

MEDICAL DISCOVERIES INC

Form 10QSB

November 15, 2004

**Table of Contents**

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

**Form 10-QSB**

(Mark One)

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

For the quarterly period ended September 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)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

**APPLICABLE ONLY TO CORPORATE ISSUERS:**

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State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: As of November 9, 2004, there were 104,581,669 shares of the issuer's Common Stock and 12,000 shares of the issuer's Series A Preferred Stock outstanding.

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

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**TABLE OF CONTENTS**

**PART I**

**FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

**ITEM 3. CONTROLS AND PROCEDURES**

**PART II**

**OTHER INFORMATION**

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**ITEM 6. EXHIBITS**

**SIGNATURES**

**INDEX TO EXHIBITS**

**EXHIBIT 31**

**EXHIBIT 32**

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**Table of Contents**

**PART I  
FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

The following financial statements are filed with this report:

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

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

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

Notes to Unaudited Financial Statements

**Table of Contents**

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

	<u>September 30, 2004</u>	<u>December 31, 2003</u>
Current assets		
Cash	\$ 434,455	\$ 424,216
Prepaid expenses		11,331
Current portion of deferred charges		12,077
	<hr/>	<hr/>
Total current assets	<u>\$ 434,455</u>	<u>\$ 447,624</u>
Current liabilities		
Accounts payable	\$ 2,331,015	\$ 2,066,727
Accrued interest	399,233	524,294
Current portion of notes payable	336,717	789,217
Convertible notes payable	193,200	498,202
	<hr/>	<hr/>
Total current liabilities	3,260,165	3,878,440
Stockholders' deficit		
Preferred stock, no par value, authorized 50,000 shares; no series designated or shares issued and outstanding		
Common stock, no par value, authorized 250,000,000 shares; 102,746,101 and 76,456,095 shares issued and outstanding at September 30, 2004 and December 31, 2003	14,389,511	12,546,957
Additional paid-in capital	2,254,363	579,363
Escrow receivable		(227,300)
Accumulated deficit - prior to development stage	(1,399,577)	(1,399,577)
Deficit accumulated during the development stage	(18,070,007)	(14,930,259)
	<hr/>	<hr/>
Total stockholders' deficit	<u>(2,825,710)</u>	<u>(3,430,816)</u>
Total liabilities and stockholders' deficit	<u>\$ 434,455</u>	<u>\$ 447,624</u>

See notes to condensed consolidated financial statements



**Table of Contents**

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		Cumulative Amounts Since November 20, 1991 (Date of Inception)
	2004	2003	2004	2003	
Revenues	\$	\$	\$	\$	\$ 157,044
Cost of goods sold					14,564
Gross profit					142,480
Research and development expenses	191,506	35,423	362,484	35,423	3,361,129
Inventory writedown					96,859
Impairment loss					9,709
License					1,001,500
General and administrative expenses	250,819	215,392	2,667,782	573,725	14,787,323
Operating loss	(442,325)	(250,815)	(3,030,266)	(609,148)	(19,114,040)
Other income (expense)					
Interest income	854		3,980		27,386
Other income	39	495	759	495	881,243
Interest expense	(27,497)	(63,142)	(114,221)	(190,108)	(1,100,132)
Forgiveness of debt					1,235,536
	(26,604)	(62,647)	(109,482)	(189,613)	(1,044,033)
Net loss available to shareholders	\$ (468,929)	\$ (313,462)	\$ (3,139,748)	\$ (798,761)	\$(18,070,007)
	\$ (0.00)	\$ (0.01)	\$ (0.03)	\$ (0.01)	



Net basic and diluted  
loss per share

Weighted average  
shares outstanding

	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
	96,482,603	55,698,856	89,667,882	55,665,523
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>

See notes to condensed consolidated financial statements

**Table of Contents**

MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A DEVELOPMENT STAGE COMPANY)  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2004, September 30, 2003, and Cumulative Amounts  
(Unaudited)

	For the Nine Months Ended September 30,		Cumulative Amounts Since November 20, 1991 (Date of Inception)
	2004	2003	
Cash flows from operating activities			
Net loss	\$(3,139,748)	\$(798,761)	\$(18,070,007)
Adjustments to reconcile net loss to net cash used by operating activities			
Common stock issued for services, expenses, and litigation	66,500	7,000	4,276,716
Stock compensation expense	1,675,000		4,811,253
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	12,108	
Deferred charges	12,077	40,614	
Accounts receivable			(7,529)
Accounts payable	264,288	292,580	2,175,106
Accrued expenses	37,905	130,797	583,680
	<hr/>	<hr/>	<hr/>
Net cash used by operating activities	(1,072,647)	(315,662)	(6,500,808)
	<hr/>	<hr/>	<hr/>
Cash flows from investing activities			
Purchase of equipment			(132,184)
Payments received on note receivable			130,000
	<hr/>	<hr/>	<hr/>
Net cash used by investing activities			(2,184)
	<hr/>	<hr/>	<hr/>

Cash flows from financing activities			
Contributed equity			131,374
Issuance of common stock	1,352,886	107,800	5,497,545
Payments on notes payable	(270,000)	(25,000)	(501,287)
Proceeds from notes payable			1,336,613
Payments on convertible notes payable			(98,500)
Proceeds from convertible notes payable		225,000	571,702
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Net cash provided by financing activities	1,082,886	307,800	6,937,447
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Net increase (decrease) in cash	10,239	(7,862)	434,455
Cash, beginning of period	424,216	14,555	
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Cash, end of period	\$ 434,455	\$ 6,693	\$ 434,455
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Supplemental disclosure of non-cash activities			
Conversion of notes payable and interest to common stock	\$ 650,468	\$	
	<u>                    </u>	<u>                    </u>	
Write off of escrow receivable	\$ 227,300	\$	
	<u>                    </u>	<u>                    </u>	

See notes to condensed consolidated financial statements

**Table of Contents**

**MEDICAL DISCOVERIES, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO UNAUDITED FINANCIAL STATEMENTS  
September 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 nine months ended September 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 our quarterly filing for the second quarter of 2004 to reflect this change, and such treatment will be consistent in the current and any 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.

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:

**Table of Contents**

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss applicable to common stockholders, as reported	\$(468,929)	\$(313,462)	\$(3,139,748)	\$(798,761)
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	\$(468,929)	\$(313,462)	\$(3,479,516)	\$(803,761)
Basic and diluted loss per share, as reported	\$ (.00)	\$ (.01)	\$ (.03)	\$ (.01)
Basic and diluted loss per share, pro forma	\$ (.00)	\$ (.01)	\$ (.04)	\$ (.01)

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

	2004	2003
Expected divided yield		
Risk free interest rate	3.8%	5.0%
Expected volatility	220%	511%
Expected life	7 years	10 years
Weighted average fair value per share	\$0.10	\$0.04

**Earnings Per Share**

Earnings per share are computed by dividing net income applicable to common shareholders by the weighted average number of shares outstanding. Potential common shares from convertible notes payable, warrants and stock options have not been included as they are anti-dilutive.

**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.

**Table of Contents**

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

During the first nine months of 2004, the Company issued 28,646,206 shares of restricted common stock, 1,189,465 of which were issued for services valued at \$66,500, 9,875,951 of which were issued upon conversion of debt and interest totaling \$650,468, and 17,580,780 of which were issued for cash totaling \$1,352,886. In connection with the sales for cash, the Company also issued warrants to purchase 2,993,779 shares of restricted common stock at \$0.18 per share, expiring 5 years from the date of issuance.

**Note 5. Expiration of Warrants.**

During the first nine 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.

**Note 6. Subsequent Events.**

On October 18, 2004, we sold 12,000 shares of our Preferred Stock and warrants to purchase 4,575,496 shares of common stock for a total offering price of \$1.2 million. Each share of Preferred Stock entitles the holder to convert the share of Preferred Stock into the number of shares of common stock resulting from multiplying \$100 by the conversion price. The conversion price is 85% of the average of the lowest three intra-day trading prices for the Company's common stock during the 10 trading days immediately preceding the conversion date, but the conversion price may not exceed \$0.1967 or be lower than \$0.05. The warrants entitle the holder to purchase up to 4,575,496 shares of common stock of the Company on or before the third anniversary of the issuance date of the warrants at \$0.1967 per share. The number of shares of common stock subject to the warrants and the exercise price are subject to equitable adjustment in connection with a stock split, stock dividend or similar transaction. In connection with that sale, we also entered into a Registration Rights Agreement with Monarch Pointe Fund, Ltd. and Mercator Advisory Group, LLC, requiring us to file a registration statement with the Securities and Exchange Commission registering the shares of common stock issuable upon conversion of the Preferred Stock and exercise of the warrants. The registration statement must be filed within 30 days of the closing of the sale of the Preferred Stock and the warrants, and the registration statement must be declared effective by the SEC no later than 90 days after it is filed.

Subsequent to the period covered by this report, the Company sold 1,835,567 shares of restricted common stock for cash totaling \$330,402. In connection with those sales, the Company also issued warrants to purchase 1,835,567 shares of restricted common stock at \$0.18 per share, expiring 5 years from the date of issuance.

**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 8 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, HIV and Cystic Fibrosis. We have concluded our pre-clinical work and are preparing to 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

## **Table of Contents**

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 have completed pre-clinical development for our initial indications and have filed an Investigative New Drug application (IND) for Cystic Fibrosis with the Food and Drug Administration (FDA). If the FDA approves our IND for Cystic Fibrosis, we will conduct our Phase I clinical tests at St. Luke's Regional Medical Center in Boise, Idaho, under the direction of Dr. Henry R. Thompson. We plan to file an IND for HIV in the first quarter of 2005. 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.

To date, we have not generated significant revenues from operations or realized a profit. Through September 30, 2004, we had incurred a cumulative net loss since inception of \$18,070,007. We believe we have sufficient capital to complete Phase I trials for Cystic Fibrosis. We are currently attempting to secure capital commitments to finance HIV clinical trials, 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**

***IND Filing for Cystic Fibrosis Completed.*** On November 10, 2004, we completed the milestone filing of our IND with the FDA for Cystic Fibrosis for a Phase I clinical trial of MDI-P in late-term Cystic Fibrosis adults. We are awaiting the FDA's receipt with the assigned IND number. If the FDA approves our IND for Cystic Fibrosis, we will conduct our Phase I clinical tests at St. Lukes Regional Medical Center in Boise, Idaho, under the direction of Dr. Henry R. Thompson.

Dr. Thompson agreed to serve as Project Manager and Principal Investigator for Medical Discovery's Phase I trials in late-term adult Cystic Fibrosis patients on September 23, 2004. Dr. Thompson is currently the director of the Cystic Fibrosis Program Therapeutics Center at Boise, Idaho's Cystic Fibrosis Clinic, located in St. Luke's Regional Medical Center. This Phase I clinical study will be conducted with MDI-P as an adjunct therapy to Tobramycin, an aminoglycoside antibiotic used to treat infections caused by many different bacteria. Plans call for MDI-P to be monitored for both its ability to synergistically improve the anti-infective activity of Tobramycin, a current front-line drug for Cystic Fibrosis patients, as well as its impact on clearing mucus from the lungs of Cystic Fibrosis study patients for improved pulmonary function.

Dr. Thompson is a gastroenterologist, having received his M.D. from Oregon Health Sciences University. He held a Fellowship in pediatric gastroenterology at Children's Hospital in Denver, at the University of Colorado Health Science's unit, where he also participated in clinical studies. Dr. Thompson has been an Assistant Professor at the University of Utah's Medical School, and is a Board certified Fellow in the American Association of Pediatrics. He has previously received grants from both the Cystic Fibrosis Foundation and the NIH. Dr. Thompson plans to use St. Luke's Boise Cystic Fibrosis Clinic for recruitment of patients in this planned study.

***Pre-Clinical Research for Cystic Fibrosis Completed.*** The completion of the IND for Cystic Fibrosis came after our completion of pre-clinical research. On October 6, 2004, we announced our receipt of the last in a series of research reports required by the FDA for the company's submission of the IND application for treating Cystic Fibrosis.

The report focused on the use of MDI-P as an adjunct therapy to Tobramycin in pulmonary infection of juvenile New Zealand rabbits. The acute study, encompassing 25 rabbits in various study arms including saline control, showed that

no inhibitory effects as a result of MDI-P occurred in rabbits also given Tobramycin, when administered intra-nasally in sequence with intra-nasal Tobramycin. When applied alone, Tobramycin showed satisfactory reduction in the extent of *Pseudomonas aeruginosa* pulmonary infection, as compared with saline control animals, and measured by bronchoalveolar lavage analysis of *Pseudomonas aeruginosa* infection from the rabbit lungs. When applied in sequence, both drugs also produced satisfactory reductions in infection.

Under FDA guidelines, when an investigational drug such as MDI-P is proposed as an adjunct therapy, the agency desires data on the potential synergistic or inhibitory effects of the drug when used with the base-line medication. This will be the case in the proposed Phase I clinical trials of MDI-P involving late-term adult Cystic Fibrosis

## **Table of Contents**

patients who are dependent upon an inhaled form of Tobramycin, brand-named TOBI, manufactured by Chiron Corporation.

Tobramycin and TOBI are registered trademarks of Chiron Corporation.

***Lack of Chronic Toxicity in MDI-P Report.*** On August 17, 2004, we announced our receipt of a chronic toxicity study of MDI-P. Chronic toxicity studies test maximum dosages over longer timeframes in order to establish safety parameters for human usage and are required for any IND filings we make. This study, when combined with our recently completed large mammal toxicology study, indicates that MDI-P is safe for use in humans under ICH guidelines, and appears non-toxic for use in human clinical trials.

The study involved the weekly injection of MDI-P into the body cavity of test mice (inter-peritoneal) for six-months, in a multi-dose regimen to establish the safety of MDI-P for use in humans. Doses ranged from 25%-100% solutions of MDI-P. Tests included body weight, together with full microscopic histopathological examination of the mouse liver, kidneys, spleen, intestines, heart and lungs. No statistically relevant changes in body weight, or morphometry or histopathology of vital organs were observed, when compared with mice receiving saline control injections or with untreated animals. The study resulted in no dose-dependency and no toxic effects.

***Private Placement Financing.*** On October 20, 2004, we completed a private placement financing consisting of convertible preferred stock and warrants, generating gross proceeds of \$1,200,000 to the Company. Mercator Advisory Group, LLC of Los Angeles, California participated in the investment through its designated accredited fund, Monarch Pointe Fund, Ltd. Ascendant Securities LLC of Irvine, California served as placement agent on the transaction. This capital infusion, when combined with funds from the private placement discussed below, will help to complete our Phase I clinical trials in Cystic Fibrosis which we plan to commence in the first quarter of 2005 once our IND is accepted by the FDA.

***Completion of Equity Financing.*** On September 29, 2004 and November 8, 2004, we completed successive tranches of a total of \$924,182 in equity financing through subscriptions of restricted common stock and warrants by private investors, in accordance with Rule 144 of the Securities Exchange Act of 1934. The investment proceeds from these financings will help complete our Phase I clinical trials in Cystic Fibrosis which we plan to commence in the first quarter of 2005 once our IND is accepted by the FDA.

***Change in Accountant.*** On October 25, 2004, Balukoff, Lindstrom & Co., P.A. was dismissed as our independent accountant. We have engaged Hanson, Barnett & Maxwell, P.C. as Balukoff, Lindstrom & Co.'s replacement. Neither Balukoff, Lindstrom & Co., P.A.'s report on the Company's financial statements for the year ended December 31, 2003, nor its report for the year ended December 31, 2002, contained an adverse opinion or a disclaimer of opinion, and neither report was qualified or modified as to uncertainty, audit scope or accounting principles, except that both reports were modified as to uncertainty regarding the ability of the company to continue as a going concern. During the years ended December 31, 2003 and December 31, 2002, and the subsequent interim periods through October 25, 2004, there were no disagreements with Balukoff, Lindstrom & Co., P.A. on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Balukoff, Lindstrom & Co., P.A., would have caused Balukoff, Lindstrom & Co., P.A. to make reference to the subject matter of the disagreement in connection with its report.

## **Results of Operations**

***Revenues and Gross Profit.*** We did not book any revenue for the three- or nine-month periods ended September 30, 2004 or September 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 \$191,506 in research and development expenses for the quarter ended September 30, 2004, on preclinical tests of MDI-P. We incurred \$35,423 in research and development expenses for the same period of 2003. Our general and administrative expenses were \$250,819 during the third quarter of 2004, as compared to \$215,392 during the quarter ended September 30, 2003. As a result of the foregoing, we sustained an operating loss of \$442,325 for the quarter ended September 30, 2004, as compared with an operating loss of \$250,815 for the same period of 2003.

## **Table of Contents**

For the nine months ended September 30, 2004 we incurred \$362,484 in research and development expenses as compared with \$35,423 during the same period of 2003. Our general and administrative expenses for the first three quarters of 2004 were \$2,667,782 as compared with \$573,725 for the first three quarters of 2003, resulting in operating losses of \$3,030,266 through September 30, 2004 and \$609,148 through September 30, 2003. The increase in general and administrative expense is due largely to a non-cash charge of \$1,577,000 taken in the first quarter of 2004 associated with the extension of certain options. The increase is also partly due to an increase in the size of our operations.

***Other Income/Expense and Net Loss.*** We booked \$854 in interest income and incurred interest expenses of \$27,497 for the quarter ended September 30, 2004, as compared with no interest income and \$63,142 in interest expenses for the same period of 2003. The decrease in interest expense is a result of our successful efforts to convert high-interest debt to equity. We also booked \$39 in other income in the third quarter of 2004. In sum, our net loss for the third quarter of 2004 was \$468,929 or a loss of less than \$0.01 per fully diluted share. For the quarter ended September 30, 2003, we incurred a net loss of \$313,462, also a loss of less than \$0.01 per fully diluted share.

For the nine months ended September 30, 2004, we booked \$3,980 in interest income and incurred interest expenses of \$114,221, as compared with no interest income and interest expenses of \$190,108 for the comparable period of 2003. Our net loss for the first three quarters of 2004 was \$3,139,748 or \$0.03 per fully diluted share. Our net loss for the first three quarters of 2003 was \$798,761 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 remainder 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 September 30, 2004, we had \$434,455 in cash and had a working capital deficit of \$2,825,710. 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.

We believe we have sufficient capital on hand to complete Phase I clinical trials for Cystic Fibrosis once the FDA approves our IND. We also believe we have sufficient capital to file our IND for HIV.

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

While our ability to obtain financing may improve in the event our IND application is approved, we cannot give assurances that we will have access to the significant capital required to take a drug through regulatory approvals and to market. We may seek a partner in the global pharmaceutical industry to help us co-develop, license, or even purchase some or all of our technologies.

#### **Off-Balance Sheet Arrangements**

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

**Table of Contents**

**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 September 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 September 30, 2004.

(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. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**



On September 9, 2004 and November 4, 2004, we completed \$243,880 and \$680,302, respectively, in equity financing through subscriptions for a total of 7,247,136 shares of restricted common stock by private investors, in accordance with Rule 144 of the Securities Exchange Act of 1934. 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. The investment proceeds will help complete our Phase I clinical trials in Cystic Fibrosis which we plan to commence in the first quarter of 2005 once our IND is accepted with the FDA.

#### **ITEM 6. EXHIBITS**

The following documents are furnished as exhibits to this Form 10-QSB. Exhibits marked with an asterisk are filed

**Table of Contents**

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-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.

**Table of Contents**

**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

**Table of Contents**

**INDEX TO EXHIBITS**

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