

MANHATTAN PHARMACEUTICALS INC  
Form 10QSB  
May 14, 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 March 31, 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.)

787 Seventh Avenue, 48th Floor, New York, New York 10019  
(Address of principal executive offices)

(212) 554-4525  
(Issuer's telephone number)

(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 May 10, 2004 there were 26,741,033 shares of the issuer's common stock, \$.001 par value, outstanding.

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**Forward-Looking Statements**

This Quarterly Report on Form 10-QSB contains statements that are not historical but are forward-looking in nature, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. In particular, the Management's Discussion and Analysis of Financial Condition and Results of Operations section in Item 2 of Part I of this Quarterly Report include 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 subsection entitled Risk Factors following Item 1 of our Amendment No. 1 to our Annual Report on Form 10-KSB/A, and should not unduly rely on these 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	March 31,	December 31,
	2004	2003
<b>Current assets:</b>		
Cash and cash equivalents	\$ 9,543,071	\$ 7,413,803
Marketable equity securities, available for sale, at market	361,100	352,147
Prepaid expenses	14,336	24,981
<b>Total current assets</b>	<b>9,918,507</b>	<b>7,790,931</b>
Property and equipment, net	39,561	8,021
<b>Total assets</b>	<b>\$ 9,958,068</b>	<b>\$ 7,798,952</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 569,445	\$ 548,595
Accrued expenses	188,341	417,425
<b>Total liabilities</b>	<b>757,786</b>	<b>966,020</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' equity :</b>		
Series A convertible preferred stock, \$.001 par value. Authorized 10,000,000 shares; 1,000,000 shares issued and outstanding (liquidation preference aggregating \$10,000,000)	1,000	1,000
Common stock, \$.001 par value. Authorized 150,000,000 shares; 26,741,033 and 23,362,396 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	26,741	23,362
Additional paid-in capital	17,850,789	14,289,535
Deficit accumulated during development stage	(8,780,676)	(7,473,205)
Dividends payable in Series A preferred shares	212,123	
Accumulated other comprehensive income (loss)	1,193	(7,760)
Unearned consulting services	(110,888)	
<b>Total stockholders' equity</b>	<b>9,200,282</b>	<b>6,832,932</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 9,958,068</b>	<b>\$ 7,798,952</b>



See accompanying notes to unaudited condensed consolidated financial statements.



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

Condensed Consolidated Statements of Operations  
(Unaudited)

	Three Months ended March 31,		Cumulative period from August 6, 2001 (inception) to March 31, 2004
	2004	2003	
Revenue	\$	\$	\$
Costs and expenses:			
Research and development	709,273	43,355	3,158,713
General and administrative	413,238	378,872	2,548,899
Impairment of intangible assets			1,248,230
Total operating expenses	1,122,511	422,227	6,955,842
Operating loss	(1,122,511)	(422,227)	(6,955,842)
Other (income) expense:			
Interest and other income	(27,163)	(2,515)	(43,242)
Interest expense		2,233	23,893
Loss on disposition of intangible assets			1,213,878
Total other (income) expense	(27,163)	(282)	1,194,529
Net loss	(1,095,348)	(421,945)	(8,150,371)
Preferred stock dividends (including imputed amounts)	(212,123)		(630,305)
Net loss applicable to common shares	\$ (1,307,471)	\$ (421,945)	\$ (8,780,676)
Net loss per common share:			
Basic and diluted	\$ (0.05)	\$ (0.02)	
Weighted average shares of common stock outstanding:			
Basic and diluted	26,145,361	19,417,795	

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		Common stock		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	Total stock holders' equity (deficiency)
	Shares	Amount	Shares	Amount							
Stock issued at \$0.0004 per share for subscription receivable		\$ 10,167,741	\$10,168		\$(6,168)	\$(4,000)		\$		\$	\$
Net loss						(56,796)					(56,796)
Balance at December 31, 2001		10,167,741	10,168		(6,168)	(4,000)	(56,796)				(56,796)
Proceeds from subscription receivable						4,000					4,000
Stock issued at \$0.0004 per share for license rights		2,541,935	2,542		(1,542)						1,000
Stock options issued for consulting services					60,589				(60,589)		
Amortization of unearned consulting services									22,721		22,721
Sales of common stock at \$0.63 per share through private placement, net of expenses		3,043,332	3,043	1,701,275							1,704,318
Net loss						(1,037,320)					(1,037,320)
Balance at December 31, 2002		15,753,008	15,753	1,754,154		(1,094,116)				(37,868)	637,923

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Common stock issued at \$0.63 per share, net of expenses	1,321,806	1,322	742,369					743,691	
Effect of reverse acquisition	6,287,582	6,287	2,329,954					2,336,241	
Amortization of unearned consulting costs							37,868	37,868	
Unrealized loss on marketable equity securities						(7,760)		(7,760)	
Payment for fractional shares for stock combination			(300)					(300)	
Preferred stock issued, net of expenses	1,000,000	1,000	9,045,176					9,046,176	
Imputed preferred stock dividend			418,182		(418,182)				
Net loss					(5,960,907)			(5,960,907)	
<hr/>									
Balance at December 31, 2003	1,000,000	1,000	23,362,396	23,362	14,289,535	(7,473,205)	(7,760)	6,832,932	
<hr/>									
Exercise of stock options		10,000	10	12,490				12,500	
Common stock issued at \$1.10 per share, net of expenses		3,368,637	3,369	3,427,796				3,431,165	
Preferred stock dividends					(212,123)	212,123			
Warrants issued for consulting services				120,968			(120,968)		
Amortization of unearned consulting costs							10,080	10,080	
Unrealized gain on marketable equity securities						8,953		8,953	
Preferred Stock Dividends									
Net loss					(1,095,348)			(1,095,348)	
<hr/>									
	1,000,000	\$1,000	26,741,033	\$26,741	\$17,850,789	\$ (8,780,676)	\$212,123	\$1,193 \$(110,888)	\$9,200,282

Balance at  
March 31,  
2004

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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)

	Three months ended March 31,		Cumulative period from August 6, 2001 (inception) to
	2004	2003	March 31, 2004
<b>Cash flows from operating activities:</b>			
Net loss	\$ (1,095,348)	\$ (421,945)	\$ (8,150,371)
<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	10,080	15,147	70,669
Amortization of intangible assets		26,393	145,162
Depreciation	2,452	478	8,668
Loss on impairment of intangible assets			1,248,230
Loss on disposition of intangible assets			1,213,878
<b>Changes in operating assets and liabilities, net of acquisition:</b>			
Decrease (increase) in prepaid expenses	10,645	(16,441)	43,909
Increase (decrease) in accounts payable	20,850	(14,929)	245,710
Decrease in accrued expenses	(229,084)	(36,715)	(351,980)
Decrease in due affiliate		(96,328)	
<b>Net cash used in operating activities</b>	<b>(1,280,405)</b>	<b>(544,340)</b>	<b>(5,525,125)</b>
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(33,992)	(5,066)	(40,546)
Cash paid in connection with acquisition		(32,808)	(32,808)
Proceeds from sale of license			200,001
<b>Net cash (used in) provided by investing activities</b>	<b>(33,992)</b>	<b>(37,874)</b>	<b>126,647</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuances of notes payable to stockholders		(136,000)	233,500
Repayments of notes payable to stockholders			(233,500)
Proceeds from issuance of note payable to bank		(600,000)	600,000
Repayment of note payable to bank			(600,000)
Proceeds from subscriptions receivable		743,691	4,000
Payment for fractional shares for stock combination			300
Proceeds from sale of common stock, net	3,431,165		5,878,573
Proceeds from sale of preferred stock, net			9,046,176
Proceeds from exercise of stock options	12,500		12,500
<b>Net cash provided by financing activities</b>	<b>3,443,665</b>	<b>7,691</b>	<b>14,941,549</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>2,129,268</b>	<b>(574,523)</b>	<b>9,543,071</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>7,413,803</b>	<b>1,721,123</b>	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 9,543,071</b>	<b>\$ 1,146,600</b>	<b>\$ 9,543,071</b>

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<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$	\$ 502	\$ 26,934
<b>Supplemental disclosure of noncash investing and financing activities:</b>			
Stock options issued for consulting services	\$		\$ 60,589
Issuance of common stock for acquisition		2,336,242	2,336,242
Marketable equity securities received in connection with sale of license			359,907

See accompanying notes to unaudited condensed consolidated financial statements.

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

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) March 31, 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 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 has reported a net loss of \$1,095,348 for the three months ended March 31, 2004. The net loss from date of inception, August 6, 2001, to March 31, 2004 amounts to \$8,150,371.

Management believes that the Company will continue to incur net losses through at least March 31, 2005. Based on the resources of the Company available at March 31, 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 March 31, 2004, a significant portion of the Company's financing has been through private placements of common and preferred stock and debt financing. 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 aggregate net proceeds of approximately \$3,431,000. 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 a price of \$1.10 per share.

Under an equity-line-of-credit arrangement, Fusion Capital has 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, but if in the future its stock price exceeds this minimum, the Company may elect to sell shares of its common stock to Fusion 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.

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

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) March 31, 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 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, 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 currently has no plans to seek financing under this arrangement.

#### (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. 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 proposed 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 15,533,533 and 4,151,535 as of March 31, 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 Manhattan Pharmaceuticals 2003 Stock Option Plan at an exercise price of \$1.65 per share. 600,000 of these options vest on January 1, 2005. An aggregate of 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.

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
March 31, 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. There were no options granted during the first quarter of 2003.

	<b>Three months ended March 31, 2004</b>	<b>Three months ended March 31, 2003</b>
Net loss, as reported	\$ (1,095,348)	\$ (421,945)
Deduct: Total stock-based employee compensation expense determined under fair value method	(282,168)	(57,603)
Net loss, pro forma	\$ (1,377,516)	\$ (479,548)
Net loss per common share - basic		
As reported	\$ (0.04)	\$ (0.00)
Pro forma	(0.05)	(0.00)

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 assumptions used for the grants in the three months ended March 31, 2004 and 2003, respectively: dividend yield of 0%; expected volatility of 82%; risk-free interest rate of 3.2%; and expected lives of eight years for each period presented.

(6) PRIVATE PLACEMENT OF COMMON AND PREFERRED 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 \$3,431,000. The Company also issued to the placement agent engaged in connection with the private placement a 5-year warrant to purchase 326,499 shares of common stock at a price of \$1.10 per share.

The proceeds from the private placement will be used to fund clinical and non-clinical research and development, working capital and general corporate purposes. Paramount BioCapital, Inc., acted as the placement agent in connection with the private placement. Three of the Company's Directors are also employees of Paramount BioCapital, Inc., a related party.

On November 7, 2003, the Company completed a private placement of 1,000,000 shares of its newly-designated Series A Convertible Preferred Stock at a price of \$10 per share, resulting in gross proceeds to the Company of \$10,000,000 (net proceeds of \$9,046,176). Each share of Series A Convertible Preferred Stock is convertible at the holder's election into shares of the company's common stock at a conversion price of \$1.10 per share. In addition, each share at the option of the holders is convertible into 9.09 shares of common stock. The Series A Convertible Preferred Stock has a payment-in-kind dividend of 5 percent payable semi-annually. Accordingly, at March 31, 2004, the Company recorded a preferred stock dividend of \$212,123.

**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 our Annual Report on Form 10-KSB for the year ended December 31, 2003. 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 on Form 10-KSB, 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 MARCH 31, 2004 VS. 2003

During the quarters ended March 31, 2004 and 2003, we had no revenue. We do not expect to have significant revenues relating to our technologies within the next twelve months.

For the quarter ended March 31, 2004, research and development expense was \$709,273 as compared to \$43,355 for the first quarter of 2003. The increase of \$665,918 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.

For the quarter ended March 31, 2004, general and administrative expense was \$413,238 as compared to \$378,872 for the quarter ended March 31, 2003. The increase of \$34,366 is due primarily to an increase in payroll expenses of approximately \$84,000 and an increase in insurance and other expenses of approximately \$33,000 and \$2,000 respectively. These increases are partially offset by decreases in legal, accounting and amortization expenses of approximately \$38,000, \$31,000 and \$26,000 respectively.

For the quarter ended March 31, 2004, interest income was \$27,163 as compared to \$2,515 for the quarter ended March 31, 2003. The increase of \$24,648 is a result of an increase in cash balances.

Net loss for the quarter ended March 31, 2004, was \$1,095,348 as compared to \$421,945 for the quarter ended March 31, 2003. This increase in net loss is attributable primarily to an increase in research and development expenses of \$665,918 and an increase in general and administrative expenses of \$34,366. These expense increases are partially offset by an increase in interest income of \$24,648.

LIQUIDITY AND CAPITAL RESOURCES

From inception to March 31, 2004, we incurred an accumulated deficit of \$8,780,676 primarily as a result of losses, and we expect to continue to incur additional losses at least through March 31, 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 and debt financing and our licensing and sale of residual royalty rights of CT-3 to Indevus. During the quarter ended March 31, 2004, we had a net increase in cash and cash equivalents of \$2,129,268. This increase primarily resulted from net cash provided by financing activities of \$3,443,665, substantially all of which was from the private placement of 3,368,637 shares of common stock at \$1.10 per share, offset by net cash used in operating activities of \$1,280,405 for the quarter ended March 31, 2004. Total cash resources as of March 31, 2004 were \$9,543,071 compared to \$7,413,803 at December 31, 2003.

Under an equity-line-of-credit arrangement, Fusion Capital has 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, but if in the future our stock price exceeds this minimum, we may elect to sell shares of our common stock to Fusion 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 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, 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. We currently have no plans to seek financing under this arrangement.

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 our 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.

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 Investigational New Drug ("IND") application 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 New Drug Application ("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 March 31, 2004, a significant portion of our financing has been through private placements of common stock and warrants and debt financing. 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 March 31, 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 the United States 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 Phase I trial. 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.



To date, we have incurred \$1,744,135 of project costs related to our development of oleoyl-estrone, of which \$756,054 was incurred in fiscal 2003, and \$262,684 has been incurred in the first quarter of 2004. Currently, we anticipate that we will need to expend approximately an additional \$1,500,000 to \$2,500,000 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 size and the design of the Phase I study 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. See also **Risk Factors** in this prospectus. 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 affect on the prospects of our business.

**Lingual Spray Propofol.** We are currently working with NovaDel to develop, manufacture and commercialize a propofol lingual spray. We expect to file an IND 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/II studies to occur 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/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 on Form 10-KSB for the year ended December 31, 2003.

To date, we have incurred \$1,414,578 of project costs related to our development of propofol lingual spray, of which \$967,989 was incurred in fiscal 2003 and \$446,589 was incurred during the first quarter of 2004. Currently, we anticipate that we will need to expend an additional \$1,500,000 to \$2,500,000 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.

#### RECENTLY ISSUED ACCOUNTING STANDARDS

In June 2002, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No.146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ( EITF ) issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit and Activity. SFAS No. 146 requires that liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. This statement also established that fair value is the objective for initial measurement of the liability. The provisions of SFAS No. 146 are effective for exit or disposal activities that initiated after December 31, 2002. The adoption of SFAS No. 146 did not have a material impact on our consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet. The Company does not have any financial instruments with such characteristics.

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

As of March 31, 2004, we carried out an evaluation, under the supervision and with the participation of our chief executive 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 March 31, 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 2. Changes in Securities.**

On January 12, 2004, the Company issued 3,368,637 shares of common stock at a price of \$1.10 per share. The Company engaged Paramount BioCapital, Inc. as a placement agent in connection with the private placement, paying an aggregate commission of approximately \$251,000, plus non-accountable expenses of \$10,000. The Company also issued to the placement agent a warrant to purchase 326,499 shares of common stock exercisable at a price of \$1.10 per share. The offer and sale of the shares of common stock and the placement agent warrants did not involve any general solicitation and was made solely to accredited investors, and was, therefore, exempt from the registration requirements of the Securities Act of 1933 pursuant to Section 4(2) and Rule 506 promulgated thereunder.

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

(a) Exhibits

Exhibit No.    Description

- |      |  |
|------|--|
| 4.1  | Form of warrant issued January 12, 2004 to Paramount BioCapital, Inc. as compensation for placement agency services rendered in connection with the Company's January 2004 private placement (incorporated by reference to Exhibit 4.18 to the Company's Form SB-2 filed January 13, 2004 (File No. 333- 111897)). |
| 10.1 | Employment Agreement dated January 2, 2004 between the Company and Dr. Leonard Firestone (incorporated by reference to Exhibit 10.10 to the Company's Form SB-2 filed January 13, 2004 (File No. 333- 111897)).  |
| 31.1 | Certification of Chief Executive Officer   |
| 31.2 | Certification of Chief Financial Officer   |
| 32.1 | Certifications of Chief Executive 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.

**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>
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<u>31.2</u>	<u>Certification of Chief Financial Officer</u>
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