

MANHATTAN PHARMACEUTICALS INC  
Form 10QSB  
November 15, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

**FORM 10-QSB**

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

OR

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

Commission file number 0-27282

**Manhattan Pharmaceuticals, Inc.**  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

36-3898269  
(I.R.S. Employer Identification No.)

810 Seventh Avenue, 4th Floor, New York, New York 10019  
(Address of principal executive offices)

(212) 582-3950  
(Issuer's telephone number)

787 Seventh Avenue, 48th Floor, New York, New York 10019  
(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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

As of November 12, 2004 there were 27,540,495 shares of the issuer's common stock, \$.001 par value, outstanding.

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**Forward-Looking Statements**

Certain statements contained in this Quarterly Report on Form 10-QSB that are forward-looking in nature are based on the current beliefs of our management as well as assumptions made by and information currently available to management, including statements related to the markets for our products, general trends in our operations or financial results, plans, expectations, estimates and beliefs. In addition, when used in this report, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as the or our management, may identify forward-looking statements. These statements, particularly those contained in Item 2 of Part I of this Report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," reflect our judgment as of the date of this Report with respect to future events, the outcome of which are subject to risks, which may have a significant impact on our business, operating results or financial condition. Drug development involves a high degree of risk and you are cautioned that these forward-looking statements are inherently uncertain. Factors that might cause such a material difference include, among others, our ability to obtain additional financing, the regulatory approval process of the FDA and other regulators, unforeseen safety issues related to our product candidates, our collaborator's ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, physician and patient acceptance of our product candidates, and other factors identified in our Annual Report on Form 10-KSB/A for the year ended December 31, 2003 under the heading "Risk Factors." Should one or more of these risks or uncertainties materialize, or should underlying

assumptions prove incorrect, actual results or outcomes may vary materially from those described herein. Accordingly, investors should unduly rely on such forward-looking statements.

**PART I - FINANCIAL INFORMATION****Item 1. Unaudited Condensed Consolidated Financial Statements****MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)

Condensed Consolidated Balance Sheets  
(Unaudited)

Assets	September 30, 2004	December 31, 2003
<b>Current assets:</b>		
Cash and cash equivalents	\$ 7,408,879	\$ 7,413,803
Marketable equity securities, available for sale, at market		352,147
Prepaid expenses	22,690	24,981
<b>Total current assets</b>	<b>7,431,569</b>	<b>7,790,931</b>
Property and equipment, net	123,513	8,021
Other assets	70,506	
<b>Total assets</b>	<b>\$ 7,625,588</b>	<b>\$ 7,798,952</b>
<b>Liabilities and Stockholders Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,386,614	\$ 548,595
Accrued expenses	88,225	417,425
<b>Total liabilities</b>	<b>1,474,839</b>	<b>966,020</b>
<b>Commitments and contingencies</b>		
<b>Stockholders equity:</b>		
Series A convertible preferred stock, \$.001 par value. Authorized 1,500,000 shares; 988,000 and 1,000,000 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively (liquidation preference aggregating \$9,684,320)	966	1,000
Common stock, \$.001 par value. Authorized 150,000,000 shares; 27,291,981 and 23,362,396 shares issued and outstanding		

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at September 30, 2004 and December 31, 2003, respectively		27,291		23,362
Additional paid-in capital		18,079,524		14,289,535
Deficit accumulated during development stage		(12,119,314)		(7,473,205)
Dividends payable in Series A preferred shares		212,690		
Accumulated other comprehensive (loss)				(7,760)
Unearned consulting costs		(50,408)		
Total stockholders' equity		6,150,749		6,832,932
Total liabilities and stockholders' equity	\$	7,625,588	\$	7,798,952

See accompanying notes to unaudited condensed consolidated financial statements.

**MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)

Condensed Consolidated Statements of Operations  
(Unaudited)

	<b>Three Months ended</b>		<b>Nine Months ended</b>		<b>Cumulative</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>period from</b>
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>	<b>August 6,</b>
					<b>2001</b>
					<b>(inception) to</b>
					<b>September 30,</b>
					<b>2004</b>
	\$	\$	\$	\$	\$
Revenue					
Costs and expenses:					
Research and development	1,678,939	377,820	2,907,173	734,351	5,356,613
General and administrative	562,752	412,730	1,443,745	1,255,446	3,579,406
Impairment of intangible assets		1,248,230		1,248,230	1,248,230
Loss on disposition of intangible assets		1,213,878		1,213,878	1,213,878
Total operating expenses	2,241,691	3,252,658	4,350,918	4,451,905	11,398,127
Operating loss	(2,241,691)	(3,252,658)	(4,350,918)	(4,451,905)	(11,398,127)
Other (income) expense:					
Interest and other income	(47,614)	(564)	(128,705)	(4,704)	(144,784)
Interest expense		933		4,089	23,893
Realized gain on sale of marketable equity securities			(71,182)		(71,182)
Total other (income) expense	(47,614)	369	(199,887)	(615)	(192,073)
Net loss	(2,194,077)	(3,253,027)	(4,151,031)	(4,451,290)	(11,206,054)
Preferred stock dividends (including imputed amounts)	(102,273)		(495,078)		(913,260)

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Net loss applicable to common shares	\$ (2,296,350)	\$ (3,253,027)	\$ (4,646,109)	\$ (4,451,290)	\$ (12,119,314)
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Net loss per common share:

Basic and diluted	\$ (0.09)	\$ (0.14)	\$ (0.17)	\$ (0.20)
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Weighted average shares of common stock outstanding:

Basic and diluted	26,866,155	23,362,396	26,585,823	22,061,978
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See accompanying notes to unaudited condensed consolidated financial statements.

**MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)

## Condensed Consolidated Statement of Stockholders' Equity (Deficiency)

(Unaudited)

	Series A convertible preferred stock Shares	Amount	Common stock Shares	Amount	Additional paid-in capital	Subscription receivable	Deficit accumulated during development stage	Dividends payable in Series A preferred shares	Accumulated other comprehensive income/(loss)	Unearned consulting costs
Stock issued at \$0.0004 per share for subscription receivable		\$	10,167,741	\$ 10,168	\$ (6,168)	\$ (4,000)	\$	\$	\$	
Net loss							(56,796)			
Balance at December 31, 2001			10,167,741	10,168	(6,168)	(4,000)	(56,796)			
Proceeds from subscription receivable						4,000				
Stock issued at \$0.0004 per share for license rights			2,541,935	2,542	(1,542)					
Stock options issued for consulting services					60,589					(60,589)
Amortization of unearned consulting services										22,721
Sales of common stock at \$0.63 per share through private placement,										



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net of expenses			3,043,332	3,043	1,701,275		
Net loss						(1,037,320)	
Balance at December 31, 2002			15,753,008	15,753	1,754,154	(1,094,116)	(37,868)
Common stock issued at \$0.63 per share, net of expenses			1,321,806	1,322	742,369		
Effect of reverse acquisition			6,287,582	6,287	2,329,954		
Amortization of unearned consulting costs							37,868
Unrealized loss on marketable equity securities							(7,760)
Payment for fractional shares for stock combination					(300)		
Preferred stock issued, net of expenses	1,000,000	1,000			9,045,176		
Imputed preferred stock dividend					418,182	(418,182)	
Net loss						(5,960,907)	
Balance at December 31, 2003	1,000,000	1,000	23,362,396	23,362	14,289,535	(7,473,205)	(7,760)
Exercise of stock options			27,600	27	30,073		
Common stock issued through private placement at			3,368,637	3,369	3,358,349		

\$1.10 per share, net of expenses									
Conversion of preferred stock to common stock	(58,669)	(59)	533,348	533	(474)				
Preferred stock dividends paid by issuance of shares	24,901	25			281,073			(282,388)	
Preferred stock dividends accrued							(495,078)	495,078	
Warrants issued for consulting services					120,968				(120,968)
Amortization of unearned consulting costs									70,560
Reversal of unrealized loss on marketable equity securities								7,760	
Net loss							(4,151,031)		
Balance at September 30, 2004	966,232	\$ 966	27,291,981	\$ 27,291	\$ 18,079,524	\$	\$(12,119,314)	\$ 212,690	\$ (50,408)

See accompanying notes to unaudited condensed consolidated financial statements.

**MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**

(A Development Stage Company)

Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	Nine months ended September 30,		Cumulative period from August 6, 2001 (inception) to September 30, 2004
	2004	2003	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (4,151,031)	\$ (4,451,290)	\$ (11,206,054)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Common stock issued for license rights			1,000
Amortization of unearned consulting costs	70,560	37,868	131,149
Amortization of intangible assets		145,162	145,162
Gain on sale of marketable equity securities	(71,182)		(71,182)
Depreciation	15,806	4,233	22,022
Loss on impairment of intangible assets		1,248,230	1,248,230
Loss on disposition of intangible assets		1,213,878	1,213,878
<b>Changes in operating assets and liabilities, net of acquisition:</b>			
Decrease in prepaid expenses	2,291	11,298	35,555
Increase in other assets	(70,506)		(70,506)
Increase in accounts payable	838,019	271,889	1,062,879
Decrease in accrued expenses	(329,200)	(121,225)	(452,096)
Decrease in due affiliate		(96,328)	
<b>Net cash used in operating activities</b>	<b>(3,695,243)</b>	<b>(1,736,285)</b>	<b>(7,939,963)</b>
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(131,298)	(6,554)	(137,852)
Cash paid in connection with acquisition		(32,808)	(32,808)
Proceeds from sale of marketable equity securities	431,089		431,089
Proceeds from sale of license		200,001	200,001
<b>Net cash provided by investing activities</b>	<b>299,791</b>	<b>160,639</b>	<b>460,430</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuances of notes payable to stockholders			233,500
Repayments of notes payable to stockholders		(136,000)	(233,500)
Proceeds from issuance of note payable to bank			600,000
Repayment of note payable to bank		(600,000)	(600,000)
Proceeds from subscriptions receivable			4,000
Payment for fractional shares for stock combination	(1,290)	300	(990)
Proceeds from sale of common stock, net	3,361,718	692,337	5,809,126
Proceeds from sale of preferred stock, net			9,046,176

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Proceeds from exercise of stock options	30,100		30,100
Net cash provided by (used in) financing activities	3,390,528	(43,363)	14,888,412
Net increase (decrease) in cash and cash equivalents	(4,924)	(1,619,009)	7,408,879
Cash and cash equivalents at beginning of period	7,413,803	1,721,123	
Cash and cash equivalents at end of period	\$ 7,408,879	\$ 102,114	\$ 7,408,879
Supplemental disclosure of cash flow information:			
Interest paid	\$	\$ 502	\$ 26,934
Supplemental disclosure of noncash investing and financing activities:			
Issuance of common stock for acquisition	\$	\$ 2,336,242	\$ 2,336,242
Marketable equity securities received in connection with			
sale of license		359,907	359,907
Stock options/warrants issued for consulting services	120,968		181,557
Preferred stock dividends	495,078		495,078
See accompanying notes to unaudited condensed consolidated financial statements.			

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
September 30, 2004

(1) BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, the financial statements do not include all information and footnotes required by accounting principles generally accepted in the United States of America for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of only normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2004 or for any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with Amendment No.1 to the Annual Report on Form 10-KSB/A of Manhattan Pharmaceuticals, Inc. and its subsidiaries (Manhattan or the Company) as of and for the year ended December 31, 2003.

(2) LIQUIDITY

The Company reported a net loss of \$4,151,031 for the nine months ended September 30, 2004. The net loss from date of inception, August 6, 2001, to September 30, 2004 amounts to \$11,206,054.

Management believes that the Company will continue to incur net losses through at least September 30, 2005. Based on the resources of the Company available at September 30, 2004, management believes that the Company will need additional equity or debt financing or will need to generate revenues during 2005 through licensing its products or entering into strategic alliances to be able to sustain its operations through 2005 and that it will need additional financing thereafter until it can achieve profitability, if ever.

The Company's continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances and its ability to realize the full potential of its technology in development. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. Through September 30, 2004, a significant portion of the Company's financing has been through private placements of common and preferred stock. Until and unless the Company's operations generate significant revenues and cash flows from operating activities, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital previously described.

As described in Note 6, on January 13, 2004, the Company completed a private placement of 3,368,637 shares of its common stock at a per share price of \$1.10. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of approximately \$3,362,000. The Company also issued to the placement agent engaged in connection with the private placement a 5-year warrant to purchase 336,864 shares of common stock at an exercise price of \$1.10 per share.

Prior to September 2004, we had an equity-line-of-credit arrangement under which Fusion Capital had committed to purchasing \$6,000,000 of the Company's common stock. The Company's stock price is currently below the \$3.40 minimum required in order for it to be able to sell shares of its common stock to Fusion Capital, but if in the future its stock price exceeds this minimum, the Company could have elected to sell shares of its common stock to Fusion Capital under the equity-line-of-credit arrangement. In addition, in November 2001, Fusion Capital waived the \$3.40

minimum and purchased from the Company under the equity-line-of-credit arrangement 83,333 shares of its common stock at a price per share of \$1.20, representing an aggregate purchase price of \$100,000. Fusion Capital again waived the \$3.40 minimum in May 2002 and purchased 2,000 shares of common stock for an aggregate purchase price of \$1,667.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
September 30, 2004

The purchase price for the common stock to be issued to Fusion Capital under the Company's equity-line-of-credit arrangement with Fusion Capital will fluctuate based on the closing price of the Company's common stock. Fusion Capital may at any time sell none, some or all of the shares of common stock purchased from the Company. Depending upon market liquidity at the time, sale by Fusion Capital of shares the Company issues to them could cause the trading price of the Company's common stock to decline. Sale of a substantial number of shares of the Company's common stock by Fusion Capital, or anticipation of such sales, could make it more difficult for the Company to sell equity or equity related securities in the future at a time and at a price that it might otherwise wish to effect sales. The Company, having no future plans to seek financing under this arrangement, terminated the equity-line-of-credit arrangement by giving written notice to Fusion Capital on September 1, 2004.

(3) REVERSE STOCK SPLIT

On July 25, 2003, the Board of Directors adopted a resolution authorizing an amendment to the certificate of incorporation providing for a 1-for-5 combination of the Company's common stock. A resolution approving the 1-for-5 combination was thereafter consented to in writing by holders of a majority of the Company's outstanding common stock. The 1-for-5 combination became effective on September 25, 2003. Accordingly, all share and per share information in these unaudited condensed consolidated financial statements has been restated to retroactively reflect the 1-for-5 combination.

(4) COMPUTATION OF NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect because the Company incurred a net loss during each period presented. The amount of potentially dilutive securities excluded from the calculation was 16,161,738 and 4,111,935 as of September 30, 2004 and 2003, respectively.

(5) STOCK OPTIONS

On January 28, 2004, the Company granted employees options to purchase an aggregate of 1,155,000 shares of common stock under the Company's 2003 Stock Option Plan at an exercise price of \$1.65 per share. 600,000 shares subject to these options vest on January 1, 2005. 489,000 shares subject to these options vest in three equal installments starting on the grant date, provided the optionee continues in service. 66,000 shares subject to these options vest in three equal installments starting one year from the grant date, provided the optionee continues in service. On February 16, 2004, the Company granted an employee an option to purchase 13,500 shares of common stock under the Manhattan Pharmaceuticals 2003 Stock Option Plan at an exercise price of \$1.60 per share. The shares subject to this option vest in three equal installments starting one year from the grant date, provided the optionee continues in service with the Company. On September 27, 2004, the Company granted directors and employees options to purchase an aggregate of 503,500 shares of common stock under the Company's 2003 Stock Option Plan at an exercise price of \$.97 per share. 340,000 shares subject to these options vest in three equal installments starting on the grant date, provided the optionee continues in service. 163,500 shares subject to these options vest in three equal installments starting one year from the grant date, provided the optionee continues in service.





MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
September 30, 2004

The Company uses the intrinsic value method of accounting for stock options pursuant to the provisions of APB Opinion No. 25. Since all of the options granted by the Company have been at exercise prices that were at least equal to the market value at the date of grant, there were no charges to operations upon issuance. Had compensation costs been determined using the Black-Scholes option pricing model in accordance with the fair value method prescribed by SFAS No. 123 for all options issued to employees and amortized over the vesting period, the Company's net loss applicable to common shares and net loss per common share (basic and diluted) would have been increased to the pro forma amounts indicated below.

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Net loss applicable to common shares, as reported	\$ (2,296,350)	\$ (3,253,027)	\$ (4,646,109)	\$ (4,451,290)
Deduct: Total stock-based employee compensation expense determined under fair value method	(432,923)	(74,763)	(997,211)	(228,210)
Net loss applicable to common shares, pro forma	\$ (2,729,273)	\$ (3,327,790)	\$ (5,643,320)	\$ (4,679,500)
Net loss per common share - basic				
As reported	\$ (0.09)	\$ (0.14)	\$ (0.17)	\$ (0.20)
Pro forma	(0.10)	(0.14)	(0.21)	(0.21)

The fair value of each option granted is estimated on the date of the grant using the Black-Scholes option pricing model with the following weighted average assumptions used for the grants in the nine months ended September 30, 2004: dividend yield of 0%; expected volatility of 82%; risk-free interest rate of 3.2%; and expected lives of eight years. The following assumptions were used for the grants in the nine months ended September 30, 2003: dividend yield of 0%, expected volatility of 147%, risk-free interest rate of 3.5%, and expected lives of eight years.

(6) PRIVATE PLACEMENT OF COMMON SHARES

On January 13, 2004, the Company completed a private placement of 3,368,637 shares of its common stock at a per share price of \$1.10. After deducting commissions and other expenses relating to the private placement, the Company received aggregate net proceeds of approximately \$3,362,000. The Company also issued to the placement agent engaged in connection with the private placement a 5-year warrant to purchase 336,864 shares of common stock at an exercise price of \$1.10 per share.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
September 30, 2004

The proceeds from the private placement are being used to fund clinical and non-clinical research and development, and for working capital and general corporate purposes. Paramount BioCapital, Inc., acted as the placement agent in connection with the private placement and received fees of \$261,404. At the time of this private placement, three of the Company's directors were employees of Paramount BioCapital, Inc. and, currently, two directors of the Company are employed by Paramount BioCapital.

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

**You should read the following discussion of our results of operations and financial condition in conjunction with Amendment No.1 to our Annual Report on Form 10-KSB/A for the year ended December 31, 2003 (the Annual Report ). This discussion includes forward-looking statements that reflect our current views with respect to future events and financial performance. We use words such as we expect, anticipate, believe, and intend and similar expressions to identify forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties inherent in future events, particularly those risks identified in the Risk Factors section of the Annual Report, and should not unduly rely on these forward looking statements. All share and per share information in this discussion has been adjusted for a 1-for-5 combination effective September 25, 2003.**

**RESULTS OF OPERATIONS**

**THREE-MONTH PERIOD ENDED SEPTEMBER 30, 2004 VS. 2003**

During the quarters ended September 30, 2004 and 2003, we had no revenue. We do not expect to have significant revenues relating to our product candidates prior to September 30, 2005.

For the quarter ended September 30, 2004, research and development expense was \$1,678,939 as compared to \$377,820 for the third quarter of 2003. The increase of \$1,301,119 is due primarily to an acceleration of pre-clinical development of our Oleoyl-estrone drug candidate and to the pre-clinical and clinical development of our Propofol Lingual Spray product candidate.

For the quarter ended September 30, 2004, general and administrative expense was \$562,752 as compared to \$412,730 for the quarter ended September 30, 2003. The increase of \$150,022 is due primarily to increases in payroll and consulting of approximately \$78,000 and investor relations expenses of approximately \$51,000. In addition we had an increase in expenses associated with scientific meetings, presentations and related travel of \$25,000, as well as increases in expenses related to hiring two new employees, rent, printing and other expenses of \$32,000, \$16,000, \$11,000 and \$20,000, respectively. These increases are partially offset by a reduction in legal and accounting fees of approximately \$43,000. Finally, in 2003 we had amortization of intangible assets of approximately \$40,000, which we did not have in the current year.

For the quarter ended September 30, 2004, interest and other income was \$47,614 as compared to interest and other expense of \$369 for the quarter ended September 30, 2003. The increase of \$47,983 is a result of an increase in cash balances.

Net loss for the quarter ended September 30, 2004 was \$2,194,077, as compared to \$3,253,027 for the quarter ended September 30, 2003. This decrease in net loss is attributable primarily to losses in 2003 on the disposition of intangible assets as a result of our sale of our remaining rights to CT-3 to Indevus Pharmaceuticals, Inc. of \$1,213,878 as well as an impairment of intangible assets of \$1,248,230 as a result of a decision by Bausch & Lomb not to pursue the Avantix cataract removal technology. This decrease in net loss is partially offset by an increase in research and development expenses of \$1,301,119 and an increase in general and administrative expenses of \$150,022. These expense increases are partially offset by an increase in interest and other income of \$47,983.

Preferred stock dividends of \$102,273 did not affect the loss per common share for the quarter ended September 30, 2004. There were no preferred stock dividend requirements in 2003.

#### NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2004 VS. 2003

During the nine months ended September 30, 2004 and 2003, we had no revenue. We do not expect to have significant revenues relating to our technologies prior to September 30, 2005.

For the nine months ended September 30, 2004, research and development expense was \$2,907,173, as compared to \$734,351 for the nine months ended September 30, 2003. The increase of \$2,172,822 is due primarily to an acceleration of pre-clinical development of our Oleoyl-estrone drug and to the pre-clinical and clinical development of our Propofol Lingual Spray product candidate.

For the nine months ended September 30, 2004, general and administrative expense was \$1,443,745 as compared to \$1,255,446 for the nine months ended September 30, 2003. The increase of \$188,299 is due primarily to increases in payroll and consulting expenses of approximately \$123,000, and investor relations expenses of approximately \$113,000. In addition, we had increases in expenses associated with scientific meetings and presentations of approximately \$59,000 and travel of approximately \$44,000 as well as expenses related to hiring new employees and other expenses of \$33,000 and \$46,000 respectively. These increases are partially offset by reductions in legal and accounting fees of approximately \$85,000. Finally, in 2003 we had amortization of intangible assets of approximately \$145,000 which we did not have in the current year.

For the nine months ended September 30, 2004, interest and other income was \$199,887, as compared to \$615 for the nine months ended September 30, 2003. The increase of \$200,502 is a result of an increase in cash balances.

Net loss for the nine months ended September 30, 2004, was \$4,151,031 as compared to \$4,451,290 for the nine months ended September 30, 2003. This decrease in net loss is attributable primarily to losses in 2003 on the disposition of intangible assets as a result of our sale of our remaining rights to CT-3 to Indevus Pharmaceuticals, Inc. of \$1,213,878 as well as an impairment of intangible assets of \$1,248,230 as a result of a decision by Bausch & Lomb not to pursue the Avantix cataract removal technology. This decrease in net loss is partially offset by an increase in research and development expenses of \$2,172,822 and an increase in general and administrative expenses of \$188,299. These expense increases are partially offset by an increase in interest and other income of \$200,502.

Preferred stock dividends of \$495,078 reduced earnings per common share for the nine months ended September 30, 2004 by \$0.02. There were no preferred stock dividend requirements in 2003.

#### LIQUIDITY AND CAPITAL RESOURCES

From inception to September 30, 2004, we have incurred an accumulated deficit of \$12,119,314 primarily as a result of losses, and we expect to continue incurring additional losses at least through September 30, 2005 and for the foreseeable future. These losses have been incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity financings and our licensing and sale of residual royalty rights of CT-3 to Indevus. During the nine months ended September 30, 2004, we had a net decrease in cash and cash equivalents of \$4,924. This decrease resulted from net cash provided by financing activities of \$3,390,528, substantially all of which was from the private placement of 3,368,637 shares of common stock at \$1.10 per share and from net cash provided by investing activities of \$299,791 which included proceeds from the sale of marketable equity securities of \$431,089, offset by net cash used in operating activities of \$3,695,243 for the nine

months ended September 30, 2004. Total cash resources as of September 30, 2004 were \$7,408,879 compared to \$7,413,803 at December 31, 2003. In addition, during the nine months ended September 30, 2004, we accrued a non-cash preferred stock dividend of \$495,078.

Prior to September 2004, we had an equity-line-of-credit arrangement under which Fusion Capital had committed to purchasing \$6,000,000 of our common stock. Our stock price is currently below the \$3.40 minimum required in order for us to be able to sell shares of our common stock to Fusion Capital, but if in the future our stock price exceeds this minimum, we could have elected to sell shares of our common stock to Fusion Capital under the equity-line-of-credit arrangement. In addition, in November 2001, Fusion Capital waived the \$3.40 minimum and purchased from us under the equity-line-of-credit arrangement 83,333 shares of our common stock at a price per share of \$1.20, representing an aggregate purchase price of \$100,000. Fusion Capital again waived the \$3.40 minimum in May 2002 and purchased 2,000 shares of common stock for an aggregate purchase price of \$1,667.

The purchase price for the common stock to be issued to Fusion Capital under our equity-line-of-credit arrangement with Fusion Capital will fluctuate based on the closing price of our common stock. Fusion Capital may at any time sell none, some or all of the shares of common stock purchased from us. Depending upon market liquidity at the time, sale by Fusion Capital of shares we issue to them could cause the trading price of our common stock to decline. Sale of a substantial number of shares of our common stock by Fusion Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity related securities in the future at a time and at a price that it might otherwise wish to effect sales. In September 2004, we terminated our agreement with Fusion Capital.

In April 2003, we entered into a license and development agreement with NovaDel Pharma, Inc. ( NovaDel ), under which we received certain worldwide, exclusive rights to develop and commercialize products related to NovaDel's proprietary lingual spray technology for delivering propofol for pre-procedural sedation. Under the terms of this agreement, we agreed to use commercially reasonable efforts to develop and commercialize the licensed products, to obtain necessary regulatory approvals and to thereafter exploit the licensed products. The agreement also provides that NovaDel will undertake to perform, at our expense, a substantial portion of the development activities, including without limitation, preparation and filing of various applications with applicable regulatory authorities.

In consideration of the license, we are required to make certain license and milestone payments. Specifically, we were required to pay a \$500,000 license fee at such time as we had completed a financing transaction resulting in aggregate gross proceeds of at least \$10,000,000. Accordingly, upon completion of our sale of \$10,000,000 of our Series A Convertible Preferred Stock in November 2003, we paid and expensed the \$375,000 balance of the license fee, having paid \$125,000 in June 2003.

We are also required to make various milestone payments to NovaDel under the license agreement as follows: \$1,000,000 payable following the date that the first filed New Drug Application ( NDA ) for lingual spray propofol is accepted for review by the FDA; \$1,000,000 following the date that the first European Marketing Application is accepted for review by any European Union country; \$2,000,000 following the date when the first filed NDA for lingual spray propofol is approved by the FDA; \$2,000,000 following the date when the first filed European Marketing Application for lingual spray propofol is approved by a European Union country; \$1,000,000 following the date on which an application for commercial approval of lingual spray propofol is approved by the appropriate regulatory authority in each of Australia, Canada, Japan and South Africa; and \$50,000 following the date on which an application for commercial approval for lingual spray propofol is approved in any other country (other than the U.S. or a member of the European Union).

In addition, we are obligated to pay to NovaDel an annual royalty based on a fixed rate of net sales of licensed products, or if greater, the annual royalty is based on our net profits from the sale of licensed products at a rate that is twice the net sales rate. In the event we sublicense the licensed product to a third party, we are obligated to pay royalties based on a fixed rate of fees or royalties received from the sublicensee until such time as we recover our out-of-pocket costs, and thereafter the royalty rate doubles. Because of the continuing development efforts required of NovaDel under the agreement, the royalty rates are substantially higher than customary for the industry.

NovaDel may terminate the agreement (i) upon 10 days' notice if we fail to make any required milestone or royalty payments, or (ii) if we become bankrupt or if a petition in bankruptcy or insolvency is filed and not dismissed within 60 days or if we become subject to a receiver or trustee for the benefit of creditors. Each party may terminate the agreement upon 30 days' written notice and an opportunity to cure in the event the other party committed a material breach or default. We may also terminate the agreement for any reason upon 90 days' notice to NovaDel.

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned pre-clinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in our existing collaborative and licensing relationships, the resources that we devote to developing manufacturing and commercializing capabilities, technological advances, the status of our competitors, our ability to establish collaborative arrangements with other organizations and our need to purchase additional capital equipment.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing, other collaborative agreements, strategic alliances, and our ability to realize the full potential of our technology in development. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Through September 30, 2004, a significant portion of our financing has resulted from private placements of common stock and warrants. Unless our operations generate significant revenues and cash flows from operating activities, we will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Management believes that we will continue to incur net losses for the foreseeable future. Based on the resources available to us at September 30, 2004, management believes that we will need additional equity or debt financing or will need to generate revenues during 2005 through licensing our products or entering into strategic alliances to be able to sustain our operations through 2005 and we will need additional financing thereafter until we can achieve profitability, if ever.

## RESEARCH AND DEVELOPMENT PROJECTS

***Oleoyl-estrone.*** In December 2003, we submitted to the FDA a pre Investigational New Drug, or IND, information package about our oleoyl-estrone development program. Utilizing the FDA's review of the pre-IND application, we have completed the design of the balance of the preclinical program for oleoyl-estrone, and are currently assembling the IND application while we complete the remaining toxicology and pharmacology studies. We expect to file the IND application by the end of 2004, assuming no unexpected findings are made during the balance of the preclinical studies. Following the FDA's allowance of our IND application, we intend to immediately begin the Phase I human program in 2005. Under our license agreement with Oleoyl-Estrone Developments, we will be required to make a \$250,000 milestone payment upon the treatment of the first patient in a U.S. Phase I trial under a company sponsored IND. Given the uncertainties inherent in early human clinical trials, it is difficult to predict with accuracy when the Phase I program will be completed and, consequently, the timing of subsequent clinical trial programs and any eventual approval by the FDA.





Through September 30, 2004, we have incurred \$3,047,570 of project costs related to our development of oleoyl-estrone, of which \$756,054 was incurred in fiscal 2003, and \$1,566,119 has been incurred in the first nine months of 2004. Currently, we anticipate that we will need to expend approximately an additional \$1,000,000 in development costs in fiscal 2004. Since oleoyl-estrone is regarded by the FDA as a new chemical entity, we are not currently able to predict the final size and the design of all Phase I studies at this time and, accordingly, we cannot currently estimate the total costs of completing development of oleoyl-estrone.

Although we currently have sufficient capital to fund our anticipated 2004 R&D expenditures relating to oleoyl-estrone, we will need to raise additional capital in order to complete the anticipated five or six year development program for the product. If we are unable to raise such additional capital, we may have to sublicense our rights to oleoyl-estrone to a third party as a means of continuing development, or, although less likely, we may be required to abandon further development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

In addition to raising additional capital, whether we are successful in developing oleoyl-estrone is dependent on numerous other factors, including unforeseen safety issues, lack of effectiveness, significant unforeseen delays in the clinical trial and regulatory approval process, both of which could be extremely costly, and inability to monitor patients adequately before and after treatments. The existence of any of these factors could increase our development costs or make successful completion of development impractical, which would have a material adverse effect on the prospects of our business.

***Lingual Spray Propofol.*** We are currently working with NovaDel to develop, manufacture and commercialize a propofol lingual spray. On July 14, 2004, we announced the results of the first human trial for lingual spray propofol, which was conducted in Wales, United Kingdom by Simbec Research Ltd. The study, which took place from February 9, 2004 to February 27, 2004, was equivalent to a Phase I safety, tolerability and pharmacokinetic study that would occur in the United States. The study was conducted on 20 healthy adult volunteers and its primary objectives were to compare the safety and tolerability of three dose levels of propofol spray to a single intravenous bolus (meaning a concentrated dose given over a short time period) low dose of propofol, as well as to determine the respective pharmacokinetic profiles and relative bioavailability of three escalating doses. Pharmacokinetic profiles reveal the manner in which a drug acts in the body over a given period of time. Bioavailability measures the degree to which a substance is available to be absorbed into the body. No serious adverse events, nor dose-dependent changes in vital signs, occurred. The mean time to maximum blood concentration of propofol following spray was approximately 30 minutes across all doses, and propofol was detectable in blood as early as 4 minutes following spray administration. The mean maximum blood concentrations plateaued at the highest of the three doses tested, and the mean bioavailability of the current spray formulation was up to 18 percent of that of the intravenous formulation. We do not expect that the results of this study can be used to satisfy FDA requirements for approval of lingual spray propofol in the United States and the study was not conducted as a substitute for studies required in the U.S. to obtain FDA approval. Rather, the trial provided us with supplemental safety and tolerability data that will be useful in designing our U.S. development plan.

We cannot begin to conduct human trials for lingual spray propofol in the United States until we submit an IND application with the FDA. We expect to file an IND with the FDA toward the end of 2004, assuming no unanticipated findings are made during the balance of the formulation and toxicology studies that will precede the filing of the IND. To date, the FDA has expressed support for our objective to pursue a bioequivalence strategy for development. We are planning Phase I studies and, if necessary, Phase II studies to occur in the United States during the first half of 2005 following IND issuance. We expect that pivotal Phase III trials will follow should bioequivalence be demonstrated, depending on the duration and outcome of the Phase I trials and, if necessary, Phase II trials. Based upon our current estimates of the schedule for development of propofol lingual spray, and submission and approval of a marketing application, we anticipate that we may begin receiving revenues from propofol lingual spray in 2006. Such an estimate is subject to numerous risks, however, including unforeseen delays in clinical development or in the regulatory approval process, unforeseen safety issues, and lack of effectiveness during the clinical trials. See also the risks identified under the section entitled "Risk Factors" in our Annual Report.

Through September 30, 2004 we have incurred \$2,309,042 of project costs related to our development of propofol lingual spray, of which \$967,989 was incurred in fiscal 2003 and \$1,341,053 was incurred during the first nine months of 2004. Currently, we anticipate that we will need to expend approximately an additional \$250,000 in development costs in fiscal 2004 and at least an aggregate of approximately \$3,000,000 to \$5,000,000 until we receive FDA approval for propofol, should we opt to continue development until then, including anticipated 2004 costs. As with our development of oleoyl-estrone, we believe we currently have sufficient capital to fund our development activities of propofol lingual spray during 2004 and 2005. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2005. We expect to raise such additional capital through debt financings or by selling shares of our capital stock. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to propofol lingual spray or abandon our development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

### **Item 3. Controls and Procedures**

As of September 30, 2004, we carried out an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in alerting them on a timely basis to material information required to be disclosed in our periodic reports to the Securities and Exchange Commission. During the quarter ended September 30, 2004, there were no significant changes in our internal controls over financial reporting that have significantly affected, or are reasonably likely to significantly affect, our internal controls over financial reporting subsequent to such evaluation.

**PART II - OTHER INFORMATION****Item 4. Submission of Matters to a Vote of Security Holders.**

The 2004 Annual Meeting of Stockholders was held at the Sheraton Manhattan Hotel, 790 Seventh Avenue, New York, New York on August 20, 2004. The stockholders took the following actions:

(i) The stockholders elected nine directors to serve until the next Annual Meeting of Stockholders. The stockholders present in person or by proxy cast the following numbers of votes in connection with the election of directors, resulting in the election of all nominees:

<u>Nominee</u>	<u>Votes For</u>	<u>Votes Withheld</u>
Leonard Firestone, M.D.	22,881,683	72,548
Neil Herskowitz	22,867,288	86,943
Malcolm Hoenlein	22,881,723	72,508
Joshua Kazam	22,670,178	284,053
Timothy McInerney	22,684,653	269,578
Joan Pons Gimbert	22,881,643	72,588
Richard I. Steinhart	22,867,288	86,943
David M. Tanen	22,883,554	70,677
Michael Weiser, M.D.	22,881,913	72,318

(ii) The stockholders ratified and approved the Company's 2003 Stock option Plan. 17,537,956 votes were cast for the proposal; 865,934 votes were cast against the proposal; 8,505 votes abstained; and there were 4,541,836 broker non-votes.

(iii) The stockholders ratified the appointment of J.H. Cohn LLP as the Company's independent registered public accounting firm for fiscal 2004. 22,931,196 votes were cast for the proposal; 20,065 votes were cast against the proposal, shares representing 2,970 votes abstained; and there were no broker non-votes.

**Item 6. Exhibits and Reports on Form 8-K**

(a)	<u>Exhibit No.</u>	<u>Description</u>
	31.1	Certification of Chief Executive Officer
	31.2	Certification of Chief Financial Officer

32.1 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

None.



**SIGNATURES**

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MANHATTAN PHARMACEUTICALS, INC.

Date: November 15, 2004

By: /s/ Leonard Firestone

\_\_\_\_\_  
Leonard Firestone  
President and Chief Executive Officer

Date: November 15, 2004

By: /s/ Nicholas J. Rossettos

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Nicholas J. Rossettos  
Chief Financial Officer and Chief Operating Officer

**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>
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31.1	Certification of Chief Executive Officer
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31.2	Certification of Chief Financial Officer
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32.1 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.