

MANHATTAN PHARMACEUTICALS INC  
Form 10-Q  
November 19, 2008

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

**FORM 10-Q**

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

For the quarterly period ended September 30, 2008

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 001-32639

**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.)

48 Wall Street, New York, New York 10005  
(Address of principal executive offices)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act).  
Yes  No

As of November 1, 2008 there were 70,624,232 shares of the issuer's common stock, \$.001 par value, outstanding.

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### Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities and Exchange Act of 1934. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “expect,” “may,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. These statements are therefore subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate to, among other factors:

- the development of our drug candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- acceptance of our products by doctors, patients or payers;
- our ability to market any of our products;
- our history of operating losses;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel;
- availability of reimbursement for our product candidates;
- the effect of potential strategic transactions on our business;
- our ability to obtain adequate financing; and
- the volatility of our stock price.

Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any 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

<b>Assets</b>	<b>September 30, 2008 (Unaudited)</b>	<b>December 31, 2007 (See Note 1)</b>
<b>Current assets:</b>		
Cash and cash equivalents	\$ 35,664	\$ 649,686
Prepaid expenses and other current assets	75,422	215,852
<b>Total current assets</b>	<b>111,086</b>	<b>865,538</b>
Investment in Hedrin JV	2,269	-
Property and equipment, net	11,920	44,533
Other assets	79,625	70,506
<b>Total assets</b>	<b>\$ 204,900</b>	<b>\$ 980,577</b>
<b>Liabilities and Stockholders' Deficiency</b>		
<b>Current liabilities:</b>		
Secured 10% notes payable	\$ 70,000	\$ -
Accounts payable	705,323	1,279,485
Accrued expenses	1,238,303	592,177
<b>Total current liabilities</b>	<b>2,013,626</b>	<b>1,871,662</b>
Exchange obligation	2,949,176	-
<b>Total liabilities</b>	<b>4,962,802</b>	<b>1,871,662</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' deficiency:</b>		
Preferred stock, \$.001 par value. Authorized 1,500,000 shares; no shares issued and outstanding at September 30, 2008 and December 31, 2007		
Common stock, \$.001 par value. Authorized 300,000,000 shares; 70,624,232 shares issued and outstanding at September 30, 2008 and December 31, 2007	70,624	70,624
Additional paid-in capital	54,566,421	54,037,361
Deficit accumulated during the development stage	(59,394,947)	(54,999,070)
<b>Total stockholders' deficiency</b>	<b>(4,757,902)</b>	<b>(891,085)</b>
<b>Total liabilities and stockholders' deficiency</b>	<b>\$ 204,900</b>	<b>\$ 980,577</b>

See accompanying notes to condensed consolidated financial statements.



**MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES**

(A Development Stage Company)

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from August 6, 2001 (inception) to September 30 2008
	2008	2007	2008	2007	
Costs and expenses:					
Research and development	\$ 498,853	\$ 1,808,958	\$ 1,864,652	\$ 7,360,040	\$ 28,353,695
General and administrative	884,705	898,063	2,600,303	2,865,161	16,452,666
In-process research and development charge	—	—	—	—	11,887,807
Impairment of intangible assets	—	—	—	—	1,248,230
Loss on disposition of intangible assets	—	—	—	—	1,213,878
Total operating expenses	1,383,558	2,707,021	4,464,955	10,225,201	59,156,276
Operating loss	(1,383,558)	(2,707,021)	(4,464,955)	(10,225,201)	(59,156,276)
Other (income) expense:					
Equity in loss of Hedrin JV	140,138	—	247,731	—	247,731
Interest and other income	(148,184)	(37,600)	(335,613)	(97,598)	(1,157,510)
Interest expense	18,804	—	18,804	475	44,838
Realized gain on sale of marketable equity securities	—	—	—	—	(76,032)
Total other (income) expense	10,758	(37,600)	(69,078)	(97,123)	(940,973)
Net loss	(1,394,316)	(2,669,421)	(4,395,877)	(10,128,078)	(58,215,303)
Preferred stock dividends (including imputed amounts)	—	—	—	—	(1,179,644)
Net loss applicable to common shares	\$ (1,394,316)	\$ (2,669,421)	\$ (4,395,877)	\$ (10,128,078)	\$ (59,394,947)
Net loss per common share:					
Basic and diluted	\$ (0.02)	\$ (0.04)	\$ (0.06)	\$ (0.15)	
Weighted average shares of common stock outstanding:					
Basic and diluted	70,624,232	70,591,623	70,624,232	67,134,882	

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	Series A convertible preferred stock Amount	Common stock Shares	Common stock Amount	Additional paid-in capital Amount	Subscription receivable Amount	Deficit accumulated during development stage Amount	Dividends payable in Series A preferred stock Amount	Accumulated other comprehensive income (loss) Amount	Unearned consulting services Amount
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
Common stock issued at \$0.63 per share, 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)
	—	—	1,321,806	1,322	742,369	—	—	—	—	—

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Common stock issued at \$0.63 per share, net of expenses										
Effect of reverse acquisition	—	—	6,287,582	6,287	2,329,954	—	—	—	—	
Amortization of unearned consulting costs	—	—	—	—	—	—	—	—	—	37,868
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(7,760)	
Payment for fractional shares for stock combination	—	—	—	—	(300)	—	—	—	—	
Preferred stock issued at \$10 per share, 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 at \$1.10, net of expenses	—	—	3,368,952	3,369	3,358,349	—	—	—	—	
Preferred stock dividend accrued	—	—	—	—	—	—	(585,799)	585,799	—	
Preferred stock dividends paid by issuance of shares	24,901	25	—	—	281,073	—	—	(282,388)	—	

Conversion of preferred stock to common stock at \$1.10 per share	(170,528)	(171)	1,550,239	1,551	(1,380)	—	—	—	—
Warrants issued for consulting services	—	—	—	—	125,558	—	—	—	—(120,968)
Amortization of unearned consulting costs	—	—	—	—	—	—	—	—	— 100,800
Unrealized gain on short-term investments and reversal of unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—20,997
Net loss	—	—	—	—	—	—	(5,896,031)	—	—
Balance at December 31, 2004	854,373	854	28,309,187	28,309	18,083,208	—	(13,955,035)	303,411	13,237 (20,168)

**MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES**

(A Development Stage Company)

Consolidated Statement of Stockholders' Equity (Deficiency)

(Unaudited)

	Series A convertible preferred stock Shares	Series A convertible preferred stock Amount	Common stock Shares	Common stock Amount	Additional paid-up capital Amount	Subscriptions receivable Amount	Development stage deficit accumulated during Amount	Dividends payable in Series A preferred stock Amount	Accumulated other comprehensive income (loss) Amount	Unearned consulting services Amount	Treasury stock (deficiency) Amount
Common stock issued at \$1.11 and \$1.15, net of expenses	—	—	11,917,680	11,918	12,238,291	—	—	—	—	—	— 12,
Common stock issued to vendor at \$1.11 per share in satisfaction of accounts payable	—	—	675,675	676	749,324	—	—	—	—	—	—
Exercise of stock options	—	—	32,400	33	32,367	—	—	—	—	—	—
Exercise of warrants	—	—	279,845	279	68,212	—	—	—	—	—	—
Preferred stock dividend accrued	—	—	—	—	—	—	(175,663)	175,663	—	—	—
Preferred stock dividends paid by issuance of shares	41,781	42	—	—	477,736	—	—	(479,074)	—	—	—
Conversion of preferred stock to common stock at \$1.10 per share	(896,154)	(896)	8,146,858	8,147	(7,251)	—	—	—	—	—	—
Share-based compensation	—	—	—	—	66,971	—	—	—	—	—	20,168
Reversal of unrealized gain on short-term investments	—	—	—	—	—	—	—	—	(12,250)	—	—

Stock issued in connection with acquisition of Tarpan Therapeutics, Inc.	—	—10,731,052	10,731	11,042,253	—	—	—	—	—	— 11,
Net loss	—	—	—	—	—	(19,140,997)	—	—	—	—(19,
Balance at December 31, 2005	—	—60,092,697	60,093	42,751,111	—	(33,271,695)	—	987	—	9,
Cashless exercise of warrants	—	—	27,341	27	(27)	—	—	—	—	—
Share-based compensation	—	—	—	—	1,675,499	—	—	—	—	— 1,
Unrealized loss on short-term investments	—	—	—	—	—	—	—	(987)	—	—
Costs associated with private placement	—	—	—	—	(15,257)	—	—	—	—	—
Net loss	—	—	—	—	—	(9,695,123)	—	—	—	— (9,
Balance at December 31, 2006	—	—60,120,038	60,120	\$ 44,411,326	—	(42,966,818)	—	—	—	— 1,
Common stock issued at \$0.84 and \$0.90 per shares, net of expenses	—	—10,185,502	10,186	7,841,999	—	—	—	—	—	— 7,
Common stock issued to directors at \$0.72 per share in satisfaction of accounts payable	—	—	27,776	28	19,972	—	—	—	—	—
Common stock issued to in connection with in-licensing agreement at \$0.90 per	—	—	125,000	125	112,375	—	—	—	—	—

share											
Common stock issued to in connection with in-licensing agreement at \$0.80 per share	—	—	150,000	150	119,850	—	—	—	—	—	—
Exercise of warrants	—	—	10,327	15	7,219	—	—	—	—	—	—
Cashless exercise of warrants	—	—	5,589	—	(6)	—	—	—	—	—	—
Share-based compensation	—	—	—	—	1,440,956	—	—	—	—	—	1,440,956
Warrants issued for consulting					83,670						
Net loss	—	—	—	—	—	—	(12,032,252)	—	—	—	(12,032,252)
Balance at December 31, 2007	—	—70,624,232	70,624	54,037,361	—	(54,999,070)	—	—	—	—	(12,032,252)
Sale of warrant					150,000						
Share-based compensation	—	—	—	—	379,060	—	—	—	—	—	379,060
Net loss	—	—	—	—	-	—	(4,395,877)	—	—	—	(4,395,877)
Balance at September 30, 2008	—	—70,624,232	70,624	54,566,421	—	(59,394,947)	—	—	—	—	(4,395,877)

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, 2008
	2008	2007	
Cash flows from operating activities:			
Net loss	\$ (4,395,877)	\$ (10,128,078)	\$ (58,215,303)
Adjustments to reconcile net loss to net cash used in operating activities:			
Equity in loss of Hedrin JV	247,731	—	247,731
Share-based compensation	379,060	1,078,185	3,744,043
Shares issued in connection with in-licensing agreement	—	232,500	232,500
Warrants issued to consultant	—	—	83,670
Amortization of intangible assets	—	—	145,162
Gain on sale of marketable equity securities	—	—	(76,032)
Depreciation	23,258	40,406	219,083
Non cash portion of in-process research and development charge	—	—	11,721,623
Loss on impairment and disposition of intangible assets	—	—	2,462,108
Loss on sale of fixed assets	18,327	—	23,917
Changes in operating assets and liabilities, net of acquisitions:			
(Increase)/decrease in prepaid expenses and other current assets	140,430	62,425	(17,177)
Increase in other assets	(9,119)	-	(79,625)
Increase /(decrease) in accounts payable	(574,162)	(520,806)	1,125,536
Increase in accrued expenses	646,126	388,627	697,982
Net cash used in operating activities	(3,524,226)	(8,846,741)	(37,684,782)
Cash flows from investing activities:			
Purchase of property and equipment	(8,972)	(9,135)	(239,607)
Cash paid in connection with acquisitions	—	—	(26,031)
Net cash provided from the purchase and sale of short-term investments, net	—	—	435,938
Proceeds from the sale of license	—	—	200,001
Net cash (used in) provided by investing activities	(8,972)	(9,135)	370,301
Cash flows from financing activities:			
Repayments of notes payable to stockholders	—	—	(884,902)
Proceeds related to sale of common stock, net	—	7,852,185	25,896,262
Proceeds from sale of preferred stock, net	—	—	9,046,176
Proceeds from exercise of warrants and stock options	—	7,228	138,219
Proceeds from the Hedrin JV Agreement, net	2,699,176	—	2,699,176
Sale of warrant	150,000	—	150,000
Proceeds from sale of 10% Secured Notes	70,000	—	70,000
Other, net	—	—	235,214

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Net cash provided by financing activities	2,919,176	7,859,413	37,350,145
Net (decrease) increase in cash and cash equivalents	(614,022)	(996,463)	35,664
Cash and cash equivalents at beginning of period	649,686	3,029,118	—
Cash and cash equivalents at end of period	\$ 35,664	\$ 2,032,655	\$ 35,664

Supplemental disclosure of cash flow information:

Interest paid	\$ —	\$ 475	\$ 26,033
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Supplemental disclosure of noncash investing and financing activities:

Common stock issued in satisfaction of accounts payable	\$ —	\$ 20,000	\$ 750,000
Imputed preferred stock dividend	—	—	418,182
Preferred stock dividends accrued	—	—	761,462
Preferred stock dividends paid by issuance of shares	—	—	9,046,176
Conversion of preferred stock to common stock	—	—	759,134
Issuance of common stock for acquisitions	—	—	13,389,226
Issuance of common stock in connection with in-licensing agreement	—	232,500	232,500
Marketable equity securities received in connection with sale of license	—	—	359,907
Warrants issued to consultant	—	—	83,670
Net liabilities assumed over assets acquired in business combination	—	—	(675,416)
Investment in Hedrin JV	250,000	—	250,000
Cashless exercise of warrants	—	6	33
Issuance of warrants to holders of 10% secured notes	—	—	—

See accompanying notes to condensed consolidated financial statements.



**MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES**  
**(A development Stage Company)**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of Manhattan Pharmaceuticals, Inc. and its subsidiaries (“Manhattan” or the “Company”) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the rules and regulations of the Securities and Exchange Commission. Accordingly, the unaudited condensed consolidated 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, 2008 or for any other interim period. These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements as of and for the year ended December 31, 2007, which are included in the Company’s Annual Report on Form 10-K for such year. The condensed balance sheet as of December 31, 2007 has been derived from the audited financial statements included in the Form 10-K for that year.

As of December 31, 2006 all of the Company’s subsidiaries had either been dissolved or merged into Manhattan. As a result, the Company had no subsidiaries during the nine month periods ended September 30, 2008 and 2007.

As of September 30, 2008, the Company has not generated any revenues from the development of its products and is therefore still considered to be a development stage company.

**Segment Reporting**

The Company has determined that it operates in only one segment currently, which is biopharmaceutical research and development.

**Income Taxes**

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board (“FASB”) Interpretation No. 48 (“FIN 48”), “Accounting for Uncertainty in Income Taxes - an interpretation of FASB No. 109”. The implementation of FIN 48 had no impact on the Company’s consolidated financial statements as the Company has no unrecognized tax benefits. The Company’s policy is to recognize interest and penalties related to income tax matters in income tax expense.

**Equity in Joint Venture**

The Company accounts for its investment in joint venture (See Note 8) using the equity method of accounting. Under the equity method, the Company records its pro-rata share of joint venture income or losses and adjusts the basis of its investment accordingly.

**MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES**  
**(A development Stage Company)**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**New Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, "Business Combinations" ("SFAS 141R"). The revision is intended to simplify existing guidance and converge rulemaking under U.S. generally accepted accounting principles with international accounting standards. SFAS 141R applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company is currently evaluating the impact of the provisions of the revision on its consolidated results of operations and financial condition.

In March 2008, the FASB issued SFAS No. 161 "Disclosures About Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133" ("SFAS 161"). SFAS 161 amends SFAS 133 by requiring expanded disclosures about an entity's derivative instruments and hedging activities. SFAS 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative instruments. SFAS 161 is effective for the Company as of January 1, 2009. The Company does not believe that SFAS 161 will have any impact on its consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS shall be effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with General Accepted Accounting Principles. We have not yet assessed the impact of adopting SFAS 162.

In February 2008, the FASB issued two Staff Positions on SFAS 157: (1) FASB Staff Position No. FAS 157-1 ("**FAS 157-1**"), "*Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement Under Statement 13,*" and (2) FASB Staff Position No. FAS 157-2 ("**FAS 157-2**"), "*Effective Date of FASB Statement No 157.*" FAS 157-1 excludes FASB Statement No. 13, *Accounting for Leases*, as well as other accounting pronouncements that address fair value measurements on lease classification or measurement under Statement 13, from SFAS 157's scope. FAS157-2 partially defers Statement 157's effective date. The adoption of FAS 157-1 and FAS 157-2 did not have a material impact on its financial statements.

In October 2008, the FASB issued FASB Staff Position No. FAS 157-3 "Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active" ("FAS 157-3"), which is effective upon issuance for all financial statements that have not been issued. FAS 157-3 clarifies the application of SFAS 157, in a market that is not active. FAS 157-3 does not have a material impact on the Company's financial position, financial performance or cash flows.

**MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES**  
**(A development Stage Company)**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

## **2. LIQUIDITY**

The Company incurred a net loss of \$4,395,877 and negative cash flows from operating activities of \$3,524,226 for the nine month period ended September 30, 2008. The net loss applicable to common shares from date of inception, August 6, 2001, to September 30, 2008 amounts to \$59,394,947.

The Company received approximately \$7.9 million net of expenses from a private placement of common stock and warrants in March 2007. This private placement is more fully described in Note 6.

The Company received approximately \$2.0 million in February 2008 and approximately \$1.0 million in June 2008 from a joint venture agreement. This joint venture agreement is more fully described in Note 8. The Company also received \$70,000 in Secured Promissory Notes in September 2008. These notes are more fully described in Note 10.

Management believes that the Company will continue to incur net losses through at least September 30, 2009 and for the foreseeable future thereafter. Based on the resources of the Company available at September 30, 2008 including the net proceeds received from the February 2008 joint venture agreement, and the September 2008 sale of 10% Secured Promissory Notes, as more fully described in note 10, and taking into consideration the net proceeds from the November 2008 12% Secured Promissory Notes, as more fully described in note 11, management believes that the Company has sufficient capital to fund its operations until the middle of 2009. Management believes that the Company has a need for capital in order to sustain its operations and will need additional equity or debt financing or will need to generate revenues through licensing of its products or entering into strategic alliances to be able to sustain its operations through 2009. Furthermore, we will need additional financing thereafter to complete development and commercialization of our products. There can be no assurances that we can successfully complete development and commercialization of our products.

These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

## **3. 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 the assumed exercise of stock options and stock warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. The amounts of potentially dilutive securities excluded from the calculation of diluted net loss per share were 19,500,189 and 18,634,521 as of September 30, 2008 and 2007, respectively. These amounts do not include the shares issuable in connection with the Hedrin JV (see Note 8); the 26,785,714 shares of common stock issuable upon exercise of the put or call rights; the up to 8,928,572 additional shares which may become issuable upon exercise of a conditionally issuable put or call rights and the 7,142,857 shares of common stock issuable upon exercise

of a conditionally issuable warrant.

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**4. SHARE-BASED COMPENSATION**

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment," ("Statement 123(R)") for employee options using the modified prospective transition method. Statement 123(R) revised Statement 123 "Accounting for Stock-based Compensation" to eliminate the option to use the intrinsic value method and required the Company to expense the fair value of all employee options over the vesting period. Under the modified prospective transition method, the Company recognized compensation cost for the nine month periods ending September 30, 2008 and 2007 based on the grant date fair value estimated in accordance with Statement 123(R). This includes (a) period compensation cost related to share-based payments granted prior to, but not yet vested, as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement 123; and (b) period compensation cost related to share-based payments granted on or after January 1, 2006. In accordance with the modified prospective method, the Company has not restated prior period results.

The Company recognizes compensation expense related to stock option grants on a straight-line basis over the vesting period. The Company recognized share-based compensation cost of \$83,396 and \$371,636 for the three month periods ended September 30, 2008 and 2007 respectively, and \$379,060 and \$1,078,185 for the nine month periods ended September 30, 2008 and 2007, respectively, in accordance with Statement 123(R). The Company did not capitalize any share-based compensation cost.

Options granted to consultants and other non-employees are accounted for in accordance with Emerging Issues Task Force ("EITF") No. 96-18 "Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and Financial Accounting Standards Board Interpretation No 28 "Accounting for Stock Appreciation Rights and Other Variable Option or Award Plans". Accordingly, such options are recorded at fair value at the date of grant and subsequently adjusted to fair value at the end of each reporting period until such options vest, and the fair value of the options, as adjusted, is amortized to consulting expense over the related vesting period. As a result of adjusting consultant and other non-employee options to fair value, the Company recognized share-based compensation (credit) / cost of \$347 and \$606, respectively, for the three-and nine months ended September 30, 2008 and \$(8,767) and \$(15,762), respectively for the three-and nine months ended September 30, 2007.

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The Company has allocated share-based compensation costs and credits to general and administrative and research and development expenses as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
General and administrative expense:				
Share-based employee compensation cost	\$ 64,071	\$ 254,870	\$ 279,476	\$ 726,414
Share-based consultant and non-employee (credit) cost	—	—	—	10,550
	\$ 64,071	\$ 254,870	\$ 279,476	\$ 736,964
Research and development expense:				
Share-based employee compensation cost	\$ 18,978	\$ 125,533	\$ 98,978	\$ 356,983
Share-based consultant and non-employee (credit) cost	347	(8,767)	606	(15,762)
	\$ 19,325	\$ 116,766	\$ 99,584	\$ 341,221
Total share-based cost	\$ 83,396	\$ 371,636	\$ 379,060	\$ 1,078,185

To compute compensation expense in 2008 and 2007, the Company estimated the fair value of each option award on the date of grant using the Black-Scholes model. The Company based the expected volatility assumption on a volatility index of peer companies as the Company did not have a sufficient number of years of historical volatility data related to its common stock for the application of Statement 123(R). The expected term of options granted represents the period of time that options are expected to be outstanding. The Company estimated the expected term of stock options by the simplified method as permitted by the Securities and Exchange Commission's Staff Accounting Bulletin No. 107 and 110. The expected forfeiture rates are based on the historical forfeiture experiences. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company has not declared a dividend on its common stock since its inception and has no intentions of declaring a dividend in the foreseeable future and therefore used a dividend yield of zero.

The following table shows the weighted average assumptions the Company used to develop the fair value estimates for the determination of the compensation charges in 2008 and 2007:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Expected Volatility	92.3%	79.7 - 93.2%	92.3%	79.7 - 93.2%
Dividend yield	-	-	-	-

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Expected term (in years)	6	6 - 8	6	6 - 8
Risk-free interest rate	2.81%	4.56% - 4.96%	2.81%	4.56% - 4.96%

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The Company has shareholder-approved stock incentive plans for employees under which it has granted non-qualified and incentive stock options. In December 2003, the Company established the 2003 Stock Option Plan (the "2003 Plan"), which provided for the granting of up to 5,400,000 options to officers, directors, employees and consultants for the purchase of common stock. The Company increased the number of shares of common stock reserved for issuance under the 2003 Plan in August 2005 by 2,000,000 shares and in May 2007 by 3,000,000 shares. At September 30, 2008, under the 2003 Plan, 10,400,000 shares of common stock were authorized for issuance. At September 30, 2008, under the 2003 Plan, options to purchase 9,539,096 shares of common stock were outstanding. At September 30, 2008, there were 860,904 shares reserved for future grants under the 2003 Plan. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally three years) and are issued at an exercise price equal to or greater than the fair market value of the shares at the date of grant. The 2003 Plan expires on December 10, 2013 or when all options have been granted, whichever is sooner. Under the 2003 Plan, the Company granted options to purchase an aggregate of 2,967,500 shares of common stock during the nine months ended September 30, 2008 at an exercise price of \$0.17 per share. In addition, 27,776 shares of common stock were issued during 2007 under the 2003 Plan.

In July 1995, the Company established the 1995 Stock Option Plan (the "1995 Plan"), which provided for the granting of options to purchase up to 130,000 shares of the Company's common stock to officers, directors, employees and consultants. The 1995 Plan was amended several times to increase the number shares reserved for stock option grants. In September 2005, the 1995 Plan expired and no further options can be granted. As of September 30, 2008, options to purchase 1,137,240 shares were outstanding under the 1995 Plan and no shares were reserved for future stock option grants.

A summary of the status of the Company's outstanding stock options as of September 30, 2008 and changes during the nine months then ended is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	8,033,808	\$ 1.25		
Granted:				
Officers	2,400,000			
Directors	375,000			
Employees	192,500			
Total granted	2,967,500	0.17		
Exercised	-			
Cancelled	(324,972)	0.17		
Outstanding at September 30, 2008	10,676,336	\$ 0.94	7.19	\$ -
Exercisable at September 30, 2008	8,093,025	\$ 1.12	6.56	
Weighted average fair value of options granted during the nine months ended September 30, 2008	\$ 0.13			



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As of September 30, 2008, the total compensation cost related to non-vested option awards not yet recognized is \$510,555. The weighted average period over which it is expected to be recognized is approximately 1.4 years.

**5. COMMITMENTS AND CONTINGENCIES**

**Swiss Pharma**

The Company has been involved in an arbitration proceeding in Switzerland with Swiss Pharma Contract LTD (“Swiss Pharma”), a clinical site that the Company used in one of its obesity trials. On September 5, 2008, the sole arbitrator in Switzerland rendered an award in favor of Swiss Pharma, awarding to Swiss Pharma a total of \$646,000 which amount includes a \$323,000 contract penalty, a final services invoice of \$48,000, reimbursement of certain of Swiss Pharma’s legal and other expenses incurred in the arbitration process of \$245,000, reimbursement of arbitration costs of \$13,000 and interest through September 5, 2008 of \$17,000. Further, the arbitrator ruled that the Company must pay interest at the rate of 5% per annum on \$371,000, the sum of the \$323,000 contract penalty and the final services invoice of \$48,000, from October 12, 2007 until paid.

The Company had previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice. The remainder of the award, \$542,000, has been expensed in September 2008. The Company has recognized research and development expense of \$267,000, general and administrative expense of \$257,000 and interest expense of \$18,000 during the quarter ended September 30, 2008. The Company will continue to accrue interest at the rate of 5% per annum on the \$371,000 until such amount has been settled.

The Company does not have sufficient cash or other current assets to satisfy the arbitrator's award.

**Contentions of a Former Employee**

In February 2007, a former employee of the Company alleged an ownership interest in two of the Company’s provisional patent applications covering our discontinued product development program for Oleoyl-estrone. Also, without articulating precise legal claims, the former employee contends that the Company wrongfully characterized the former employee’s separation from employment as a resignation instead of a dismissal in an effort to harm the former employee’s immigration sponsorship efforts, and, further, to wrongfully deprive the former employee of the former employee’s alleged rights in two of the Company’s provisional patent applications. The former employee is seeking an unspecified amount in damages. The Company refutes the former employee’s contentions and intends to vigorously defend itself should the former employee file claims against the Company. There have been no further developments with respect to these contentions.

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**Employment Agreements**

The Company has employment agreements with two employees for the payment of aggregate annual base salaries of \$675,000 as well as performance based bonuses. These agreements have a remaining term of six months for one of the employees, and nine months for the second employee, and have a total remaining obligation under these agreements of \$419,589 as of September 30, 2008.

**6. PRIVATE PLACEMENT OF COMMON SHARES**

On March 30, 2007, the Company entered into a series of subscription agreements with various institutional and other accredited investors for the issuance and sale in a private placement of an aggregate of 10,185,502 shares of its common stock for total net proceeds of approximately \$7.85 million, after deducting commissions and other costs of the transaction. Of the total amount of shares issued, 10,129,947 were sold at a per share price of \$0.84, and an additional 55,555 shares were sold to an entity affiliated with a director of the Company, at a per share price of \$0.90, the closing sale price of the common stock on March 29, 2007. Pursuant to the subscription agreements, the Company also issued to the investors 5-year warrants to purchase an aggregate of 3,564,897 shares of common stock at an exercise price of \$1.00 per share. The warrants are exercisable during the period commencing June 30, 2008 and ending March 30, 2012. Gross and net proceeds from the private placement were \$8,559,155 and \$7,852,185, respectively.

Pursuant to these subscription agreements the Company filed a registration statement on Form S-3 covering the resale of the shares issued in the private placement, including the shares issuable upon exercise of the investor warrants and the placement agent warrants, with the Securities and Exchange Commission on May 9, 2007, which was declared effective by the Securities and Exchange Commission on May 18, 2007.

The Company engaged Paramount BioCapital, Inc. ("Paramount"), an affiliate of a significant stockholder of the Company, as its placement agent in connection with the private placement. In consideration for its services, the Company paid aggregate cash commissions of approximately \$600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares at an exercise price of \$1.00 per share.

**7. IN-LICENSING TRANSACTIONS**

**Altoderm License Agreement**

On April 3, 2007, the Company entered into a license agreement for "Altoderm" (the "Altoderm Agreement") with Thornton & Ross LTD ("T&R"). Pursuant to the Altoderm Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate using sodium cromoglicate for the treatment of atopic dermatitis. In accordance with the terms of the Altoderm Agreement, the Company issued 125,000 shares of its common stock, valued at \$112,500, and made a cash payment of \$475,000 to T&R upon the execution of the agreement. These amounts have been included in research and development expense. Further, the Company agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 and 875,000 shares of common stock upon the achievement of various clinical and regulatory milestones. The Company also agreed to pay royalties on net sales of products using the licensed patent rights at rates ranging from 10% to 20%, depending on the level of annual net sales, and subject to an annual minimum royalty payment of \$1 million in each year following the first commercial sale of Altoderm. The Company may sublicense the patent rights. The Company

agreed to pay T&R 30% of the royalties received by the Company under such sublicense agreements.

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**Altolyn License Agreement**

On April 3, 2007, the Company and T&R also entered into a license agreement for “Altolyn” (the “Altolyn Agreement”). Pursuant to the Altolyn Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altolyn, an oral formulation product candidate using sodium cromoglicate for the treatment of mastocytosis, food allergies, and inflammatory bowel disorder. In accordance with the terms of the Altolyn Agreement, the Company made a cash payment of \$475,000 to T&R upon the execution of the agreement. This amount is included in research and development expense. Further, the Company agreed to make future cash milestone payments to T&R in an aggregate amount of \$5,675,000 upon the achievement of various clinical and regulatory milestones. The Company also agreed to pay royalties on net sales of products using the licensed patent rights at rates ranging from 10% to 20%, depending on the level of annual net sales, and subject to an annual minimum royalty payment of \$1 million in each year following the first commercial sale of Altolyn. The Company may sublicense the patent rights. The Company agreed to pay T&R 30% of the royalties received by the Company under such sublicense agreements.

**Hedrin License Agreement**

On June 26, 2007, the Company entered into an exclusive license agreement for “Hedrin” (the “Hedrin License Agreement”) with T&R and Kerris, S.A. (“Kerris”). Pursuant to the Hedrin License Agreement, the Company has acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin™, a non-insecticide product candidate for the treatment of head lice. In addition, on June 26, 2007, the Company entered into a supply agreement with T&R pursuant to which T&R will be the Company’s exclusive supplier of Hedrin product (the “Hedrin Supply Agreement”).

In consideration for the license, the Company issued to T&R and Kerris (jointly, the “Licensor”) a combined total of 150,000 shares of its common stock valued at \$120,000. In addition, the Company also made a cash payment of \$600,000 to the Licensor. These amounts are included in research and development expense. Further, the Company agreed to make future milestone payments to the Licensor in the aggregate amount of \$2,500,000 upon the achievement of various clinical, regulatory, and patent issuance milestones, as well as up to \$2,500,000 in a one-time success fee based on aggregate sales of the product by the Company and its licensees of at least \$50,000,000. The Company also agreed to pay royalties of 8% (or, under certain circumstances, 4%) on net sales of licensed products. The Company’s exclusivity under the Hedrin License Agreement is subject to an annual minimum royalty payment of \$1,000,000 (or, under certain circumstances, \$500,000) in each of the third through seventh years following the first commercial sale of Hedrin. The Company may sublicense its rights under the Hedrin License Agreement with the consent of Licensor and the proceeds resulting from such sublicenses will be shared with the Licensor.

Pursuant to the Hedrin Supply Agreement, the Company has agreed that it and its sublicensees will purchase their respective requirements of the Hedrin product from T&R at agreed upon prices. Under certain circumstances where T&R is unable to supply Hedrin products in accordance with the terms and conditions of the Hedrin Supply Agreement, the Company may obtain products from an alternative supplier subject to certain conditions. The term of the Hedrin Supply Agreement ends upon termination of the Hedrin License Agreement.

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**8. JOINT VENTURE**

In February 2008, the Company and Nordic Biotech Advisors ApS through its investment fund Nordic Biotech Venture Fund II K/S ("Nordic") entered into a 50/50 joint venture agreement (the "Hedrin JV Agreement") to develop and commercialize the Company's North American rights (under license) to its Hedrin product.

Pursuant to the Hedrin JV Agreement, Nordic formed a new Danish limited partnership, Hedrin Pharmaceuticals K/S, (the "Hedrin JV") and provided it with initial funding of \$2.5 million and the Company assigned and transferred its North American rights in Hedrin to the Hedrin JV in return for a \$2.0 million cash payment from the Hedrin JV and equity in the Hedrin JV representing 50% of the nominal equity interests in the Hedrin JV. At closing the Company recognized an investment in the Hedrin JV of \$250,000 and an exchange obligation of \$2,058,683. The exchange obligation represents the Company's obligation to Nordic to issue the Company's common stock in exchange for all or a portion of Nordic's equity interest in the Hedrin JV upon the exercise by Nordic of the put issued to Nordic in the Hedrin JV Agreement transaction. The put is described below.

The original terms of the Hedrin JV Agreement also provided that should the Hedrin JV be successful in achieving a payment milestone, namely that by September 30, 2008, the FDA determines to treat Hedrin as a medical device, Nordic will purchase an additional \$2.5 million of equity in the Hedrin JV, whereupon the Hedrin JV will pay the Company an additional \$1.5 million in cash and issue additional equity in the JV valued at \$2.5 million, thereby maintaining the Company's 50% ownership interest in the Hedrin JV. These terms have been amended as described below.

In June 2008 the Hedrin JV Agreement was amended (the "Hedrin JV Amended Agreement"). Under the amended terms Nordic invested an additional \$1.0 million, for a total of \$3.5 million, in the Hedrin JV and made an advance of \$250,000 to the Hedrin JV and the Hedrin JV made an additional \$1.0 million payment, for a total of \$3.0 million, to the Company. The Hedrin JV also distributed additional ownership equity sufficient for each of the Company and Nordic to maintain their ownership interest at 50%. Under the amended terms, upon classification of Hedrin by the FDA as a Class II or Class III medical device Nordic is obligated to invest an additional \$1.25 million, for a total investment of \$5 million, into the Hedrin JV, the Hedrin JV is obligated to pay an additional \$0.5 million, for a total of \$3.5 million, to the Company, the \$250,000 that Nordic advanced to the Hedrin JV in June becomes an equity investment in the Hedrin JV by Nordic and the Hedrin JV is obligated to issue to the Company and Nordic additional ownership interest in the Hedrin JV, thereby maintaining each of the Company's and Nordic's 50% ownership interest in the Hedrin JV. The Company's exchange obligation increased by \$894,546 as a result of the June 2008 closing. The \$894,546 represents the gross amount paid in June 2008 by the Hedrin JV to the Company of \$1,000,000 offset by the costs of the Hedrin JV Agreement transaction recognized by the Company subsequent to the February closing.

During the nine months ended September 30, 2008 the Company recognized \$247,731 of equity in the loss of the Hedrin JV. At September 30, 2008, the Company's investment in the Hedrin JV is \$2,269 and the Company's exchange obligation is \$2,949,176.

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Nordic has an option to put all or a portion of its equity interest in the Hedrin JV to the Company in exchange for the Company's common stock. The shares of the Company's common stock to be issued upon exercise of the put will be calculated by multiplying the percentage of Nordic's equity in the Hedrin JV that Nordic decides to put to the Company multiplied by the dollar amount of Nordic's investment in Limited Partnership divided by \$0.14, as adjusted from time to time. The put option is exercisable immediately and expires at the earlier of ten years or when Nordic's distributions from the Limited Hedrin JV exceed five times the amount Nordic invested in the Hedrin JV.

The Company has an option to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for the Company's common stock. The Company cannot begin to exercise its call until the price of the Company's common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 25% of its call option. During the second 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 50% of its call option on a cumulative basis. During the third 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 75% of its call option on a cumulative basis. During the fourth 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 100% of its call option on a cumulative basis. The shares of the Company's common stock to be issued upon exercise of the call will be calculated by multiplying the percentage of Nordic's equity in the Limited Partnership that the Company calls, as described above, multiplied by the dollar amount of Nordic's investment in the Hedrin JV divided by \$0.14. Nordic can refuse the Company's call by either paying the Company up to \$1.5 million or forfeiting all or a portion of their put, calculated on a pro rata basis for the percentage of the Nordic equity interest called by the Company.

The Hedrin JV is responsible for the development and commercialization of Hedrin for the North American market and all associated costs including clinical trials, if required, regulatory costs, patent costs, and future milestone payments owed to T&R, the licensor of Hedrin.

The Hedrin JV has engaged the Company to provide management services to the Limited Partnership in exchange for a management fee, which for 2008, on an annualized basis, is \$527,000. As of September 30, 2008, the Company has recognized \$315,036 of other income from management fees earned from the Hedrin JV which is included in the Company's Condensed Consolidated Statement of Operations for the nine months ended September 30, 2008 as a component of interest and other income.

Nordic paid to the Company a non-refundable fee of \$150,000 at the closing for the right to receive a warrant covering 7.1 million shares of the Company's common stock, exercisable for \$0.14 per share. The warrant is issuable 90 days from closing, provided Nordic has not exercised all or a part of its put, as described below. The Company issued the warrant to Nordic on April 30, 2008. The per share exercise price of the warrant was based on the volume weighted average price of the Company's common stock for the period prior to the signing of the Hedrin JV Agreement.

The Hedrin JV's Board consists of 4 members, 2 appointed by the Company and 2 appointed by Nordic. Nordic has the right to appoint one of the directors as chairman of the Board. The chairman has certain tie breaking powers.

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After the closing, at Nordic's request, the Company will nominate a person identified by Nordic to serve on the Company's Board of Directors.

The Company granted Nordic registration rights for the shares to be issued upon exercise of the warrant, the put or the call. The Company filed an initial registration statement on May 1, 2008. The registration statement was declared effective on October 15, 2008. The Company is required to file additional registration statements, if required, within 45 days of the date the Company first knows that such additional registration statement was required. The Company is required to use commercially reasonable efforts to cause the additional registration statements to be declared effective by the Securities and Exchange Commission ("SEC") within 105 calendar days from the filing date (the "Effective Date"). If the Company fails to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of filing the Company will be required to pay to Nordic, or its assigns, an amount in cash, as partial liquidated damages, equal to 0.5% per month of the amount invested in the Hedrin JV by Nordic until the registration statement is declared effective by the SEC. In no event shall the aggregate amount payable by the Company exceed 9% of the amount invested in the Hedrin JV by Nordic.

The profits of the Hedrin JV will be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership, which are currently 50% to each, except that Nordic will get a minimum distribution from the Hedrin JV equal to 5% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Limited Partnership. If the Hedrin JV realizes a profit equal to or greater than a 10% royalty on Hedrin sales, then profits will be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership. However, in the event of a liquidation of the Limited Partnership, Nordic's distribution in liquidation will be at least equal to the amount Nordic invested in the Hedrin JV (\$5 million if the payment milestone described above is met, \$3.5 million if it is not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

## **9. AMERICAN STOCK EXCHANGE**

In September 2007, the Company received notice from the staff of The American Stock Exchange, or AMEX, indicating that the Company was not in compliance with certain continued listing standards set forth in the AMEX Company Guide. Specifically, AMEX notice cited the Company's failure to comply, as of June 30, 2007, with section 1003(a)(ii) of the AMEX Company Guide as the Company had less than \$4,000,000 of stockholders' equity and had losses from continuing operations and /or net losses in three or four of our most recent fiscal years and with section 1003(a)(iii) which requires the Company to maintain \$6,000,000 of stockholders' equity if the Company has experienced losses from continuing operations and /or net losses in its five most recent fiscal years.

In order to maintain our AMEX listing, the Company was required to submit a plan to AMEX advising the exchange of the actions the Company has taken, or will take, that would bring the Company into compliance with all the continued listing standards by April 16, 2008. The Company submitted such a plan in October 2007. If the Company is not in compliance with the continued listing standards at the end of the plan period, or if the Company has not made progress consistent with the plan during the period, AMEX staff could have initiated delisting proceedings.

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Under the terms of the Hedrin JV Agreement, the number of potentially issuable shares represented by the put and call features thereof and the warrant issuable to Nordic, would exceed 19.9% of the Company's total outstanding shares and would be issued at a price below the greater of book or market value. As a result, under AMEX regulations, the Company would not have been able to complete the transaction without first receiving either stockholder approval for the transaction, or a formal "financial viability" exception from AMEX's stockholder approval requirement. The Company estimated that obtaining stockholder approval to comply with AMEX regulations would take a minimum of 45 days to complete. The Company discussed the financial viability exception with AMEX for several weeks and had neither received the exception nor been denied the exception. The Company determined that our financial condition required the Company to complete the transaction immediately, and that the Company's financial viability depended on the completion of the Hedrin JV Agreement without further delay.

Accordingly, to maintain the Company's financial viability, on February 28, 2008, the Company announced that it had formally notified AMEX that the Company intended to voluntarily delist its common stock from AMEX. The delisting became effective on March 26, 2008.

The Company's common stock now trades on the Over the Counter Bulletin Board under the symbol "MHAN". The Company intends to maintain corporate governance, disclosure and reporting procedures consistent with applicable law.

**10. 10% PROMISSORY NOTES**

In September 2008, Manhattan entered into a series of 10% secured promissory notes (the "10% Notes") with certain of our directors, officers and an employee (the "10% Note Holders") for aggregate of \$70,000. Principal and interest on the Notes shall be paid in cash on March 10, 2009 unless paid earlier by us. Pursuant to the secured promissory notes, we also issued to the Note Holders 5-year warrants to purchase an aggregate of 140,000 of our common stock at an exercise price of \$0.20 per share. Manhattan granted to the Note Holders a continuing security interest in certain specific refunds, deposits and repayments due Manhattan and expected to be repaid to Manhattan in the next several months. At September 30, 2008 accrued an unpaid interest on the 10% Notes amounted to \$351 and is reflected in the accompanying Balance Sheet as of September 30, 2008 as a component of accrued expenses.



**MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES**  
**(A development Stage Company)**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**11. SUBSEQUENT EVENT - 12% PROMISSORY NOTES**

On November 19,, 2008 the Company completed the first closing on a financing transaction. The Company sold \$1 million of 12% senior secured notes (the 12% Notes) and issued warrants to the investors to purchase 33 million shares of the Company's common stock at \$0.09 per share. The warrants expire on December 31, 2013. The Company realized net proceeds from the financing of \$0.8 million.

The financing transaction has a \$1,000,000 minimum amount, which has been met, a \$2,500,000 maximum amount and an overallotment of \$1,000,000 for a total of \$3,500,000. The financing transaction is still active and there maybe additional closings.

National Securities Corporation ("National") was the placement agent for the transaction. National's compensation for acting is placement agent is a cash fee of 10% of the gross proceeds received, a non-accountable expense allowance of 1.5% of the gross proceeds and a warrant to purchase such number of shares of the Company's common stock equal to 15% of the shares underlying the warrants issued to the investors. At the first closing the Company paid \$0.1 million in placement agent fees and a non-accountable expense allowance, and issued a warrant to purchase 5 million shares of the Company's common stock at \$0.09 per share. The warrant expires on December 13, 2013.

The 12% Notes mature two years after issuance. Interest on the 12% Notes is compounded quarterly and payable at maturity. The 12% Notes are secured by a pledge of certain of the Company's assets.

The net proceeds of this first closing are to be paid out in monthly installments of \$0.1 million. The monthly installments are to be paid as of the first of every month retroactive to October 1, 2008.

The issuance to the investors of warrants to purchase shares of the Company's common stock at \$0.09 per share changes the number of shares represented by the Nordic Put and the number of shares and exercise price of the Nordic Warrant. The Nordic Put and Nordic Warrant were issued at a value of \$0.14 per share and were issued with anti-dilution rights. The issuance of any securities at a value of less than \$0.14 per share activates Nordic's anti-dilution rights. The Nordic Put and the Nordic Warrant are now exercisable at a price of \$0.09 per share. The following table shows the effect of Nordic's anti-dilution rights.

	Shares Issuable upon the exercise of Nordic's Put	Additional Shares Issuable upon the exercise of Nordic's Put, if certain conditions are met	Shares Issuable upon the exercise of Nordic's Warrant	Total Shares Issuable upon the exercise of Nordic's Put and Warrant
Before the financing	26,785,714	8,928,572	7,142,857	42,857,143
Antidilution shares	14,880,953	4,960,317	3,968,254	23,809,524
After the financing	41,666,667	13,888,889	11,111,111	66,666,667

## Item 2. Management's Discussion and Analysis 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-K for the year ended December 31, 2007 (the "Annual Report") and our financial statements as of and for the three and nine month period ended September 30, 2008 included elsewhere in this report.**

We were incorporated in Delaware in 1993 under the name Atlantic Pharmaceuticals, Inc. and, in March 2000, we changed our name to Atlantic Technology Ventures, Inc. In 2003, we completed a "reverse acquisition" of privately held Manhattan Research Development, Inc. In connection with this transaction, we also changed our name to Manhattan Pharmaceuticals, Inc.

During 2005 we merged with Tarpan Therapeutics, Inc. ("Tarpan"). Tarpan was a privately held New York based biopharmaceutical company developing dermatological therapeutics. Through the merger, we acquired Tarpan's primary product candidate, topical PTH (1-34) for the treatment of psoriasis. In consideration for their shares of Tarpan's capital stock, the stockholders of Tarpan received an aggregate of approximately 20% of our then outstanding common shares. This transaction was accounted for as a purchase of Tarpan by the Company.

We are a development stage biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have four product candidates:

- Hedrin, a novel, non-insecticide treatment for head lice, which we are developing through Hedrin Pharmaceuticals K/S, a joint venture between the Company and Nordic Biotech Fund II K/S ;
  - Topical PTH (1-34) for the treatment of psoriasis;
  - Altoderm, a proprietary formulation of topical cromolyn sodium for the treatment of atopic dermatitis;
  - and Altolyn, a proprietary site specific tablet formulation of oral cromolyn sodium for the treatment of mastocytosis.

We do not currently have sufficient funding for further development of PTH (1-34), Altoderm and Altolyn. We are in discussion with T&R regarding next steps for Altoderm and Altolyn.

We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

In July 2007 we discontinued development of two product candidates, oral Oleoyl-estrone ("OE") and Propofol Lingual Spray.

You should read the following discussion of our results of operations and financial condition in conjunction with the condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. 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. You 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 under the heading "Risk Factors" following Item 1 in the Annual Report on Form 10-K, and should not unduly rely on these forward-looking statements.

**RESULTS OF OPERATIONS**

NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2008 VS 2007

	<b>Nine Months ended September 30,</b>			
	<b>2008</b>	<b>2007</b>	<b>Increase (decrease)</b>	<b>% Increase (decrease)</b>
<b>COSTS AND EXPENSES</b>				
<i>Research and development</i>				
Share-based compensation	\$ 100,000	\$ 341,000	(\$241,000)	(71)%
Other research and development expense	\$ 1,765,000	\$ 7,019,000	(\$5,254,000)	(75)%
Total research and development expense	\$ 1,865,000	\$ 7,360,000	(\$5,495,000)	(75)%
<i>General and administrative</i>				
Share-based compensation	\$ 279,000	\$ 737,000	(\$458,000)	(62)%
Other general and administrative expense	\$ 2,321,000	\$ 2,128,000	\$ 193,000	9%
Total general and administrative expense	\$ 2,600,000	\$ 2,865,000	(\$265,000)	(9)%
<b>Other (income) expense</b>	(\$69,000)	(\$97,000)	(\$28,000)	(29)%
<b>NET LOSS</b>	\$ 4,396,000	\$ 10,128,000	(\$5,732,000)	(57)%

During each of the nine months ended September 30, 2008 and 2007 we did not recognize any revenues. We are considered a development stage company, and do not expect to have revenues relating to our technologies prior to September 30, 2009, if at all.

For the nine months ended September 30, 2008 total research and development expense was \$1,865,000 as compared to \$7,360,000 for the nine months ended September 30, 2007. The decrease of \$5,495,000, or 75%, is attributable to decreases of \$2,632,000 in development projects discontinued during 2007 (OE and Propofol), of \$799,000 for Hedrin, of \$800,000 for Altoderm, of \$620,000 for Altolyn and of \$402,000 for PTH (1-34). The costs incurred during the nine months ended September 30, 2008 for OE and Propofol were \$267,000 associated with the Swiss Pharma arbitration award. During the nine months ended September 30, 2007 the majority of the development costs incurred for Altoderm, Altolyn and Hedrin relate to in-licensing costs.

For the nine months ended September 30, 2008 total general and administrative expense was \$2,600,000 as compared to \$2,865,000 for the nine months ended September 30, 2007. The decrease of \$265,000, or 9%, is primarily attributable to decreases of \$458,000 in share-based compensation, of \$52,000 in the costs associated with being a public company, of \$46,000 in personnel costs and \$202,000 of business development costs offset by the costs associated with the Swiss Pharma arbitration of \$493,000.

For the nine months ended September 30, 2008, other income was \$69,000 as compared to \$97,000 for the nine months ended September 30, 2007. The decrease of \$28,000, or 29%, is due primarily to \$315,000 of management fees received in accordance with the services agreement from the Nordic JV, offset by the equity in loss of the Hedrin JV of \$248,000 and a decrease in interest income which resulted from lower average balances in interest bearing cash and short-term investment accounts.

Net loss for the nine months ended September 30, 2008 was \$4,396,000 as compared to \$10,128,000 for the nine months ended September 30, 2007. The decrease of \$5,732,000, or 57%, in net loss is principally attributable to decreases in research and development expense of \$5,495,000 and in general and administrative expense of \$265,000 and a decrease in other income of \$28,000.

QUARTER ENDED SEPTEMBER 30, 2008 VS 2007

	2008	2007	Quarter ended September 30, Increase (decrease)	% Increase (decrease)
<b>COSTS AND EXPENSES</b>				
<i>Research and development</i>				
Share-based compensation	\$ 19,000	\$ 117,000	(\$98,000)	(84)%
Other research and development expense	\$ 480,000	\$ 1,692,000	(\$1,212,000)	(72)%
Total research and development expense	\$ 499,000	\$ 1,809,000	(\$1,310,000)	(72)%
<i>General and administrative</i>				
Share-based compensation	\$ 64,000	\$ 255,000	(\$191,000)	(75)%
Other general and administrative expense	\$ 821,000	\$ 643,000	\$ 178,000	28%
Total general and administrative expense	\$ 885,000	\$ 898,000	\$ (13,000)	(1)%
<b>Other (income) expense</b>	\$ 11,000	(\$38,000)	\$ 49,000	129%
<b>NET LOSS</b>	\$ 1,395,000	\$ 2,669,000	(\$1,274,000)	(48)%

During each of the quarters ended September 30, 2008 and 2007 we did not recognize any revenues. We are considered a development stage company, and do not expect to have revenues relating to our technologies prior to September 30, 2009, if at all.

For the quarter ended September 30, 2008 total research and development expense was \$499,000 as compared to \$1,809,000 for the quarter ended September 30, 2007. The decrease of \$1,310,000, or 72%, is attributable to decreases of \$248,000 in development projects discontinued during 2007 (OE and Propofol), of \$50,000 for Hedrin, of \$171,000 for Altoderm, of \$87,000 for Altolyn and of \$657,000 for PTH (1-34). The costs during the three months ended September 30, 2008 for OE and Propofol were \$267,000 associated with the Swiss Pharma arbitration award.

For the quarter ended September 30, 2008 total general and administrative expense was \$885,000 as compared to \$898,000 for the quarter ended September 30, 2007. The decrease of \$13,000, or 1%, is primarily attributable to decreases of \$191,000 in stock-based compensation, of \$74,000 in the costs associated with being a public company and of \$81,000 of business development costs offset by an increase in personnel costs of \$35,000 and the costs associated with the Swiss Pharma arbitration of \$301,000.

For the quarter ended September 30, 2008, other expense was \$11,000 as compared to other income of \$38,000 for the quarter ended September 30, 2007. The increase of \$49,000, or 129%, is due primarily to \$183,000 of management fees received in accordance with the services agreement from the Nordic JV offset by the equity in loss of the Hedrin JV of \$140,000.

Net loss for the quarter ended September 30, 2008 was \$1,395,000 as compared to \$2,669,000 for the quarter ended September 30, 2007. The decrease of \$1,274,000, or 48%, in net loss is principally attributable to decreases in research and development expense of \$1,310,000 and \$13,000 in general and administrative expense offset by an increase in other expense of \$48,000.

## **LIQUIDITY AND CAPITAL RESOURCES**

From inception to September 30, 2008, we incurred a deficit during the development stage of \$59 million primarily as a result of our net losses and preferred stock dividends. We expect to continue to incur additional losses through at least September 30, 2009 and for the foreseeable future thereafter. 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.

Management believes that the Company will continue to incur net losses through at least September 30, 2009 and for the foreseeable future thereafter. Based on the resources of the Company available at September 30, 2008 including the net proceeds received from the February 2008 joint venture agreement, and the September 2008 sale of 10% Secured Promissory Notes and taking into consideration the net proceeds from the sale of the November 2008 12% Secured Promissory Notes management believes that the Company has sufficient capital to fund its operations until the middle of 2009. Management believes that the Company has a need for capital in order to sustain its operations and will need additional equity or debt financing or will need to generate revenues through licensing of its products or entering into strategic alliances to be able to sustain its operations through 2009. Furthermore, we will need additional financing thereafter to complete development and commercialization of our products. There can be no assurances that we can successfully complete development and commercialization of our products.

We have financed our operations since inception primarily through equity financing. During the nine months ended September 30, 2008, we had a net decrease in cash and cash equivalents of \$614,000. This decrease resulted principally from the net cash used in operating activities of \$3.5 million, partially offset by the net proceeds from the Hedrin JV Agreement of \$2.8 million. Total liquid resources as of September 30, 2008 were \$0.03 million compared to \$0.60 million at December 31, 2007.

### **Liquidity**

As of September 30, 2008, we had a working capital deficit of \$1.9 million as compared to a working capital deficit of \$1.0 million at December 31, 2007. This \$0.9 million increase in the working capital deficit is primarily due to decreases in cash of \$614,000 and prepaid expenses and other current assets of \$140,000, the issuance of \$70,000 of secured notes payable and an increase in accounts payable and accrued expenses of \$72,000

On November 12, 2008 the Company completed the first closing on a financing transaction. The Company sold \$1 million of 12% senior secured notes (the 12% Notes). The Company realized net proceeds from the financing of \$0.8 million.

The financing transaction has a \$1,000,000 minimum amount, a \$2,500,000 maximum amount and an overallotment of \$1,000,000 for a total of \$3,500,000. The Company expects that there will be another closing but does not yet know how much that closing will be for.

### ***March 2007 Private Placement***

On March 30, 2007, we entered into a series of subscription agreements with various institutional and other accredited investors for the issuance and sale in a private placement of an aggregate of 10,185,502 shares of our common stock for net proceeds of approximately \$7.9 million. Of the total amount of shares issued, 10,129,947 were sold at a per share price of \$0.84, and an additional 55,555 shares were sold to an entity affiliated with a director of the Company, at a per share price of \$0.90, the closing sale price of the common stock on March 29, 2007. Pursuant to the subscription agreements, we also issued to the investors 5-year warrants to purchase an aggregate of 3,564,897 shares of our common stock at an exercise price of \$1.00 per share. The warrants are exercisable during the period commencing September 30, 2008 and ending March 30, 2012.

Pursuant to these subscription agreements the Company filed a registration statement covering the resale of the shares issued in the private placement, including the shares issuable upon exercise of the investor warrants and the placement agent warrants, with the Securities and Exchange Commission on May 9, 2007, which was declared effective by the Securities and Exchange Commission on May 18, 2007.

The Company engaged Paramount BioCapital, Inc. ("Paramount"), a related party, as its placement agent in connection with the private placement. In consideration for its services, we paid aggregate cash commissions of approximately \$600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares at an exercise price of \$1.00 per share.

### **JOINT VENTURE AGREEMENT**

In February 2008, the Company and Nordic Biotech Advisors ApS through its investment fund Nordic Biotech Venture Fund II K/S ("Nordic") entered into a 50/50 joint venture agreement (the "Hedrin JV Agreement") to develop and commercialize the Company's North American rights (under license) to its Hedrin product.

Pursuant to the Hedrin JV Agreement, Nordic formed a new Danish limited partnership, Hedrin Pharmaceuticals K/S, (the "Hedrin JV") and provided it with initial funding of \$2.5 million and the Company assigned and transferred its North American rights in Hedrin to the Hedrin JV in return for a \$2.0 million cash payment from the Hedrin JV and equity in the Hedrin JV representing 50% of the nominal equity interests in the Hedrin JV.

The original terms of the Hedrin JV Agreement also provided that should the Hedrin JV be successful in achieving a payment milestone, namely that by September 30, 2008, the FDA determines to treat Hedrin as a medical device, Nordic will purchase an additional \$2.5 million of equity in the Hedrin JV, whereupon the Hedrin JV will pay the Company an additional \$1.5 million in cash and issue to the Company an additional \$2.5 million in equity in the Hedrin JV, thereby maintaining the Company's 50% ownership interest in the Hedrin JV. These terms have been amended as described below.

In June 2008 the Hedrin JV Agreement was amended (the "Hedrin JV Amended Agreement"). Under the amended terms Nordic invested an additional \$1.0 million, for a total of \$3.5 million, in the Hedrin JV and made an advance of \$250,000 to the Hedrin JV and the Hedrin JV made an additional \$1.0 million payment, for a total of \$3.0 million, to the Company. The Hedrin JV also distributed additional ownership equity sufficient for each of the Company and Nordic to maintain their ownership interest at 50%. Under the amended terms, upon classification of Hedrin by the FDA as a Class II or Class III medical device Nordic is obligated to invest an additional \$1.25 million, for a total investment of \$5 million, into the Hedrin JV, the Hedrin JV is obligated to pay an additional \$0.5 million, for a total of \$3.5 million, to the Company and the Hedrin JV is obligated to issue to the Company and Nordic additional ownership interest in the Hedrin JV, thereby maintaining each of the Company's and Nordic's 50% ownership interest in the Hedrin JV.



As of September 30, 2008, the Company has included the total \$3.0 million cash payments received to date in exchange obligation in the attached condensed consolidated financial statements, as described below.

Nordic has an option to put all or a portion of its equity interest in the Hedrin JV to the Company in exchange for the Company's common stock. The shares of the Company's common stock to be issued upon exercise of the put will be calculated by multiplying the percentage of Nordic's equity in the Hedrin JV that Nordic decides to put to the Company multiplied by the dollar amount of Nordic's investment in Limited Partnership divided by \$0.14, as adjusted from time to time. The put option is exercisable immediately and expires at the earlier of ten years or when Nordic's distributions from the Limited Hedrin JV exceed five times the amount Nordic invested in the Hedrin JV.

The Company has an option to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for the Company's common stock. The Company cannot begin to exercise its call until the price of the Company's common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 25% of its call option. During the second 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 50% of its call option on a cumulative basis. During the third 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 75% of its call option on a cumulative basis. During the fourth 30 consecutive trading day period in which the Company's common stock closes at or above \$1.40 per share the Company can exercise up to 100% of its call option on a cumulative basis. The shares of the Company's common stock to be issued upon exercise of the call will be calculated by multiplying the percentage of Nordic's equity in the Limited Partnership that the Company calls, as described above, multiplied by the dollar amount of Nordic's investment in the Hedrin JV divided by \$0.14. Nordic can refuse the Company's call by either paying the Company up to \$1.5 million or forfeiting all or a portion of their put, calculated on a pro rata basis for the percentage of the Nordic equity interest called by the Company.

The Hedrin JV is responsible for the development and commercialization of Hedrin for the North American market and all associated costs including clinical trials, if required, regulatory costs, patent costs, and future milestone payments owed to T&R, the licensor of Hedrin.

The Hedrin JV has engaged the Company to provide management services to the Limited Partnership in exchange for a management fee, which for 2008, on an annualized basis, is \$527,000. As of September 30, 2008, the Company has recognized \$315,036 of other income from management fees earned from the Hedrin JV which is included in the Company's Condensed Consolidated Statement of Operations for the nine months ended September 30, 2008 as a component of interest and other income.

Nordic paid to the Company a non-refundable fee of \$150,000 at the closing for the right to receive a warrant covering 7.1 million shares of the Company's common stock, exercisable for \$0.14 per share. The warrant is issuable 90 days from closing, provided Nordic has not exercised all or a part of its put, as described above. The Company issued the warrant to Nordic on April 30, 2008. The per share exercise price of the warrant was based on the volume weighted average price of the Company's common stock for the period prior to the signing of the Hedrin JV Agreement.



The Hedrin JV's Board consists of 4 members, 2 appointed by the Company and 2 appointed by Nordic. Nordic has the right to appoint one of the directors as chairman of the Board. The chairman has certain tie breaking powers.

At Nordic's request, the Company will nominate a person identified by Nordic to serve on the Company's Board of Directors.

The Company granted Nordic registration rights for the shares to be issued upon exercise of the warrant, the put or the call. The Company filed an initial registration statement on May 1, 2008. The registration statement was declared effective on October 15, 2008. The Company is required to file additional registration statements, if required, within 45 days of the date the Company first knows that such additional registration statement was required. The Company is required to use commercially reasonable efforts to cause the additional registration statements to be declared effective by the Securities and Exchange Commission ("SEC") within 105 calendar days from the filing date (the "Effective Date"). If the Company fails to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of filing the Company will be required to pay to Nordic, or its assigns, an amount in cash, as partial liquidated damages, equal to 0.5% per month of the amount invested in the Hedrin JV by Nordic until the registration statement is declared effective by the SEC. In no event shall the aggregate amount payable by the Company exceed 9% of the amount invested in the Hedrin JV by Nordic.

The profits of the Hedrin JV will be shared by the Company and Nordic in accordance with their respective equity interests in Limited Partnership, which are currently 50% to each, except that Nordic will get a minimum distribution from the Hedrin JV equal to 5% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Limited Partnership. If the Hedrin JV realizes a profit equal to or greater than a 10% royalty on Hedrin sales, then profits will be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership. However, in the event of a liquidation of the Limited Partnership, Nordic's distribution in liquidation will be at least equal to the amount Nordic invested in the Hedrin JV (\$5 million if the payment milestone described above is met, \$3.5 million if it is not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

### **American Stock Exchange**

In September 2007, we received notice from the staff of The American Stock Exchange, or AMEX, indicating that we were not in compliance with certain continued listing standards set forth in the AMEX Company Guide. Specifically, AMEX notice cited our failure to comply, as of June 30, 2007, with section 1003(a)(ii) of the AMEX Company Guide as we had less than \$4,000,000 of stockholders' equity and had losses from continuing operations and /or net losses in nine or four of our most recent fiscal years and with section 1003(a)(iii) which requires us to maintain \$6,000,000 of stockholders' equity if we have experienced losses from continuing operations and /or net losses in its five most recent fiscal years.

In order to maintain our AMEX listing, we were required to submit a plan to AMEX advising the exchange of the actions we have taken, or will take, that would bring us into compliance with all the continued listing standards by April 16, 2008. We submitted such a plan in October 2007. If we were not in compliance with the continued listing standards at the end of the plan period, or if we had made progress consistent with the plan during the period, AMEX staff could have initiated delisting proceedings.

Under the terms of our joint venture agreement with Nordic, the number of potentially issuable shares represented by the put and call features thereof and the warrant issuable to Nordic, would exceed 19.9% of our total outstanding shares and would be issued at a price below the greater of book or market value. As a result, under AMEX regulations, we would not have been able to complete the transaction without first receiving either stockholder approval for the transaction, or a formal “financial viability” exception from AMEX’s stockholder approval requirement. We estimated that obtaining stockholder approval to comply with AMEX regulations would take a minimum of 45 days to complete. We discussed the financial viability exception with AMEX for several weeks and had neither received the exception nor been denied the exception. We determined that our financial condition required us to complete the transaction immediately, and that our financial viability depended on our completion of the transaction without further delay.

Accordingly, to maintain our financial viability, on February 28, 2008, we announced that we had formally notified AMEX that we intended to voluntarily delist our common stock from AMEX. The delisting became effective on March 26, 2008.

Our common stock now trades on the Over the Counter Bulletin Board under the symbol “MHAN”. We intend to maintain corporate governance, disclosure and reporting procedures consistent with applicable law.

## **Commitments**

### *General*

We often contract with third parties to facilitate, coordinate and perform agreed upon research and development of our product candidates. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and nonclinical testing costs based on the work performed under the contracts.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. This method of payment often does not match the related expense recognition resulting in either a prepayment, when the amounts paid are greater than the related research and development costs recognized, or an accrued liability, when the amounts paid are less than the related research and development costs recognized.

The Company has been involved in an arbitration proceeding in Switzerland with Swiss Pharma Contract LTD (“Swiss Pharma”), a clinical site that the Company used in one of its obesity trials. On September 5, 2008, the sole arbitrator in Switzerland rendered an award in favor of Swiss Pharma, awarding to Swiss Pharma a total of \$646,000 which amount includes a \$323,000 contract penalty, a final services invoice of \$48,000, reimbursement of certain of Swiss Pharma’s legal and other expenses incurred in the arbitration process of \$245,000, reimbursement of arbitration costs of \$13,000 and interest through September 5, 2008 of \$17,000. Further, the arbitrator ruled that the Company must pay interest at the rate of 5% per annum on \$371,000, the sum of the \$323,000 contract penalty and the final services invoice of \$48,000, from October 12, 2007 until paid.

The Company had previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice. The remainder of the award, \$542,000, has been expensed in September. The Company has recognized research and development expense of \$267,000, general and administrative expense of \$257,000 and interest expense of \$18,000 during the quarter ended September 30, 2008. The Company will continue to accrue interest at the rate of 5% per annum on the \$371,000 until such amount has been settled.

The Company does not have sufficient cash or other current assets to satisfy the arbitrator's award.

In February 2007, a former employee of the Company alleged an ownership interest in two of the Company's provisional patent applications covering our discontinued product development program for Oleoyl-estrone. Also, without articulating precise legal claims, the former employee contends that the Company wrongfully characterized the former employee's separation from employment as a resignation instead of a dismissal in an effort to harm the former employee's immigration sponsorship efforts, and, further, to wrongfully deprive the former employee of the former employee's alleged rights in two of the Company's provisional patent applications. The former employee is seeking an unspecified amount in damages. The Company refutes the former employee's contentions and intends to vigorously defend itself should the former employee file claims against the Company. There have been no further developments with respect to these contentions.

### *Development Commitments*

#### **Hedrin**

On June 26, 2007, we entered into an exclusive license agreement for Hedrin (the "Hedrin License Agreement") with Thornton & Ross Ltd, or T&R, and Kerris, S.A., or Kerris (jointly, the "Licensor"). Pursuant to the Hedrin License Agreement, we acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin<sup>TM</sup> a non-insecticide product candidate for the treatment of pediculosis (head lice). In addition, on June 26, 2007, we entered into a supply agreement with T&R pursuant to which T&R will be our exclusive supplier of Hedrin product (the "Hedrin Supply Agreement").

In consideration for the license, we issued to Licensor 150,000 shares of our common stock valued at \$120,000. In addition, we also made a cash payment to the Licensor of \$600,000. These amounts are included in research and development expense.

Further, we agreed to make future milestone payments to the Licensor comprised of various combinations of cash and common stock in respective aggregate amounts of \$2,500,000 upon the achievement of various clinical and regulatory milestones as follows: \$250,000 upon acceptance by the U. S. Food and Drug Administration, or the FDA, of an Investigational New Drug application, or an IND; \$1,000,000 upon the achievement of a successful outcome of a Phase 3 clinical trial; \$700,000 upon the final approval of an NDA by the FDA; \$300,000 upon the issuance of a U.S. patent on Hedrin; and \$250,000 upon receipt of marketing authorization in Canada.

We also agreed to pay royalties of 8% (or, under certain circumstances, 4%) on net sales of licensed products. Our exclusivity under the Hedrin License Agreement is subject to an annual minimum royalty payment of \$1,000,000 (or, under certain circumstances, \$500,000) in each of the third through seventh years following the first commercial sale of Hedrin. We may sublicense our rights under the Hedrin License Agreement with the consent of the Licensor and the proceeds resulting from such sublicenses will be shared with the Licensor.

In February 2008, we entered into the Hedrin JV Agreement. The Hedrin JV is now responsible for all obligations to T&R under the Hedrin License and Supply Agreements. As of the date of the Hedrin JV Agreement, none of the milestones had been reached and sales had not commenced, therefore, we have no obligations to T&R for any such milestones or royalties.

Pursuant to the Hedrin Supply Agreement, we have agreed that we and our sublicensees will purchase their respective requirements of the Hedrin product from T&R at agreed upon prices. Under certain circumstances where T&R is unable to supply Hedrin product in accordance with the terms and conditions of the Hedrin Supply Agreement, we may obtain products from an alternative supplier subject to certain conditions. The term of the Hedrin Supply Agreement ends upon termination of the Hedrin License Agreement.

#### **Topical PTH (1-34)**

Through our April 2005 acquisition of Tarpan Therapeutics, Inc., or Tarpan, we acquired a sublicense agreement with IGI, Inc. dated April 14, 2004. Under the IGI sublicense agreement we hold the exclusive, world-wide, royalty bearing sublicense to develop and commercialize the licensed technology. Under the terms of the IGI sublicense agreement, we are responsible for the cost of the nonclinical and clinical development of the project, including research and development, manufacturing, laboratory and clinical testing and trials and marketing of licensed products.

The IGI sublicense agreement requires us to make certain milestone payments as follows: \$300,000 payable upon the commencement of a Phase 2 clinical trial; \$500,000 upon the commencement of a Phase 3 clinical trial; \$1,500,000 upon the acceptance of an NDA application by the FDA; \$2,400,000 upon the approval of an NDA by the FDA; \$500,000 upon the commencement of a Phase 3 clinical trial for an indication other than psoriasis; \$1,500,000 upon the acceptance of and NDA application for an indication other than psoriasis by the FDA; and \$2,400,000 upon the approval of an NDA for an indication other than psoriasis by the FDA.

During 2007, we achieved the milestone of the commencement of Phase 2 clinical trial. As a result \$300,000 became payable to IGI. This \$300,000 is included in research and development expense for the year ended December 31, 2007. Payment was made to IGI in February 2008.

In addition, we are obligated to pay IGI, Inc. an annual royalty of 6% on annual net sales up to \$200,000,000. In any calendar year in which net sales exceed \$200,000,000, we are obligated to pay IGI, Inc. an annual royalty of 9% on such excess. Through September 30, 2008, sales have not commenced, therefore, we have not paid any such royalties.

IGI, Inc. may terminate the agreement (i) upon 60 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 is filed, or if we are placed in the hands of a receiver or trustee for the benefit of creditors. IGI, Inc. may terminate the agreement upon 60 days' written notice and an opportunity to cure in the event we commit a material breach or default. Eighteen months from the date of the IGI sublicense agreement, we may terminate the agreement in whole or as to any portion of the PTH patent rights upon 90 days' notice to IGI, Inc.

In July 2008, the Company announced top-line results from its Phase 2a clinical study of topical PTH (1-34) for the treatment of psoriasis. This multi-center, randomized, double-blind, vehicle-controlled, parallel group study was designed to assess the safety and preliminary efficacy of two dose levels of topical PTH (1-34) for the treatment of mild to moderate plaque psoriasis. While the study did achieve the primary safety objective, the data did not demonstrate a statistically significant improvement in the overall disease severity of treatment lesions or signs and symptoms of psoriasis (redness, scaling, plaque thickness, and itch) as compared to the vehicle (placebo) gel. Topical PTH (1-34) appeared to be well tolerated with no serious adverse events reported. The Company intends to further analyze and assess these data in order to determine appropriate next steps for the program.



## **Altoderm**

On April 3, 2007, we entered into a license agreement for “Altoderm,” with T&R. Pursuant to the Altoderm license agreement, we acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate with the active ingredient cromolyn sodium (also known as sodium cromoglicate) for the treatment of atopic dermatitis. In accordance with the terms of the Altoderm license agreement, we issued 125,000 shares of our common stock, valued at \$112,500, and made a cash payment of \$475,000 to T&R upon the execution of the agreement. These amounts have been included in research and development expense.

Further, we agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 and 875,000 shares of our common stock upon the achievement of various clinical and regulatory milestones as follows: \$450,000 upon acceptance by the FDA of an IND; 125,000 shares of our common stock upon the first dosing of a patient in the first Phase 2 clinical trial; 250,000 shares of our common stock and \$625,000 upon the first dosing of a patient in the first Phase 3 clinical trial; \$1,000,000 upon the achievement of a successful outcome of a Phase 3 clinical trial; \$1,100,000 upon the acceptance for filing of an NDA application by the FDA; 500,000 shares of our common stock and \$2,000,000 upon the final approval of an NDA by the FDA; and \$500,000 upon receipt of marketing authorization in Canada.

In addition, we are obligated to pay T&R an annual royalty of 10% on annual net sales of up to \$100,000,000; 15% of the amount of annual net sales in excess of \$100,000,000 and 20% of annual net sales in excess of \$200,000,000. There is a minimum royalty of \$1,000,000 per year. There is a one-time success fee of \$10,000,000 upon the achievement of cumulative net sales of \$100,000,000. Through September 30, 2008, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

## **Altolyn**

On April 3, 2007, we and T&R also entered into a license agreement for Altolyn. Pursuant to the Altolyn license agreement, we acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altolyn, an oral formulation product candidate using cromolyn sodium for the treatment of mastocytosis, food allergies, and inflammatory bowel disorder. In accordance with the terms of the Altolyn license agreement, we made a cash payment of \$475,000 to T&R upon the execution of the agreement. This amount is included in research and development expense.

Further, we agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 upon the achievement of various clinical and regulatory milestones. as follows: \$450,000 upon acceptance for filing by the FDA of an IND; \$625,000 upon the first dosing of a patient in the first Phase 3 clinical trial; \$1,000,000 upon the achievement of a successful outcome of a Phase 3 clinical trial; \$1,100,000 upon the acceptance for filing of an NDA application by the FDA; \$2,000,000 upon the final approval of an NDA by the FDA; and \$500,000 upon receipt of marketing authorization in Canada.

In addition, we are obligated to pay T&R an annual royalty of 10% on annual net sales of up to \$100,000,000; 15% of the amount of annual net sales in excess of \$100,000,000 and 20% of annual net sales in excess of \$200,000,000. There is a minimum royalty of \$1,000,000 per year. There is a one-time success fee of \$10,000,000 upon the achievement of cumulative net sales of \$100,000,000.

Through September 30, 2008, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

## **Summary of Contractual Commitments**

### ***Employment Agreements***

The Company has employment agreements with two employees for the payment of aggregate annual base salaries of \$675,000 as well as performance based bonuses. These agreements have a remaining term of nine months for one of the employees, and six months for the second employee, and have a total remaining obligation under these agreements of \$419,589 as of September 30, 2008.

### ***Capital Resources***

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 commercializing capabilities, 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, 2008, substantially all of our financing has been through private placements of common stock, preferred stock and warrants to purchase common stock. Until 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 and negative cash flows from operating activities for the foreseeable future.

Based on the resources of the Company available at September 30, 2008 including the net proceeds received from the February 2008 joint venture agreement, and the September 2008 sale of 10% Secured Promissory Notes and taking into consideration the net proceeds from the sale of the November 2008 12% Secured Promissory Notes management believes that the Company has sufficient capital to fund its operations until the middle of 2009. Management believes that the Company has a need for capital in order to sustain its operations and will need additional equity or debt financing or will need to generate revenues through licensing of its products or entering into strategic alliances to be able to sustain its operations through 2009. Furthermore, we will need additional financing thereafter to complete development and commercialization of our products. There can be no assurances that we can successfully complete development and commercialization of our products.

## Research and Development Projects

### *Hedrin*

In collaboration with Nordic and through the Hedrin JV we are developing Hedrin for the treatment of pediculosis (head lice). To date, Hedrin has been clinically studied in 326 subjects and is currently marketed as a device in Western Europe and as a pharmaceutical in the United Kingdom.

In a randomized, controlled, equivalence clinical study conducted in Europe by T&R, Hedrin was administered to 253 adult and child subjects with head louse infestation. The study results, published in the British Medical Journal in June 2005, demonstrated Hedrin's equivalence when compared to the insecticide treatment, phenothrin, the most widely used pediculicide in the United Kingdom. In addition, according to the same study, the Hedrin-treated subjects experienced significantly less irritation (2%) than those treated with phenothrin (9%).

An additional clinical study published in the November 2007 issue of PLoS One, an international, peer-reviewed journal published by the Public Library of Science (PLoS), demonstrated Hedrin's superior efficacy compared to a United Kingdom formulation of malathion, a widely used insecticide treatment in both Europe and North America. In this randomized, controlled, assessor blinded, parallel group clinical trial, 73 adult and child subjects with head lice infestations were treated with Hedrin or malathion liquid. Using intent-to-treat analysis, Hedrin achieved a statistically significant cure rate of 70% compared to 33% with malathion liquid. Using the per-protocol analysis Hedrin achieved a highly statistically significant cure rate of 77% compared to 35% with malathion. In Europe it has been widely documented that head lice had become resistant to European formulations of malathion, and we believe this resistance had influenced these study results. To date, there have been no reports of resistance to U.S. formulations of malathion. Additionally, Hedrin treated subjects experienced no irritant reactions, and Hedrin showed clinical equivalence to malathion in its ability to inhibit egg hatching. Overall, investigators and study subjects rated Hedrin as less odorous, easier to apply, and easier to wash out, and 97% of Hedrin treated subjects stated they were significantly more inclined to use the product again versus 31% of those using malathion.

In February 2008, we entered into the Hedrin JV Agreement. The Hedrin JV is now responsible for all obligations to T&R under the Hedrin License and Supply Agreements. In the United States, the Hedrin JV is pursuing the development of Hedrin as a medical device. We expect that the FDA will require at least one clinical trial for the approval of this product candidate.

As of September 30, 2008, we have incurred \$1,083,000 of project costs for the development of Hedrin. \$12,000 of such costs were incurred during the nine months ended September 30, 2008. We do not expect to incur any other costs for the development of Hedrin as the Hedrin JV is now responsible for the development of Hedrin.

In September 2008, the FDA directed Hedrin to the Center for Devices and Radiological Health (CDRH) division of the U.S. Food and Drug Administration (FDA) for review as a device.



***Topical PTH (1-34).***

We are developing Topical PTH (1-34) as a topical treatment for psoriasis. In August 2003, researchers, led by Michael Holick, Ph.D., MD, Professor of Medicine, Physiology, and Biophysics at Boston University Medical Center, reported positive results from a US Phase 1/2 clinical trial evaluating the safety and efficacy of Topical PTH (1-34) as a topical treatment for psoriasis. This double-blind, placebo controlled trial in 15 patients compared Topical PTH (1-34) formulated in the Novasome® Technology versus the Novasome® vehicle alone. Following 8 weeks of treatment, the topical application of Topical PTH (1-34) resulted in complete clearing of the treated lesion in 60% of patients and partial clearing in 85% of patients. Additionally, there was a statistically significant improvement in the global severity score. Ten patients continued into an open label extension study in which the Psoriasis Area and Severity Index, or PASI, was measured; PASI improvement across all 10 patients achieved statistically significant improvement compared to baseline. This study showed Topical PTH (1-34) to be a safe and effective treatment for plaque psoriasis with no patients experiencing any clinically significant adverse events.

Due to the high response rate seen in patients in the initial trial with Topical PTH (1-34) we believe that it may have an important clinical advantage over current topical psoriasis treatments. A follow on physician IND Phase 2a trial involving Topical PTH (1-34) was initiated in December 2005 under the auspices of Boston University. In April 2006, we reported a delay in its planned Phase 2a clinical study of Topical PTH (1-34) due to a formulation issue. We believe that we have resolved this issue through a new gel formulation of Topical PTH (1-34) and have filed new patent applications in the U.S. for this new proprietary formulation.

In September 2007, the U.S. FDA accepted our corporate Investigational New Drug (IND) application for this new gel formulation of Topical PTH (1-34), and in October 2007, we initiated and began dosing subjects in a phase 2a clinical study of Topical PTH (1-34) for the treatment of psoriasis. This U.S. multi-center, randomized, double-blind, vehicle-controlled, parallel group study is designed to evaluate safety and preliminary efficacy of Topical PTH (1-34) for the treatment of psoriasis. 61 subjects have been enrolled and randomized to receive one of two dose levels of Topical PTH (1-34), or vehicle, for an 8 week treatment period. In this study the vehicle is the topical formulation without the active ingredient, PTH (1-34).

As of September 30, 2008, we have incurred \$6,566,000 of project costs related to our development of Topical PTH (1-34). These project costs have been incurred since April 1, 2005, the date of the Tarpan Therapeutics acquisition. During the nine months ended September 30, 2008, we incurred \$1,355,000 of these costs.

As with the development of our other product candidates, we do not currently have sufficient capital to fund our planned development activities of Topical PTH (1-34) beyond the ongoing phase 2a trial. We will, therefore, need to raise additional capital in order to complete our planned R&D activities for Topical PTH (1-34). To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to Topical PTH (1-34) or abandon our development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

Since PTH (1-34) is already available in the injectable form, we should be able to utilize much of the data that is publicly available in planning our future studies. However, since PTH (1-34) will be used topically, bridging studies will need to be performed and we are not able to realistically predict the size and the design of those studies at this time.

In July 2008, the Company announced top-line results from its Phase 2a clinical study of topical PTH (1-34) for the treatment of psoriasis. This multi-center, randomized, double-blind, vehicle-controlled, parallel group study was designed to assess the safety and preliminary efficacy of two dose levels of topical PTH (1-34) for the treatment of mild to moderate plaque psoriasis. While the study did achieve the primary safety objective, the data did not demonstrate a statistically significant improvement in the overall disease severity of treatment lesions or signs and symptoms of psoriasis (redness, scaling, plaque thickness, and itch) as compared to the vehicle (placebo) gel. Topical PTH (1-34) appeared to be well tolerated with no serious adverse events reported. The Company intends to further analyze and assess these data in order to determine appropriate next steps for the program.

### *Altoderm*

We are developing Altoderm for the pruritis (itch) associated with dermatologic conditions including atopic dermatitis. In a Phase 3, randomized, double-blind, placebo-controlled, parallel-group, clinical study (conducted in Europe by T&R.) the compound was administered for 12 weeks to 114 subjects with moderately severe atopic dermatitis. The placebo (vehicle) used in this study was the Altoderm product without the active ingredient. In the study results, published in the British Journal of Dermatology in February 2005, Altoderm demonstrated a statistically significant reduction (36%) in atopic dermatitis symptoms. During the study, subjects were permitted to continue with their existing treatment, in most cases this consisted of emollients and topical steroids. A positive secondary outcome of the study was a 35% reduction in the use of topical steroids for the Altoderm treated subjects. Further analysis of the clinical data, performed by us showed that Altoderm treated subjects also experienced a 57% reduction in pruritis.

Altoderm is currently being tested in a second, ongoing Phase 3, randomized, double-blind, vehicle-controlled clinical study (also conducted in Europe by T&R). Analysis of the preliminary data from the initial 12 week, blinded portion of this clinical trial has been completed. The vehicle used in this study was the Altoderm product without the active ingredient, cromolyn sodium. The preliminary data indicate Altoderm was safe and well tolerated, and showed a trend toward improvement in pruritis, but the efficacy results were inconclusive. Altoderm treated subjects and vehicle only treated subjects experienced a similar improvement (each greater than 30%), and therefore, the study did not achieve statistical significance. We believe these outcomes were due to suboptimal study design where subjects were unrestricted in their use of concomitant therapies such as topical steroids and immunomodulators. The placebo (vehicle) used in this study was the Altoderm product without the active ingredient, cromolyn sodium. Analysis of the preliminary open label data beginning at week 13 of the study, show vehicle treated subjects demonstrating further improvement when switched to Altoderm. Given the promising clinical data obtained from the first European Phase 3 study, and the symptom improvements reported in the ongoing European Phase 3 study, both we and Thornton & Ross Limited believe there is significant potential for Altoderm and will continue development of this product candidate.

On March 6, 2008, we announced we had successfully completed a pre-IND meeting with the FDA. Based on a review of the submitted package for Altoderm, including data from the two previously reported Phase 3 clinical studies, the FDA determined that following completion of certain nonclinical studies, and the acceptance of an IND, Phase 2 clinical studies may be initiated in the U.S. The FDA also concurred that the proposed indication of pruritis associated with dermatologic conditions including atopic dermatitis can be pursued. We do not currently have sufficient funding for further development of Altoderm and are in discussions with T&R regarding next steps.

As of September 30, 2008, we have incurred \$1,098,000 for the development of Altoderm. We incurred \$86,000 of such costs during the nine months ended September 30, 2008.

### ***Altolyn***

We are developing Altolyn for the treatment of mastocytosis. On March 6, 2008, we announced we had successfully completed a pre-IND meeting with the FDA. Based on a review of the submitted package for Altolyn, the FDA concurred that the proposed indication of mastocytosis can be pursued and that the 505(b)(2) NDA would be an acceptable approach provided a clinical bridge is established between Altolyn and Gastrocrom<sup>®</sup>, the oral liquid formulation of cromolyn sodium currently approved in the U.S. to treat mastocytosis. The FDA also affirmed that a single, Phase 3 study demonstrating the efficacy of Altolyn over placebo, may be sufficient to support a product approval in the U.S. In addition, the FDA also concurs that no additional nonclinical studies will be required to support an IND application. We are working with T&R and the current United Kingdom manufacturer of Altolyn to develop a GMP compliant manufacturing process.

Early clinical experience with Altolyn in the United Kingdom, suggests promising activity in patients with various allergic disorders, including food allergy and inflammatory bowel conditions. We may pursue these as additional indications. We do not currently have sufficient funding for further development of Altolyn and are in discussions with T&R regarding next steps.

As of September 30, 2008, we have incurred \$826,000 for the development of Altolyn. We incurred \$36,000 of such costs during the nine months ended September 30, 2008.

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

We have not entered into any off-balance sheet arrangements.

### **New Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, "Business Combinations" ("SFAS 141R"). The revision is intended to simplify existing guidance and converge rulemaking under U.S. generally accepted accounting principles with international accounting standards. SFAS 141R applies prospectively to business combinations where the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company is currently evaluating the impact of the provisions of the revision on its consolidated results of operations and financial condition.

In March 2008, the FASB issued SFAS No. 161 "Disclosures About Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133" ("SFAS 161"). SFAS 161 amends SFAS 133 by requiring expanded disclosures about an entity's derivative instruments and hedging activities. SFAS 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of and gains and losses on derivative instruments, and disclosures about credit-risk-related contingent features in derivative instruments. SFAS 161 is effective for the Company as of January 1, 2009. The Company does not believe that SFAS 161 will have any impact on its consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS shall be effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with General Accepted Accounting Principles. We have not yet assessed the impact of adopting SFAS 162.



In February 2008, the FASB issued two Staff Positions on SFAS 157: (1) FASB Staff Position No. FAS 157-1 (**"FAS 157-1"**), *"Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement Under Statement 13,"* and (2) FASB Staff Position No. FAS 157-2 (**"FAS 157-2"**), *"Effective Date of FASB Statement No 157."* FAS 157-1 excludes FASB Statement No. 13, *Accounting for Leases*, as well as other accounting pronouncements that address fair value measurements on lease classification or measurement under Statement 13, from SFAS 157's scope. FAS157-2 partially defers Statement 157's effective date. The adoption of FAS 157-1 and FAS157-2 did not have a material impact on its financial statements.

In October 2008, the FASB issued FASB Staff Position No. FAS 157-3 "Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active" ("FAS 157-3"), which is effective upon issuance for all financial statements that have not been issued. FAS 157-3 clarifies the application of SFAS 157, in a market that is not active. FAS 157-3 does not have a material impact on the Company's financial position, financial performance or cash flows.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Our exposure to market risk is confined to our cash and cash equivalents. We have attempted to minimize risk by investing in high-quality financial instruments, primarily money market funds with no security having an effective duration longer than 90 days. If the market interest rate decreases by 100 basis points or 1%, the fair value of our cash and cash equivalents portfolio would have minimal to no impact on the carrying value of our portfolio. We did not hold any derivative instruments as of September 30, 2008, and we have never held such instruments in the past.

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

As of September 30, 2008, 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 as of that date were effective to ensure that information required to be disclosed in the reports we file under the Securities and Exchange Act is recorded, processed, summarized and reported on an accurate and timely basis.

The Company's management, including its Chief Executive Officer and its Chief Financial Officer, does not expect that disclosure controls or internal controls over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

#### **Changes in Internal Control**

During the quarter ended September 30, 2008, there were no changes in internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

The Company has been involved in an arbitration proceeding in Switzerland with Swiss Pharma Contract LTD (“Swiss Pharma”), a clinical site that the Company used in one of its obesity trials. On September 5, 2008, the sole arbitrator in Switzerland rendered an award in favor of Swiss Pharma, awarding to Swiss Pharma a total of \$646,000 which amount includes a \$323,000 contract penalty, a final services invoice of \$48,000, reimbursement of certain of Swiss Pharma’s legal and other expenses incurred in the arbitration process of \$245,000, reimbursement of arbitration costs of \$13,000 and interest through September 5, 2008 of \$17,000. Further, the arbitrator ruled that the Company must pay interest at the rate of 5% per annum on \$371,000, the sum of the \$323,000 contract penalty and the final services invoice of \$48,000, from October 12, 2007 until paid.

The Company had previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice. The remainder of the award, \$542,000, has been expensed in September 2008. The Company has recognized research and development expense of \$267,000, general and administrative expense of \$258,000 and interest expense of \$18,000 during the quarter ended September 30, 2008. The Company will continue to accrue interest at the rate of 5% per annum on the \$371,000 until such amount has been settled.

The Company does not have sufficient cash or other current assets to satisfy the arbitrator's award.

**Item 1A. Risk Factors**

We have not had material changes to our risk factor disclosure in our Annual Report on Form 10-K for the year ended December 31, 2007 under the caption “Risk Factors” following Item 1 of such report.

**Item 6. Exhibits**

<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.

**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 19, 2008

By: /s/ Douglas Abel

Douglas Abel  
President and Chief Executive Officer

Date: November 19, 2008

By: /s/ Michael G. McGuinness

Michael G. McGuinness  
Chief Operating and Financial Officer



**Index to Exhibits Filed with this Report**

**Item 6. Exhibits**

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