

MEDICAL DISCOVERIES INC

Form 10QSB/A

November 15, 2004

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

**Form 10-QSB/A**

(Mark One)

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

For the quarterly period ended June 30, 2004

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-12627

**MEDICAL DISCOVERIES, INC.**

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

Utah

87-0407858

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(State or other jurisdiction of incorporation or organization)

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

738 Aspenwood Lane, Twin Falls, Idaho 83301

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(Address of principal executive offices)

(208) 736-1799

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(Issuer's telephone number, including area code)

N/A

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(Former name, former address and former fiscal year, if changed since last report)

**APPLICABLE ONLY TO CORPORATE ISSUERS:**

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: As of July 29, 2004, there were 93,581,577 shares of the issuer's Common Stock outstanding.

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act):  
Yes  No

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**Explanatory Note**

The purpose of this amendment on Form 10-QSB/A to the Quarterly Report on Form 10-QSB of Medical Discoveries, Inc. for the quarter ended June 30, 2004 is to restate our interim consolidated financial statements for the quarter ended June 30, 2004 and related disclosures as of and for the quarter ended June 30, 2004. Generally, no attempt has been made in this Form 10-QSB/A to modify or update other disclosures presented in the original report on Form 10-QSB except as required to reflect the effects of the restatement. The Form 10-QSB/A generally does not reflect events occurring after the filing of the Form 10-QSB or modify or update those disclosures, including the exhibits to the Form 10-QSB, affected by subsequent events. Information not affected by the restatement is unchanged and reflects the disclosures made at the time of the original filing of the Form 10-QSB on August 16, 2004. Accordingly, this Form 10-QSB/A should be read in conjunction with our filings made with the Securities and Exchange Commission subsequent to the filing of the original Form 10-QSB, including any amendments to those filings. The following items have been amended as a result of the restatement:

Part I Item 1. Financial Statements

Part I Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Part II Item 2. Changes in Securities

There are two principal changes in the restatement. The first is to correct our disclosure relating to extension of certain options. We initially reported that due to a change in the expiration date of certain options, the options would be subject to variable accounting treatment. We have since determined that the options are not subject to variable accounting treatment, but rather a remeasurement of the options as if they were newly granted. See Note 1 to the Consolidated Financial Statements for a further explanation. The second is to correct an error in the cumulative net loss from inception to date as reflected on the Statements of Operations. While we previously reported the correct cumulative net loss on the Statements of Cash Flows, the same figure as reported on the Statements of Operations was erroneous based on an apparent incorrect calculation in 1999, which error had been carried forward. We do not believe the difference to be material, but have elected to correct this error in the 2003 10-KSB and subsequent filings. In addition to the principal changes outlined above, we have made other non-material adjustments in the financial statement disclosures to conform to the disclosures we will file with our Quarterly Report on Form 10-QSB for the quarter ended September 30, 2004.

For convenience and ease of reference, we are filing our quarterly report in its entirety with the applicable changes.

**PART I  
FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

The following financial statements are filed with this report:

Condensed Consolidated Balance Sheet as of June 30, 2004, (unaudited) and December 31, 2003 (unaudited)

Condensed Consolidated Statements of Operations for the three- and six-month periods ended June 30, 2004 (unaudited) and June 30, 2003 (unaudited) and cumulative amounts since inception through June 30, 2004 (unaudited)

Condensed Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2004 (unaudited) and June 30, 2003 (unaudited) and cumulative amounts since inception through June 30, 2004 (unaudited)



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MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED CONSOLIDATED BALANCE SHEET  
As of June 30, 2004 and December 31, 2003  
(Unaudited)

	<u>June 30, 2004</u>	<u>December 31, 2003</u>
Current assets		
Cash	\$ 346,929	\$ 424,216
Prepaid expenses		11,331
Current portion of deferred charges		12,077
	<hr/>	<hr/>
Total current assets	\$ 346,929	\$ 447,624
	<hr/>	<hr/>
Current liabilities		
Accounts payable	\$ 2,358,365	\$ 2,066,727
Accrued interest	526,810	524,294
Current portion of notes payable	469,217	789,217
Convertible notes payable	448,202	498,202
	<hr/>	<hr/>
Total current liabilities	3,802,594	3,878,440
Stockholders' deficit		
Escrow receivable		(227,300)
Additional paid-in capital	2,254,363	579,363
Common stock, no par value, authorized 100,000,000 shares; 91,225,271 and 76,456,095 shares issued and outstanding at June 30, 2004 and December 31, 2003	13,290,627	12,546,957
Accumulated deficit prior to development stage	(1,399,577)	(1,399,577)
Deficit accumulated during the development stage	(17,601,078)	(14,930,259)
	<hr/>	<hr/>
Total stockholders' deficit	(3,455,665)	(3,430,816)
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Total liabilities and stockholders' deficit	\$ 346,929	\$ 447,624
	<hr/>	<hr/>

See notes to condensed consolidated financial statements





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MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
For the Three and Six Months Ended June 30, 2004 and Cumulative Amounts  
(Unaudited)

	For the Three Months		For the Six Months		Cumulative Amounts Since November 20, 1991 (Date of Inception)
	Ended June 30,		Ended June 30,		
	2004	2003	2004	2003	
Revenues	\$	\$	\$	\$	157,044
Cost of goods sold					14,564
Gross profit					142,480
Research and development expenses	132,335		170,978		3,169,623
Inventory writedown					96,859
Impairment loss					9,709
License					1,001,500
General and administrative expenses	369,270	211,132	2,416,963	358,333	14,536,504
Operating loss	(501,605)	(211,132)	(2,587,941)	(358,333)	(18,671,715)
Other income (expense)					
Interest income	1,426		3,126		26,532
Other income	720		720		881,204
Interest expense	(33,048)	(68,933)	(86,724)	(126,966)	(1,072,635)
Forgiveness of debt					1,235,536
	(30,902)	(68,933)	(82,878)	(126,966)	1,070,637
Net loss	\$ (532,507)	\$ (280,065)	\$ (2,670,819)	\$ (485,299)	\$ (17,601,078)
Net basic and diluted loss per share	\$ (0.01)	\$ (0.01)	\$ (0.03)	\$ (0.01)	

Weighted average shares outstanding	<u>92,393,559</u>	<u>55,698,856</u>	<u>88,478,847</u>	<u>55,649,132</u>
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See notes to condensed consolidated financial statements

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MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
For the Six Months Ended June 30, 2004, June 30, 2003, and Cumulative Amounts  
(Unaudited)

	<b>For the Six Months Ended June 30,</b>		<b>Cumulative Amounts Since November 20, 1991 (Date of Inception)</b>
	<b>2004</b>	<b>2003</b>	
Cash flows from operating activities			
Net loss	\$(2,670,819)	\$(485,299)	\$(17,601,078)
Adjustments to reconcile net loss to net cash used by operating activities			
Common stock options issued for services			3,136,253
Common stock issued for services, expenses, and litigation	75,954	7,000	4,277,170
Stock compensation expense	1,675,000		1,675,000
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	32	(1)
Deferred charges	12,077	20,051	1
Accounts receivable			(7,529)
Accounts payable	293,150	163,872	2,203,968
Accrued expenses	2,516	88,427	548,291
Net cash used by operating activities	(600,791)	(205,917)	(6,028,952)
Cash flows from investing activities			
Purchase of equipment			(132,184)
Payments received on note receivable			130,000
Net cash used by investing activities			(2,184)
Cash flows from financing activities			
Contributed equity			131,374

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Issuance of common stock	718,504	10,800	4,863,163
Payments on notes payable	(195,000)	(25,000)	(426,287)
Proceeds from notes payable		225,000	1,336,613
Payments on convertible notes payable			(98,500)
Proceeds from convertible notes payable			571,702
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Net cash provided by financing activities	523,504	210,800	6,378,065
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Net increase (decrease) in cash	(77,287)	4,883	346,929
Cash, beginning of period	424,216	14,555	
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Cash, end of period	\$ 346,929	\$ 19,438	\$ 346,929
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Supplemental disclosure of non-cash activities			
Retirement of notes payable of common stock	\$ 175,000	\$	
	<u>                    </u>	<u>                    </u>	<u>                    </u>

See notes to condensed consolidated financial statements

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**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO UNAUDITED FINANCIAL STATEMENTS  
June 30, 2004**

**Note 1. Basis of Presentation.**

*Unaudited Interim Financial Statements*

The accompanying unaudited financial statements have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments and disclosures necessary to a fair presentation of these financial statements have been included. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's 2003 Annual Report on Form 10-KSB for the year ended December 31, 2003, as filed with the Securities and Exchange Commission. Certain reclassifications and other corrections for rounding have been made in prior period financial statements to conform to the current period presentation. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant inter-company transactions and balances have been eliminated in consolidation.

*Stock Based Compensation and Restatement*

The Company has two incentive stock option plans wherein 24,000,000 shares of the Company's common stock can be issued. The Company granted 700,000 fully vested stock options during the six months ended June 30, 2004 to consultants with an exercise price of \$.05. These options were valued at \$98,000 using the Black Scholes pricing model using the following weighted average assumptions: risk free interest rate of 3.8%, expected dividend yield of 0%, volatility of 220% and an expected life of 7 years.

During the first quarter of 2004, the Company extended the expiration date of options to purchase an aggregate amount of 18,403,000 shares of stock. As a result of such extension, such options expire from between 2011 to 2013. Initially we reported that due to the change in expiration date, the options were subject to variable accounting treatment. We have subsequently determined that the options are not subject to variable accounting treatment, but rather a remeasurement of the options as if they were newly granted. This remeasurement resulted in an expense to the Company totaling \$1,577,000. We have amended this quarterly filing for the second quarter of 2004 to reflect this change, and such treatment will be consistent in subsequent periods. The expense associated with the variable accounting treatment for the second quarter of 2004 has been restated from \$2,022,500 to zero. There was no change to the first quarter expense.

In October 1995, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123, which established financial accounting and reporting standards for stock-based compensation. This standard defines a fair value method of accounting for an employee stock option or similar equity instrument. In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, which revised certain provisions of adopting a fair value method of accounting for stock options and required certain additional disclosures regarding stock options. These statements give entities the choice between adopting the fair value method or continuing to use the intrinsic value method under Accounting Principles Board (APB) Opinion No. 25 with footnote disclosures of the pro forma effects if the fair value method had been adopted. The Corporation has opted for the latter approach.

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The Company accounts for its stock options under Accounting Principles Board (APB) Opinion No. 25 using the intrinsic value method. The Company has elected not to adopt the provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (FAS 123). In accordance with Financial Accounting Standards (SFAS) No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, pro-forma net income, stock-based compensation expense, and earnings per share using the fair value method are stated as follows:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Net loss applicable to common shareholders, as reported	\$ (532,507)	\$ (280,065)	\$ (2,670,819)	\$ (485,229)
Add: Stock-based employee compensation expense included in reported net loss			1,577,000	
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards			(1,916,768)	(5,000)
Pro forma net loss applicable to common shareholders	<u>\$ (532,507)</u>	<u>\$ (280,065)</u>	<u>\$ (3,010,587)</u>	<u>\$ (490,229)</u>
Basic and diluted loss per share, as reported	<u>\$ (.01)</u>	<u>\$ (.01)</u>	<u>\$ (.03)</u>	<u>\$ (.01)</u>
Basic and diluted loss per share, pro forma	<u>\$ (.01)</u>	<u>\$ (.01)</u>	<u>\$ (.03)</u>	<u>\$ (.01)</u>

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

	<b>2004</b>	<b>2003</b>
Expected dividend yield		
Risk free interest rate	3.8%	5.00%
Expected volatility	220%	511%
Expected life	7 years	10 years
Weighted average fair value per share	\$ 0.10	\$ 0.04



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**Note 2. Going Concern Considerations.**

The Company's recurring losses from the Company's development-stage activities in current and prior years raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible effects on the recoverability and classification of assets or amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern. The Company is attempting to raise additional capital to sustain operations. However, there can be no assurance that these plans will be successful.

**Note 3. Commitment Regarding Peregrine Stock.**

Peregrine Properties, LLC, a Utah limited liability company (Peregrine), entered into an agreement to provide \$500,000 to the Company to fund testing and research steps necessary to continue development of MDI-P. The studies were 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 had been recorded on the balance sheet in equity under the caption escrow receivable. On March 22, 2002, the parties entered into an agreement the result of which was 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. Subsequent to the period end, the Company and Peregrine resolved the matter 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 and exercisable at any time within 3 years. The Company also wrote off the escrow receivable against common stock.

**Note 4. Issuance of Common Stock.**

During the first six months of 2004, the Company issued 17,125,376 shares of restricted common stock, 1,419,316 of which were issued for services valued at \$75,954, 2,083,333 of which were issued upon conversion of \$175,000 in debt, and 13,622,727 of which were issued for cash of \$718,504 at \$0.04 to \$0.11 per share.

**Note 5. Expiration of Warrants.**

During the first six months of 2004, warrants to purchase 1,666,005 shares of common stock of the Company at prices ranging between \$0.10 and \$0.40 per share expired.

**ITEM 2. 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 2 through 6 and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-KSB for the year ended December 31, 2003 (the 2003 10-KSB).

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.

### **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 indications, Cystic Fibrosis and HIV. We plan in the near

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future to conclude our pre-clinical work and enter the clinic in our initial target indications. If our Cystic Fibrosis or 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 priorities are to develop and commercialize MDI-P as a pharmaceutical for the treatment of Cystic Fibrosis and 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) during the fourth quarter of this year. If the FDA approves the IND for HIV, we will begin a Phase I clinical test at the Harvard School of Medicine using a protocol designed by Dr. Bruce Dezube. If our Cystic Fibrosis IND is approved, we will likewise enter the clinic. We are currently developing the Cystic Fibrosis protocol and exploring test site candidates.

To date, we have not generated significant revenues from operations or realized a profit. Through June 30, 2004, we had incurred a cumulative net loss since inception of \$17,601,078. We are currently attempting to secure capital commitments to finance the completion of our pre-clinical analysis, file our INDs for MDI-P as Cystic Fibrosis and HIV therapeutics, determine additional potential indications for MDI-P, and to otherwise 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 Events**

***Addition of Cystic Fibrosis as Lead Indication.*** On August 4, 2004, we announced that our clinical development objectives have been broadened to include Cystic Fibrosis (CF) as a lead indication, together with HIV. Both Initial New Drug applications (IND s) are expected to be filed with the FDA in Q4 of 2004 under a Drug Master File, which is a submission to the Food and Drug Administration that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

The decision to elevate CF to a clinical development status on par with HIV has come about for a number of reasons:

Unlike HIV, which has numerous existing therapeutics in the market, CF has no existing life-extending therapies. The average age of mortality is 31 years, and CF represents an FDA Orphan Indication, which could mean 7 years of exclusivity in the U.S. and 10 years in the EU.

Medical Discoveries now possesses pre-clinical data (a CF-like murine model) from the University of Washington Medical School showing that MDI-P provides exemplary pathogen-killing effect for the pulmonary infections characteristic of CF patients. Equally important, MDI-P appears to also process the mucus in CF-like lungs, allowing the viscous-state mucus to be removed from the plugged airways. As a result, MDI-P may represent a life-extending therapy for CF patients.

While CF has an incidence of only 30,000 new cases/year in the U.S., there resides a surviving population approaching one million CF patients, with a similar number in the EU. Therefore, the market value of this indication may represent a multi-billion/year potential for MDI-P, should clinical therapeutic results be sufficiently strong. The unmet medical need of this CF population is substantial, with no drugs currently in the market or to MDI s knowledge under development which might offer a comparable life-extending effect.

We expect an expedited FDA review and approval for Phase I clinical trials in CF. It is possible that CF could be approved for human clinical trials prior to us gaining similar approval for trials in HIV, due to a general absence of competing, life-extending therapies in CF. Therefore, the addition of CF as a lead indication should serve as insurance that we will be allowed by the FDA to start trials for at least one of these indications in Q1 of 2005.

We will consider the option of retaining CF as an indication for full development and marketing on our own, using a small detail sales force, given the limited number of qualified CF sites (117 in the US, with only 18 primary sites).

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Unlike other indications such as HIV and asthma, where we will most likely pursue an out-licensing strategy, we could then retain all of the profits from CF sales, which could begin in as little as 2.5 years.

We believe this adoption of multiple indications is the most prudent strategy to ensure timely start of clinical trials as early as possible in 2005. With the addition of CF to the first priority status, together with HIV, we now have improved our odds of starting at least one of these two indications in the clinic in Q1 of 2005.

A Drug Master File is a valuable vehicle and procedure for use when a potential contractor or partner needs to review proprietary components involving the drug MDI-P and the device which makes it. While the FDA must have all of our proprietary information to consider one or more INDs, the DMF allows other parties to reference part of this protected information without learning all of it. Filing a DMF clears the way for us to develop and share our proprietary information with others, while still providing all of our information to the FDA in pursuit of clinical tests.

***Cystic Fibrosis Study Results.*** The decision to include CF as a co-lead indication for MDI-P found its genesis in the third in a series of pre-clinical research reports from Dr. Emil Chi, Chairman of the Department of Histopathology at the University of Washington Medical School. This trial, the results of which were announced on May 20, 2004, studied MDI-P as a potential therapeutic agent for the treatment of the symptoms of CF.

Results from this study showed that, 48 hours after treatment, MDI-P-treated CF-like mice lungs evidenced: a) a 60% reduction in mucus secretion; b) a 49% reduction in white blood cellular infiltration; and c) a 42% reduction in lung edema, as contrasted with untreated CF-like mice. In MDI-P-treated mice, the associated level of lung hemorrhage was reduced by 39%, the level of neutrophil lung infiltration was reduced by 49%, and eosinophil lung infiltration was reduced by 86%, as contrasted with untreated CF-like mice. The 100% MDI-P solution provided a 100% host-sparing effect against this fatal CF-like condition. No overt signs of toxicity were found in the primary organs (lungs, liver, spleen, kidneys, brain) of mice treated with MDI-P.

In this study of 48 mice, it was found that MDI-P is a useful agent to reduce primary measures of disease in CF, including bacterial infection, mucus secretion, cellular infiltration, lung edema (swelling with excess fluid), lung hemorrhage, and lung infiltration by neutrophils and eosinophils, the principal white blood cells responding to allergic and infectious pathogens. Excessive presence of neutrophils and eosinophils can lead to cell death in surrounding tissues, causing serious health problems from their over-expression.

These findings were established in a new mucus overproduction mouse model designed to more closely mimic the CF disease condition found in humans. This mouse model starts with OVA-induced, chronic asthmatic mice, which are then infected intranasally with *P. aeruginosa* to establish a lung disease state comparable with CF patients. Almost all CF patients evidence *P. aeruginosa* colonization at some time during the disease process, associated with progressive deterioration of lung function in CF. With mice mimicking human asthma in this model, the airway is filled with mucus occlusion and the airway becomes infected following inoculation with *P. aeruginosa*. The data provided evidence that MDI-P inhibits *P. aeruginosa* growth and colonization in this mouse model with airway mucus hypersecretion.

Infection with *Pseudomonas aeruginosa*, a common bacterium, plays a major role in the pulmonary inflammation and injury associated with CF. Lung inflammation may also lead to more widespread systemic effects on other organs, including the pancreas. CF affects approximately 1 in 2,500 live births and qualifies as an orphan indication with the FDA, with some 30,000 new cases reported annually in the U.S. and an estimated 900,000 patients surviving up to age 30.

***Pharmacokinetics Report.*** On August 10, 2004, we announced our receipt of a pharmacokinetics (PK) report, which studied the processes of bodily absorption, distribution, metabolism, and excretion (ADME) of in rabbits.

Pharmacokinetics describes the time course of drug concentrations in plasma (and sometimes in other fluids and tissues) resulting from a particular dosing regimen.

This study indicates that MDI-P has an average half-life in-vivo of 17.3 minutes, within a range of 10-20 minutes. Compared with most drugs, where the PK half-life thresholds typically range from many hours to days, this indicates that MDI-P's pathogen-killing activity is compressed within very short timeframes. Furthermore, because toxicity is frequently associated with long half-lives of drug residues in the liver, heart, brain and other vital organs, the truncated half-life of MDI-P has very favorable characteristics associated with lower toxicity profiles.

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One of the primary reasons cited for the failure of new drug candidates in FDA clinical trials is the lack of a suitable pharmacokinetics (PK) profile. It has been estimated that almost 40% of the attrition of all drug candidates is linked to poor PK. This important milestone report is required for our IND submissions under a Drug Master File, set for Q4 2004.

MDI-P proved not amenable to traditional radioactive tagging of active ingredients to determine ADME. Consequently, MDI contracted through Clagett Consulting with the University of Washington's Mass Spectrometry Lab to design and conduct novel, highly specialized, sensitive tests of MDI-P administered in rabbits. These assays detect the presence of the solution in the peripheral blood of the rabbits.

ACP (Acyl-protected hydroxylamine), used frequently to detect oxygen radicals in chemistry, was used as a surrogate marker for the reactive oxygen species present in MDI-P, in a two-compartmental model of pharmacokinetics (from blood plasma into tissue, and back into the blood).

The methodology employed by the UW Mass Spectrometry Lab in this PK study used a High Pressure Liquid Chromatography (HPLC) separator and UV absorption. The measurements for PK were achieved at the picogram-nanogram per mL range, an extraordinary level of sensitivity not previously reported in the literature for reactive oxygen species. Pharmacokinetic statistical analysis was made by Clagett Consulting using Summit Research's established PK Solutions software suite.

Despite the valuable insights obtained from in vitro ADME screening assays, in vivo drug exposure is still emphasized by drug discovery teams when making decisions about molecules within a Structure-Activity Relationship (SAR), which explores the correlations between chemical structure and measured activity. Having reliable data on MDI-P's absorption, distribution, metabolism and excretion is thus an important benchmark in MDI's IND submissions to the FDA.

***Large Mammal Toxicity Report.*** 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 the 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 performed at the University of Albany's Genomics Laboratory. Over the past several years, genomic technologies have evolved that enable the simultaneous analysis of the expression of hundreds to thousands of genes. The analysis and evaluation of gene and protein expression changes that modulate toxic responses can help supplement the mechanistic understanding of how drug treatments in animals and humans possibly induce toxicity in one or more tissues or organs. We wanted to determine whether MDI-P affects the up-or-down-regulation of any controlling genes in toxicity or immuno-regulation. Livers from the rabbit were used to isolate RNA and perform such analyses using Affymatrix GeneChips.

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 (ALT) and aspartate aminotransferase levels (AST), both of which provide sensitive measures of hepatic toxicity

serum protein and albumin levels

bound urinary nitrogen (Bun) levels

serum calcium levels

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.

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**Results of Operations**

**Revenues and Gross Profit.** We did not book any revenue for the three- or six-month periods ended June 30, 2004 or June 30, 2003. As we continue to pursue pre-clinical and clinical testing of MDI-P as a pharmaceutical for the treatment of Cystic Fibrosis and 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 incurred \$132,335 in research and development expenses for the quarter ended June 30, 2004, on preclinical tests of MDI-P. We did not have any research and development expenses for the same period of 2003. Our general and administrative expenses were \$369,270 during the second quarter of 2004, as compared to \$211,132 during the quarter ended June 30, 2003. The increase over the same period of 2003 was due primarily to increased expenses from financing activities, patent filings, and from our annual meeting of shareholders. As a result of the foregoing, we sustained an operating loss of \$501,605 for the quarter ended June 30, 2004, as compared with an operating loss of \$211,132 for the same period of 2003.

For the six months ended June 30, 2004 we incurred \$170,978 in research and development expenses as compared with no such expenses during the same period of 2003. Our general and administrative expenses for the first half of 2004 were \$2,416,963 as compared with \$358,333 for the first half of 2003, resulting in operating losses of \$2,587,941 through June 30, 2004 and \$358,333 through June 30, 2003. The increase in operating expenses in 2004 was due primarily to a one-time non-cash change of \$1,577,000 booked in the first quarter as a result of extending the expiration date of options outstanding.

**Other Income/Expense and Net Loss.** We booked \$1,426 in interest income and incurred interest expenses of \$33,048 for the quarter ended June 30, 2004, as compared with no interest income and \$68,933 in interest expenses for the same period of 2003. The decreased interest expense is a result of our successful efforts to convert high-interest debt to equity. The increase in interest income relates to our higher cash position after successful capital raising efforts. We also booked \$720 in other income in the second quarter of 2004. In sum, our net loss for the second quarter of 2004 was \$532,507 or a loss of \$0.01 per fully diluted share. For the quarter ended June 30, 2003, we incurred a net loss of \$280,065, a loss of less than \$0.01 per fully diluted share.

For the six months ended June 30, 2004, we booked \$3,126 in interest income and incurred interest expenses of \$86,724, as compared with no interest income and interest expenses of \$126,966 for the comparable period of 2003. Our net loss for the first half of 2004 was \$2,670,819 or \$0.03 per fully diluted share. Our net loss for the first half of 2003 was \$485,299 or \$0.01 per fully diluted share.

**Future 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 the remainder of 2004 in research and development expenses over the prior year as we continue to implement our commercialization strategy. Similarly, we expect our higher general and administrative expenses for the first half of 2004 to continue as we increase the size of our operations. As a result, we expect to sustain a greater net loss in 2004, than we have in recent years.

**Liquidity and Capital Resources**

As of June 30, 2004, we had \$346,929 in cash and had a working capital deficit of \$3,455,665. 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 private issuances of equity.



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 cannot assure you we will be successful. 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 \$300,000 in research and development to file IND applications with the FDA for MDI-P as a Cystic Fibrosis and HIV therapy. In addition, we estimate we will need to expend an additional \$220,000 in debt service and general and administrative

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costs between now and when we hope to file the INDs in Q4 2004. Given our current cash position, we are approximately \$300,000 short to advance our highest priority targets, Cystic Fibrosis and HIV, to the next development milestone.

Once an IND application is submitted, and assuming it is approved, we will need additional capital to initiate Phase I clinical trials for each indication 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 per indication and the cost to complete Phase III testing and obtain approval of an NDA to be in the tens of millions of dollars per indication.

While our ability to obtain financing may improve in the event our IND application is approved, we cannot give assurances that we will have 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.

### **Cautionary Statement for Forward Looking Information**

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. Those risks and uncertainties include, but are not limited to, our lack of significant operating revenues and lack of profit to date, our need for substantial and immediate additional capital, the fact that we may dilute existing shareholders through additional stock issuances, the extensive governmental regulation to which we are subject, the fact that our technologies remain unproven, the intense competition we face from other companies and other products, and our reliance upon potentially inadequate intellectual property. Those risks and certain other uncertainties are discussed in more detail in the 2003 10-KSB. There may also be other factors, including those discussed elsewhere in this report, that may cause our actual results to differ from the forward-looking statements. Any forward-looking statements made by us or on our behalf should be considered in light of these factors.

**ITEM 3. CONTROLS AND PROCEDURES**

(a) Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act ), as of June 30, 2004. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2004.

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

**PART II  
OTHER INFORMATION**

**ITEM 2. CHANGES IN SECURITIES**

(c) We sold the following unregistered securities during the period covered by this report. 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.

4,900,000 shares of restricted common stock at \$0.04 per share.

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

We held an Annual Meeting of Shareholders on May 21, 2004 at which the shareholders considered and voted as follows on the items described below:

1. The shareholders considered whether to elect the following persons as directors, each to serve until the 2005 annual meeting of shareholders and until his or her respective successor shall have been duly elected and shall qualify:

<u>Name of Nominee</u>	<u>Votes For</u>	<u>Votes Withheld/Abstentions</u>
David R. Walker	73,821,575	371,264
Judy M. Robinett	73,787,656	405,183
Larry Anderson	73,930,156	262,683

2. The shareholders considered whether to ratify the selection of Balukoff Lindstrom 7 Co., P.A. as independent accountants of the Company for the fiscal year ending December 31, 2004. There were 74,021,628 votes cast in favor, 23,821 votes cast against and 147,390 abstentions, which vote was sufficient for approval.

3. The shareholders considered whether to amend and restate the Company's Articles of Incorporation to increase the authorized shares of common stock of the Company from 100 million to 250 million and to authorize 50 million shares of undesignated preferred stock of the Company to be designated in the future by the Board of Directors without further action by the shareholders. There were 56,472,656 votes cast in favor, 354,842 votes cast against and 95,732 abstentions, which vote was sufficient for approval.

4. The shareholders considered whether to approved the Company's 2002 Stock Incentive Plan. There were 55,869,352 votes cast in favor, 753,538 votes cast against and 300,340 abstentions, which vote was sufficient for approval.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits.

The following documents are furnished as exhibits to this Form 10-QSB. 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>
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-

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KSB for the fiscal year ended December 31, 1994, and incorporated herein by reference).

- 10.1 Employment Agreement dated as of May 15, 2002 between Medical Discoveries, Inc. and Judy M. Robinett (filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 2002, and incorporated herein by reference).
- 10.2 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).
- 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.\*

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\* Filed herewith.

(b) Reports on Form 8-K.

The Company filed a Current Report on Form 8-K on May 20, 2004. Subsequent to the period for which this report covers, the Company has also filed Current Reports on Form 8-K on July 16, 2004, August 4, 2004 and August 10, 2004.

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**SIGNATURES**

In accordance with the requirements 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

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Judy M. Robinett  
President and Chief Executive Officer

Date: November 15, 2004

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**INDEX TO EXHIBITS**

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