition in the market for MDI-P is intense and will likely further intensify. We are aware of private and government entities that have studied and used MDI-P-like products in Russia, Japan and the United States for several years. If MDI-P gains recognition, we anticipate that international pharmaceutical companies will be interested in investing or competing in this market. Our present and future competitors may be able to develop and commercialize technologies quicker than we can. In addition, even if we do successfully commercialize our technologies, there can be no assurance that our products will gain significant market share as we attempt to compete with more traditional anti-infective products and methods.

Our Intellectual Property May Not Be Adequately Protected. Our technology is not necessarily novel; thus 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, there can be no assurance 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 patents outside of North America, as well as other obstacles, may limit our ability to enforce any patents outside of the United States. There can also be no assurance that any patent issued to us will not be infringed or circumvented by others or that others will not obtain patents that we would need to license or circumvent. There