MANHATTAN PHARMACEUTICALS INC Form 424B3 October 16, 2008

> Pursuant to Rule 424(b)(3) File No. 333-150580

#### **PROSPECTUS**

#### Manhattan Pharmaceuticals, Inc.

## 33,928,571 Shares Common Stock

This prospectus relates to 33,928,571 shares of common stock of Manhattan Pharmaceuticals, Inc. for the sale from time to time by a certain holder of our securities, or by its pledgees, assignees and other successors-in-interest. Of these shares, (i) 26,785,714 shares are issuable upon exercise of the selling securityholder's right to put all or a portion of the selling securityholder's equity interest in a limited partnership of which we and the selling securityholder are partners and (ii) 7,142,857 shares are issuable upon exercise of an outstanding warrant held by the selling securityholder. We will not receive any proceeds from the sales of the shares of common stock by the selling securityholder. We will not receive cash proceeds from the exercise of all or any portion of the put right exercisable for shares of common stock being registered in this offering; however, in the event of any such exercise, we will receive all or a portion of the selling securityholder's equity interest in the limited partnership. We will receive the proceeds of any cash exercise of the warrant.

The distribution of securities offered hereby may be effected in one or more transactions that may take place on the Over the Counter Bulletin Board, including ordinary brokers' transactions, privately negotiated transactions or through sales to one or more dealers for resale of such securities as principals, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling securityholder.

The prices at which the selling securityholder may sell the shares in this offering will be determined by the prevailing market price for the shares or in negotiated transactions. Our common stock is traded on the Over the Counter Bulletin Board under the symbol "MHAN." On October 14, 2008, the last reported sales price for our common stock on the Over the Counter Bulletin Board was \$0.06 per share.

These securities involve a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus for factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 15, 2008.

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This prospectus contains service marks, trademarks and tradenames of Manhattan Pharmaceuticals, Inc.

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#### PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus and may not contain all the information that is important to you. This prospectus includes information about the securities being offered as well as information regarding our business. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the section entitled "Risk Factors" beginning on page 7 and our financial statements and related notes. Unless the context otherwise requires, all references to "we," "us," "our company," or "the company" in this prospectus refer collectively to Manhattan Pharmaceuticals, Inc., a Delaware corporation.

#### Overview

We are a clinical stage specialty pharmaceutical 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 in development: Hedrin<sup>TM</sup>, a novel, non-insecticide treatment for pediculosis (head lice); Topical PTH (1-34) for the treatment of psoriasis; Altoderm<sup>TM</sup> (topical cromolyn sodium) for the treatment of pruritus associated with dermatologic conditions including atopic dermatitis; and Altolyn<sup>TM</sup> (oral tablet cromolyn sodium) for the treatment of mastocytosis. We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs. Hedrin is being developed through a joint venture between us and Nordic Biotech Venture Fund II K/S.

#### **Recent Developments**

#### The Hedrin JV

We and Nordic Biotech Venture Fund II K/S, or Nordic, entered into a joint venture agreement on January 31, 2008, which was amended on February 18, 2008 and on June 9, 2008. Pursuant to the joint venture agreement, in February 2008, (i) Nordic contributed cash in the amount of \$2.5 million to Hedrin Pharmaceuticals K/S, a newly formed Danish limited partnership, or the Hedrin JV, in exchange for 50% of the equity interests in the Hedrin JV, and (ii) we contributed certain assets to North American rights (under license) to our Hedrin product to the Hedrin JV in exchange for \$2.0 million in cash and 50% of the equity interests in the Hedrin JV. On or around June 30, 2008, in accordance with the terms of the joint venture agreement, Nordic contributed an additional \$1.25 million in cash to the Hedrin JV, \$1.0 million of which was distributed to us and equity in the Hedrin JV was distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Pursuant to the joint venture agreement, upon the classification by the U.S. Food and Drug Administration, or the FDA, of Hedrin as a Class II or Class III medical device, Nordic will be required to contribute to the Hedrin JV an additional \$1.25 million in cash, \$0.5 million of which will be distributed to us and equity in the Hedrin JV will be distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Upon classification by the FDA of Hedrin as a Class II or Class III medical device, the Hedrin JV will have received a total of \$1.5 million cash to be applied toward the development and commercialization of Hedrin in North America. If classification of Hedrin by the FDA as a Class II or Class III medical device is not received by June 30, 2009, then Nordic will not be obligated to make the final milestone payment of \$1.25 million, the Hedrin JV will return to Nordic \$250,000 of the \$1.5 million Nordic contributed in June 2008 and Nordic will receive an additional 20% ownership of the joint venture and enhanced control over the joint venture's operations and other important decision-making powers.

The Hedrin JV will be 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 Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV will engage us to provide management services to the Hedrin JV in exchange for an annualized management fee, which for 2008, on an annualized basis, is \$527,000. The profits of the Hedrin JV will be shared by us and Nordic in accordance with our respective equity interests in the Hedrin JV, of which we each currently hold 50%, except that Nordic is entitled to receive a minimum return each year from the Hedrin JV equal to 6% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Hedrin JV, before any distribution is made to us. If the Hedrin JV realizes a profit in excess of the Nordic minimum return in any year, then such excess shall first be distributed to us until our distribution and the Nordic minimum return are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. However, in the event of a liquidation of the Hedrin JV, Nordic's distribution in liquidation must equal the amount Nordic invested in the Hedrin JV (\$5 million if all of the milestones described above are met and \$3.5 million if they are not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV before any distribution is made to us. If the Hedrin JV's assets in liquidation exceed the Nordic liquidation preference amount, then any excess shall first be distributed to us until our distribution and the Nordic liquidation preference amount are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

Pursuant to the terms of the joint venture agreement, Nordic has the right to nominate one person for election or appointment to our board of directors. The Hedrin JV's board of directors consists of four members, two members appointed by us and two members 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. In the event that the final payment milestone described above is not achieved by March 30, 2009, then the Hedrin JV 's board of directors will increase to five members, two appointed by us and three appointed by Nordic.

Pursuant to the joint venture agreement, Nordic has the right to put all or a portion of its interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the amount of Nordic's investment in the Hedrin JV divided by \$0.14, as adjusted from time to time for stock splits and other specified events, multiplied by a conversion factor, which is (i) 1.00 for so long as Nordic's distributions from the Hedrin JV are less than the amount of its investment, (ii) 1.25 for so long as Nordic's distributions from the Hedrin JV are less than two times the amount of its investment but greater than or equal to the amount of its investment amount, (iii) 1.50 for so long as Nordic's distributions from the Hedrin JV are less than three times the amount of its investment but greater than or equal to two times the amount of its investment amount, (iv) 2.00 for so long as Nordic's distributions from the Hedrin JV are less than four times the amount of its investment but greater than or equal to three times the amount of its investment amount and (v) 3.00 for so long as Nordic's distributions from Hedrin JV are greater than or equal to four times the amount of its investment. The put right expires upon the earlier to occur of (i) February 25, 2018 and (ii) 30 days after the date when Nordic's distributions from the Hedrin JV exceed five times the amount Nordic has invested in the Hedrin JV (or 10 days after such date if we have provided Nordic notice thereof).

Pursuant to the joint venture agreement, we have the right to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the portion of Nordic's investment in the Hedrin JV that we call by the dollar amount of Nordic's investment as of such date in the Hedrin JV, divided by \$0.14, as adjusted from time to time for stock splits and other specified events. The call right is only exercisable by us if the price of our common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 25% of the call right. During the second 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 50% of the call right on a cumulative basis. During the third consecutive 30 trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 75% of the call

right on a cumulative basis. During the fourth consecutive 30 days in which our common stock closes at or above \$1.40 per share, we may exercise up to 100% of the call right on a cumulative basis. Nordic may refuse the call, either by paying \$1.5 million multiplied by the percentage of Nordic's investment being called or forfeiting an equivalent portion of the put right, calculated on a pro rata basis for the percentage of the Nordic equity interest called by us. The call right expires on February 25, 2013.

For purposes of Nordic's right to put, and our right to call, all or a portion of Nordic's equity interest in the Hedrin JV, the amount of Nordic's investment is currently \$3,750,000; provided, that if, by June 30, 2009, the FDA either does not formally classify Hedrin as a Class II or Class III medical device or formally designates Hedrin as a drug and refers regulation thereof to the FDA Center for Drug Evaluation and Research, the amount of Nordic's investment will be reduced to \$3,500,000 and if by June 30, 2009, the FDA formally classifies Hedrin as a Class II or Class III medical device then upon Nordic's payment of the final milestone payment, Nordic's investment will be increased to \$5,000,000.

In connection with our joint venture agreement, on February 25, 2008, Nordic paid us a non-refundable fee of \$150,000 in exchange for the right to receive a warrant to purchase up to 7,142,857 shares of our common stock at \$0.14 per share, as adjusted from time to time for stock splits and other specified events, if Nordic did not exercise all or part of its put right on or before April 30, 3008. As of April 30, 2008, Nordic had not exercised all or any portion of its put right and we issued the warrant to Nordic.

In connection with the joint venture agreement, we and Nordic entered into a registration rights agreement, on February 25, 2008, as modified pursuant to a letter agreement, dated September 17, 2008, pursuant to which we agreed to file with the Securities and Exchange Commission, or the SEC, by no later than 10 calendar days following the date on which our Annual Report on Form 10-K for the year ended December 31, 2007 is required to be filed with the SEC, which was subsequently waived by Nordic until May 1, 2008, an initial registration statement registering the resale by Nordic of any shares of our common stock issuable to Nordic through the exercise of the warrant or the put right. We also have agreed to file with the SEC any additional registration statements which may be required no later than 45 days after the date we first know such additional registration statement is required; provided, however, that (i) in the case of the classification by the FDA of Hedrin as a Class II or Class III medical device described above and the payment in full by Nordic of the related final milestone payment of \$1.25 million, the registration statement with respect to the additional shares of our common stock relating to such additional investment must be filed within 45 days after achievement of such classification; and (ii) in the event we provide Nordic with notice of exercise of our right to call all or a portion of Nordic's equity interest in the Hedrin JV, a registration statement with respect to the shares of our common stock payable to Nordic in connection with such call right (after giving effect to any reduction in the number of such shares resulting from Nordic's refusal of all or a portion of such call in accordance with the terms of our joint venture agreement) must be filed within 16 days after delivery of such notice to Nordic. If we fail to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of the required filing date or in the case of the registration statement of which this prospectus forms a part, by October 17, 2008 or if we receive comments from the SEC with respect to such registration statement, November 17, 2008, or otherwise fail to diligently pursue registration with the SEC in accordance with the terms of the registration rights agreement, we will be required to pay as partial liquidated damages and not as a penalty, to Nordic or its assigns, an amount equal to 0.5% of the amount invested in the Hedrin JV by Nordic pursuant to the joint venture agreement per month until the registration rights agreement is declared effective by the SEC; provided, however, that in no event shall the aggregate amount payable by us exceed 9% of the amount invested in the Hedrin JV by Nordic under the joint venture agreement.

#### **September 2008 Promissory Note and Warrant Issuance**

On September 11, 2008, we issued secured 10% promissory notes to certain of our directors and officers and an employee for aggregate principal amount of \$70,000. Principal and interest on the notes are payable in cash on March 10, 2009 unless paid earlier by us. In connection with the issuance of the notes, we issued to the noteholders 5-year warrants to purchase an aggregate of 140,000 shares of our common stock at an exercise price of \$0.20 per share. We granted to the noteholders a continuing security interest in certain specific refunds, deposits and repayments due to us and expected to be repaid to us in the next several months.

#### **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 three 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.

#### **Corporate History – Merger Transaction(s)**

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." From an accounting perspective, the accounting acquirer is considered to be Manhattan Research Development, Inc. and accordingly, the historical financial statements are those of Manhattan Research Development, Inc.

During 2005, we merged with Tarpan Therapeutics, Inc., or 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 10,731,000 shares of our common stock, representing approximately 20% of our then outstanding common shares. This transaction was accounted for as a purchase of Tarpan by us.

#### **Principal Executive Offices**

Our executive offices are located at 48 Wall Street, New York, NY 10005 USA. Our telephone number is (212) 582-3950 and our internet address is www.manhattanpharma.com.

## The Offering

Common Stock Offered by Selling Securityholder (1): 33,928,571 shares

Common Stock Issued and Outstanding as of September

15, 2008(2):

70,624,232 shares

Common Stock Issued and Outstanding after this

Offering (3):

104,552,803 shares

Use of Proceeds: We will not receive cash

proceeds from the exercise of all or any portion of the put right exercisable for shares of common stock being registered in this offering; however, in the event of any such exercise, we will receive all or a portion of the selling securityholder's equity interest in Hedrin Pharmaceuticals K/S, a Danish limited partnership of which we and the selling securityholder are partners. We also will receive the proceeds of any cash exercise of the warrant.

Over the Counter Bulletin Board Symbol: MHAN

<sup>(1)</sup> Includes (i) 26,785,714 shares of our common stock which are issuable upon exercise of the selling securityholder's right to put all or a portion of the selling securityholder's equity interest in Hedrin Pharmaceuticals K/S and (ii) 7,142,857 shares of our common stock issuable upon exercise of an outstanding warrant held by the selling securityholder.

<sup>(2)</sup> Excludes approximately 19,590,189 shares of our common stock issuable upon exercise of outstanding warrants and options to purchase shares of our common stock and up to 42,857,143 shares issuable, or which may become issuable, upon exercise of the selling securityholder's right to put, and our right to call, all or a portion of the selling securityholder's equity interest in Hedrin Pharmaceuticals K/S and the warrant held by the selling securityholder.

<sup>(3)</sup> Based on the number of shares of our common stock outstanding as of September 15, 2008. Excludes approximately 19,590,189 shares issuable upon exercise of outstanding warrants and options to purchase shares of our common stock.

## **Summary Financial Information**

The summary financial information for the fiscal years ended December 31, 2007 and 2006 was derived from our financial statements that have been audited by J.H. Cohn LLP for the fiscal years then ended. The summary financial information for the six months ended June 30, 2008 and 2007 and for the cumulative period from August 6, 2001 to June 30, 2008 was derived from our unaudited financial data but, in the opinion of management, reflects all adjustments necessary for a fair presentation of the results for such periods. The summary financial information presented below should be read in conjunction with our audited financial statements and related notes appearing in this prospectus beginning on page F-1. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our financial statements for the fiscal years ended December 31, 2007 and 2006 and for the six months ended June 30, 2008 and 2007.

	Year Ended D	ece)	ember 31,	S	Six Months End	dec	<b>A</b>	period ugust	lative from 6, 2001 ion) to
	2007		2006		2008		2007	20	08
					(unaudi	tec	d)(i)	(unaudited)	
Statements of Operations Data:									
Revenue	\$ 0	\$	0 \$	\$	0	\$	0 \$		0
Research and development									
expense	\$ 8,535,687	\$	6,172,845	\$	1,365,799	\$	5,551,082 \$	27,	854,842
General and administrative									
expense	\$ 3,608,270	\$	3,827,482 \$			\$	1,967,098 \$		567,961
Stock-based compensation	\$ 1,440,956	\$	1,675,499	\$	295,664	\$	706,549 \$	3,0	660,647
Net loss attributable to common									
shares	\$ (12,032,252)	\$	(9,695,123)\$			\$	(7,458,657)\$	(58,	000,631)
Net loss per common share	\$ (0.18)	\$	(0.16) §	\$	(0.04)	\$	(0.11)		N/A
Statements of Cash Flows Data:									
Net cash used in operating activities	\$ (10,229,711)	\$	(7,750,738)		(2,903,970)		(6,090,775)\$	(37,0	064,526)
Net cash provided by (used in) financing activities	\$ 7,859,413	\$	(15,257)\$	\$	2,853,230	\$	7,861,381 \$	37,	284,199
Cash dividends declared	\$ 0	\$	0 \$	\$	0	\$	0 \$		0
				_	At		• .		
				D	ecember 31, 2007		At June 30, 2008	3	
Dulana Charta Duta							(unaudited)		
Balance Sheets Data: Total assets			ф		000 577	ø	072.2	40	
Total liabilities			\$ \$		980,577 1,871,662	\$	,		
Total nabilities  Total stockholders' deficiency			\$		(891,085)				
Total stockholders deficiency			Ф		(091,003)	φ	(3,440,9	02)	
6									

#### **RISK FACTORS**

An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. You should carefully consider the following risk factors and the other information contained elsewhere in this prospectus before making an investment in our securities.

#### Risks Related to Our Business

We currently have no product revenues and will need to raise additional funds in the future. If we are unable to obtain the funds necessary to continue our operations, we will be required to delay, scale back or eliminate one or more of our drug development programs.

We have generated no product revenues to date and will not generate product revenues unless and until we receive approval from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities for our product candidates. We have already spent substantial funds developing our potential products and business, however, and we expect to continue to have negative cash flow from our operations for at least the next several years. As of December 31, 2007 and June 30, 2008, we had \$0.6 million and \$0.6 million, respectively, of cash and cash equivalents. We will have to raise funds immediately to maintain operations. We will still have to raise substantial additional funds to complete the development of our product candidates and to bring them to market. Beyond the capital requirements mentioned above, our future capital requirements will depend on numerous factors, including:

the results of any clinical trials;

the scope and results of our research and development programs;

the time required to obtain regulatory approvals;

our ability to establish and maintain marketing alliances and collaborative agreements; and

the cost of our internal marketing activities.

Additional financing may not be available on acceptable terms, if at all. If adequate funds are not available, we will be required to delay, scale back or eliminate one or more of our product development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish.

# We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. We have incurred losses in every period since our inception on August 6, 2001. For the six months ended June 30, 2008, for the year ended December 31, 2007 and for the period from August 6, 2001 (inception) through June 30, 2008, we incurred net losses applicable to common shares of \$3,001,561, \$12,032,252 and \$58,000,631 respectively. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

continue to undertake nonclinical development and clinical trials for our product candidates;

seek regulatory approvals for our product candidates;

· implement additional internal systems and infrastructure;

lease additional or alternative office facilities; and

hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

As a result of our continued losses, our independent auditors have included an explanatory paragraph in our financial statements for the fiscal years ended December 31, 2007 and 2006, expressing doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our independent auditors will make it more difficult for us to secure additional financing or enter into strategic relationships with distributors on terms acceptable to us, if at all, and likely will materially and adversely affect the terms of any financing that we may obtain. If revenues grow slower than we anticipate, or if operating expenses exceed our expectations or cannot be adjusted accordingly, we may not achieve profitability and the value of your investment could decline significantly.

## We have a limited operating history upon which to base an investment decision.

We are a development-stage company and have not yet demonstrated any ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

continuing to undertake nonclinical development and clinical trials;

participating in regulatory approval processes;

formulating and manufacturing products; and

conducting sales and marketing activities.

Since inception as Manhattan Research Development, Inc., our operations have been limited to organizing and staffing, and acquiring, developing and securing our proprietary technology and undertaking nonclinical and clinical trials of principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

# We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidates.

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions.

In order to obtain FDA approval of any of our drug product candidates, we must first submit to the FDA an IND, which will set forth our plans for clinical testing of our product candidates. We are unable to estimate the size and timing of the clinical and non clinical trials required to bring our drug product candidates to market and, accordingly, cannot estimate the time when development of these product candidates will be completed. When the clinical testing for our drug product candidates is complete, we will submit to the FDA an Investigational New Drug Application, or NDA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as nonclinical studies, as well as

human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses.

The development, testing, production and marketing of medical devices also is subject to regulation by the FDA. Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive either 510(k) clearance or pre-market approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. The FDA's 510(k) clearance process usually takes several months, but it can take longer and is unpredictable. The process of obtaining pre-market approval is much more costly and uncertain than the 510(k) clearance process and it can take much longer. Testing, preparation of necessary applications and the processing of those applications by the FDA is expensive and time consuming. We do not know if the FDA will act favorably or quickly in making such reviews, and significant difficulties or costs may be encountered by us in our efforts to obtain FDA clearance and approval. The FDA may also place conditions on clearance and approvals that could restrict commercial applications of such products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

The FDA has substantial discretion in the drug and medical device approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Delays in obtaining regulatory approvals may:

delay commercialization of, and our ability to derive product revenues from, our product candidates;

impose costly procedures on us; and

diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our products. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We have not yet made any determination as to which foreign jurisdictions we may seek approval and have not undertaken any steps to obtain approvals in any foreign jurisdiction.

#### Clinical trials are very expensive, time consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our drug product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

slower than expected rates of patient recruitment;

inability to monitor patients adequately during or after treatment; and

· inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or other applications or the conduct of these trials.

#### The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans or effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs or other applications with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

# Physicians and patients may not accept and use our products.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product will depend upon a number of factors including:

- ·perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
  - · cost-effectiveness of our product relative to competing products;
  - · availability of reimbursement for our products from government or other healthcare payers; and
  - · effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

#### Our drug and device-development programs depend upon third-party researchers who are outside our control.

We currently are collaborating with several third-party researchers, for the development of our drug and device product candidates. Accordingly, the successful development of our drug and device product candidates will depend on the performance of these third parties. These collaborators will not be our employees, however, and we cannot control the amount or timing of resources that they will devote to our programs. Our collaborators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug and device development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs and devices, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

# We rely exclusively on third parties to formulate and manufacture our drug and device product candidates.

We have no experience in drug and device product formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own drug and device product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store and distribute product supplies for our clinical trials. If any of our drug or device product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture our products. Our anticipated future reliance on a limited number of third-party manufacturers, exposes us to the following risks:

- ·We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- ·Our third-party manufacturers might be unable to formulate and manufacture our products in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- ·Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- ·Manufacturers of drug and medical devices are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- ·If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

# We have no experience selling, marketing or distributing products and no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain such collaborative relationships, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

If we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future products developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have product candidates that will compete with ours already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

developing drugs;

· undertaking nonclinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

## Developments by competitors may render our products or technologies obsolete or non-competitive.

Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We currently do not directly own the rights to any issued patents. We license the exclusive rights to a total of four issued patents relating to our current product candidates, which expire from 2013 to 2022. See "Business – Intellectual Property and License Agreements."

However, with regard to the patents covered by our license agreements and any future patents issued to which we will have rights, we cannot predict:

•the degree and range of protection any patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;

if and when patents will issue;

- ·whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- · whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

If we infringe the rights of third parties, we could be prevented from selling products and forced to pay damages and defend against litigation, which could adversely affect our ability to execute our business plan.

Our business is substantially dependent on the intellectual property on which our product candidates are based. To date, we have not received any threats or claims that we may be infringing on another's patents or other intellectual property rights. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

obtain licenses, which may not be available on commercially reasonable terms, if at all;

redesign our products or processes to avoid infringement;

stop using the subject matter claimed in the patents held by others;

pay damages; or

·defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

government and health administration authorities;

private health maintenance organizations and health insurers; and

other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

## We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may suffer.

## If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in nonclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

# We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. We currently carry clinical trial insurance in an amount up to \$5,000,000, which may be inadequate to protect against potential product liability claims or may inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. Although we intend to maintain clinical trial insurance during any clinical trials, this may be inadequate to protect us against any potential claims. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

#### **Risks Related to Our Securities**

Our current officers, directors and principal stockholders have substantial control over us and may such control over all corporate actions requiring stockholder approval, irrespective of how our other stockholders including purchasers in this offering may vote.

Our directors, executive officers and principal stockholders beneficially own 55,421,093 shares, or approximately 50.03%, of our outstanding voting stock as of September 15, 2008, including 4,801,933 shares underlying outstanding options, 8,566,576 shares underlying outstanding warrants and 26,785,714 shares underlying Nordic's put right or, subject to the satisfaction of certain conditions and certain exceptions, our call right, pursuant to our joint venture agreement with Nordic Biotech Venture Fund II K/S. In addition, Nordic alone beneficially owns 33,928,571 shares, or approximately 32.5%, of our outstanding voting stock as of June 30, 2008, including 7,142,857 shares underlying its warrant and 26,785,714 shares underlying Nordic's put right or, subject to the satisfaction of certain conditions and certain exceptions, our call right, pursuant to our joint venture agreement with Nordic Biotech Venture Fund II K/S and excluding an additional 8,928,572 shares underlying the put or call right pursuant to the joint venture agreement that remain subject to the satisfaction of certain conditions. Accordingly, these persons and their respective affiliates will have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

# Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

During the last two fiscal years, our stock price has traded at a low of \$0.08 in the third quarter of 2008 to a high of \$1.64 in the first quarter of 2006. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

•publicity regarding actual or potential clinical results relating to products under development by our competitors or us;

·delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;

achievement or rejection of regulatory approvals by our competitors or us;

announcements of technological innovations or new commercial products by our competitors or us;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

regulatory developments in the United States and foreign countries;

economic or other crises and other external factors;

period-to-period fluctuations in our revenues and other results of operations;

changes in financial estimates by securities analysts; and

sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

Because our common stock has been delisted from the American Stock Exchange, you may not be able to resell your shares at or above the price at which you purchased your shares, or at all.

As a result of our common stock having been delisted from the American Stock Exchange, the liquidity of our common stock may be reduced, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock.

#### Penny stock regulations may impose certain restrictions on marketability of our securities.

The Securities and Exchange Commission has adopted Rule 15g-9 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

that a broker or dealer approve a person's account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

obtain financial information and investment experience objectives of the person; and

·make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in

penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also must be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of your stock.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our stock in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

If you are not an institutional investor, you may purchase our securities in this offering only if you reside within certain states and may engage in resale transactions only in those states and a limited number of other jurisdictions.

If you are not an "institutional investor," you will need to be a resident of certain jurisdictions to purchase our securities in this offering. The definition of an "institutional investor" varies from state to state but generally includes financial institutions, broker-dealers, banks, insurance companies and other qualified entities. In order to prevent resale transactions in violation of states' securities laws, you may engage in resale transactions only in the states and in other jurisdictions in which an applicable exemption is available or a registration application has been filed and accepted. This restriction on resale may limit your ability to resell the securities purchased in this offering and may impact the price of our shares.

If you are not an institutional investor, you generally will not be permitted to purchase shares in this offering unless there is an available exemption or we register the shares covered by this prospectus in such states.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business," and elsewhere in this prospectus contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as "indicates," "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of such terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on these statements, which speak only as of the date of this prospectus. We are under no duty to update any of the forward-looking statements after the date of this prospectus to conform such statements to actual results.

#### **USE OF PROCEEDS**

We are registering shares of our common stock pursuant to registration rights granted to the selling securityholder. We will not receive any of the proceeds from the sale of the common stock by the selling securityholder named in this prospectus. All proceeds from the sale of the common stock will be paid directly to the selling securityholder.

We will not receive cash proceeds from the exercise of all or any portion of the put right exercisable for shares of common stock being registered in this offering; however, in the event of any such exercise, we would receive all or a portion of the selling securityholder's equity interest in the Hedrin Pharmaceuticals K/S. If all of the warrant exercisable for shares of common stock being registered in this offering is exercised for cash, we could receive net proceeds of up to approximately \$1,000,000. We intend to use the estimated net proceeds received upon exercise of the warrant, if any, for working capital and general corporate purposes. The warrant may not be exercised, and we cannot assure you that the warrant will be exercised.

We have agreed to pay all costs, expenses and fees relating to registering the shares of our common stock referenced in this prospectus. The selling securityholder will pay any brokerage commissions and/or similar charges incurred for the sale of such shares of our common stock.

#### PRICE RANGE FOR OUR COMMON STOCK

Our common stock traded on the American Stock Exchange "AMEX" under the symbol "MHA" during the years ended December 31, 2006 and 2007 and for the period from January 1, 2008 to March 26, 2008. On March 26, 2008, our common stock was voluntarily delisted from the AMEX and began trading on the Over the Counter Bulletin Board under the symbol "MHAN". The following table lists the high and low price for our common stock as quoted, in U.S. dollars, on the American Stock Exchange or the Over the Counter Bulletin Board for the periods indicated:

	High	Low
2006	_	
First Quarter	\$ 1.640	\$ 1.160
Second Quarter	\$ 1.360	\$ 0.075
Third Quarter	\$ 0.880	\$ 0.620
Fourth Quarter	\$ 0.920	\$ 0.620
2007		
First Quarter	\$ 0.960	\$ 0.700
Second Quarter	\$ 1.100	\$ 0.690
Third Quarter	\$ 0.780	\$ 0.220
Fourth Quarter	\$ 0.230	\$ 0.090
2008		
First Quarter	\$ 0.230	\$ 0.110
Second Quarter	\$ 0.180	\$ 0.100
Third Quarter (through August 28, 2008)	\$ 0.200	\$ 0.100

The number of holders of record of our common stock as of August 1, 2008 was 453.

#### **DIVIDEND POLICY**

To date, we have not paid any dividends on our common stock and we do not intend to pay dividends for the foreseeable future, but intend instead to retain earnings, if any, for use in our business operations. The payment of dividends in the future, if any, will be at the sole discretion of our board of directors and will depend upon our debt and equity structure, earnings and financial condition, need for capital in connection with possible future acquisitions and other factors, including economic conditions, regulatory restrictions and tax considerations. We cannot guarantee that we will pay dividends or, if we pay dividends, the amount or frequency of these dividends.

#### SELECTED FINANCIAL INFORMATION

The selected financial information for the fiscal years ended December 31, 2007 and 2006 and for the cumulative period from August 6, 2001 to December 31, 2007 was derived from our financial statements that have been audited by J.H. Cohn LLP for the fiscal years then ended. The summary financial information for the six months ended June 30, 2008 and 2007 was derived from our unaudited financial data but, which in the opinion of management, reflects all adjustments necessary for a fair presentation of the results for such periods. The selected financial information presented below should be read in conjunction with our audited financial statements and related notes appearing in this prospectus beginning on page F-1. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our financial statements for the fiscal years ended December 31, 2007 and 2006 and for the six months ended June 30, 2008 and 2007.

		Year Ended D 2007	)ece	ember 31, 2006	S	Six Months En 2008 (unaud		d June 30, 2007	per Augu (inc Dec Augu (inc	mulative riod from ust 6, 2001 eption) to ember 31, ust 6, 2001 eption) to une 30, 2008 naudited)
Statements of Operations						`			Ì	
Data:	Φ.		Φ.		Α.		Φ.		Φ.	
Revenue	\$	0	\$	0 3	\$	0	\$	0	\$	0
Research and development	ф	0.525.607	ф	6 170 045	ф	1 265 500	ф	5 551 000	Φ.	27.054.042
expense General and administrative	\$	8,535,687	\$	6,172,845	<b>&gt;</b>	1,365,799	\$	5,551,082	<b>)</b>	27,854,842
	\$	3,608,270	\$	3,827,482	Ф	1,715,598	\$	1,967,098	Φ	15,567,961
expense Stock-based compensation	\$	1,440,956	\$	1,675,499			\$	706,549		3,660,647
Net loss attributable to common	Ψ	1,440,730	Ψ	1,073,477	Ψ	273,004	Ψ	700,547	Ψ	3,000,047
shares	\$	(12,032,252)	\$	(9,695,123)	\$	(3,001,561)	\$	(7,458,657)	\$ C	58,000,631)
Net loss per common share	\$	(0.18)	\$	(0.16)			\$	(0.11)	Ψ (.	N/A
1		()	Ċ	(=)		(2.2.2)		()		
Statements of Cash Flows										
Data:										
Net cash used in operating										
activities	\$	(10,229,711)	\$	(7,750,738)		(2,903,970)		(6,090,775)	\$ (	37,064,526)
Net cash provided by (used in)										
financing activities	\$	7,859,413	\$	(15,257)			\$	7,861,381		37,284,199
Cash dividends declared	\$	0	\$	0 3	\$	0	\$	0	\$	0
						At				
					D	ecember 31,		At		
					_	2007		June 30, 20	08	
								(unaudited		
Balance Sheets Data:										
Total assets				\$		980,577			,340	
Total liabilities				\$		1,871,662	\$	4,420	,322	

Total stockholders' deficiency \$ (891,085) \$ (3,446,982)

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in the "Risk Factors" section of this prospectus. Actual results may differ materially from those contained in any forward-looking statements. The following discussion should be read in conjunction with "Selected Financial Information" and our financial statements and notes thereto included elsewhere in this prospectus.

#### Overview

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 us.

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 in development:

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

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

We announced in July 2007 that we are discontinuing 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 consolidated financial statements and notes thereto appearing elsewhere in this prospectus. 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" and should not unduly rely on these forward-looking statements.

## **Results of Operations**

Six-Month Period Ended June 30, 2008 vs. Six-Month Period Ended June 30, 2007

	Six Months er	ıded	June 30,		Increase	% Increase	
	2008	2007			(decrease)	(decrease)	
COSTS AND EXPENSES							
Research and development							
Share-based compensation	\$ 80,000	\$	224,000	\$	(144,000)	(64)%	
Other research and development							
expense	\$ 1,286,000	\$	5,327,000	\$	(4,041,000)	(76)%	
Total research and development							
expense	\$ 1,366,000	\$	5,551,000	\$	(4,185,000)	(75)%	
General and administrative							
Share-based compensation	\$ 215,000	\$	482,000	\$	(267,000)	(55)%	
Other general and administrative							
expense	\$ 1,500,000	\$	1,485,000	\$	15,000	1%	
Total general and administrative							
expense	\$ 1,715,000	\$	1,967,000	\$	(252,000)	(13)%	
Other income	\$ 79,000	\$	59,000	\$	20,000	34%	
NET LOSS	\$ (3,002,000)	\$	(7,459,000)	\$	(4,457,000)	(60)%	

During each of the six months ended June 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 June 30, 2009, if at all.

For the six months ended June 30, 2008, total research and development expense was \$1,366,000 as compared to \$5,551,000 for the six months ended June 30, 2007. The decrease of \$4,185,000, or 75%, is attributable to decreases of \$2,511,000 in development projects discontinued during 2007 (OE and propofol), of \$860,000 for Hedrin, \$595,000 for Altoderm and \$490,000 for Altolyn offset by an increase in development costs for PTH (1-34) of \$271,000. There were no development costs in the six months ended June 30, 2008 for OE or propofol. During the six months ended June 30, 2007 the majority of the development costs incurred for Altoderm, Altolyn and Hedrin relate to in-licensing costs. The increase in development costs for PTH (1-34) is due to the costs of the ongoing Phase 2a clinical study.

For the six months ended June 30, 2008, total general and administrative expense was \$1,715,000 as compared to \$1,967,000 for the six months ended June 30, 2007. The decrease of \$252,000, or 13%, is primarily attributable to a decrease of \$267,000 in stock-based compensation.

For the six months ended June 30, 2008, other income was \$79,000 as compared to \$59,000 for the six months ended June 30, 2007. The increase of \$20,000, or 34%, 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 \$108,000 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 six months ended June 30, 2008, was \$3,002,000 as compared to \$7,459,000 for the six months ended June 30, 2007. The decrease of \$4,457,000, or 60%, in net loss is principally attributable to decreases in research and development expense of \$4,185,000 and in general and administrative expense of \$252,000 and an increase in other income of \$20,000.

Three-Month Period Ended June 30, 2008 vs. Three-Month Period Ended June 30, 2007

	Three Months ended June 30, 2008 2007			Increase (decrease)	% Increase (decrease)
COSTS AND EXPENSES					
Research and development					
Share-based compensation	\$ 27,000	\$	122,000	\$ (95,000)	(77)%
Other research and development					
expense	\$ 539,000	\$	3,750,000	\$ (3,211,000)	(86)%
Total research and development					
expense	\$ 566,000	\$	3,872,000	\$ (3,306,000)	(85)%
General and administrative					
Share-based compensation	\$ 75,000	\$	250,000	\$ (175,000)	(70)%
Other general and administrative					
expense	\$ 826,000	\$	803,000	\$ 23,000	3%
Total general and administrative					
expense	\$ 901,000	\$	1,053,000	\$ (152,000)	(14)%
Other income	\$ 45,000	\$	30,000	\$ 15,000	50%
NET LOSS	\$ (1,442,000)	\$	(4,895,000)	\$ (3,473,000)	(71)%

During each of the quarters ended June 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 June 30, 2009, if at all.

For the quarter ended June 30, 2008, total research and development expense was \$566,000 as compared to \$3,872,000 for the quarter ended June 30, 2007. The decrease of \$3,306,000, or 85%, is attributable to decreases of \$1,075,000 in development projects discontinued during 2007 (OE and propofol), of \$869,000 for Hedrin, \$674,000 for Altoderm, \$523,000 for Altolyn and\$165,000 for PTH (1-34). There were no development costs in the three months ended June 30, 2008 for OE or propofol. During the three months ended June 30, 2007 the majority of the development costs incurred for Altoderm, Altolyn and Hedrin relate to in-licensing costs.

For the quarter ended June 30, 2008, total general and administrative expense was \$901,000 as compared to \$1,053,000 for the quarter ended June 30, 2007. The decrease of \$152,000, or 14%, is primarily attributable to a decrease of \$175,000 in stock-based compensation.

For the quarter ended June 30, 2008, other income was \$45,000 as compared to \$30,000 for the quarter ended June 30, 2007. The increase of \$15,000, or 50%, is due primarily to \$132,000 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 \$88,000 and a \$29,000 decrease in interest income which resulted from lower average balances in interest bearing cash and short-term investment accounts.

Net loss for the quarter ended June 30, 2008 was \$1,442,000 as compared to \$4,895,000 for the quarter ended June 30, 2007. The decrease of \$3,473,000, or 71%, in net loss is principally attributable to a decreases in research and development expense of \$3,306,000 and \$152,000 in general and administrative expense offset by an increase in other income of \$15,000.

## Fiscal Year ended December 31, 2007 versus Fiscal Year Ended December 31, 2006

During each of the years ended December 31, 2007 and 2006, we had no revenues, and are considered a development stage company. We do not expect to have revenues relating to our products prior to December 31, 2008.

	Years ended December 31,					Increase	% Increase
		2007		2006		(decrease)	(decrease)
Costs and expenses							
Research and development							
Share-based compensation	\$	539,000	\$	529,000	\$	10,000	1.89%
In-license, milestone and related fees		2,245,000		250,000		1,995,000	798.00%
Other research and development							
expenses		5,752,000		5,394,000		358,000	6.64%
Total research and development							
expenses		8,536,000		6,173,000		2,363,000	38.28%
General and administrative							
Share-based compensation		902,000		1,147,000		(245,000)	(21.36)%
Other general and administrative							
expenses		2,706,000		2,680,000		26,000	0.97%
Total general and administrative							
expenses		3,608,000		3,827,000		(219,000)	(5.72)%
Other income		112,000		305,000		(193,000)	(63.28)%
Net loss	\$	12,032,000	\$	9,695,000	\$	2,337,000	24.11%

For the year ended December 31, 2007, research and development expense was \$8,536,000 as compared to \$6,173,000 for the year ended December 31, 2006. This increase of \$2,363,000, or 38.3%, is primarily comprised of an increase in in-license, milestone and related fees of \$1,995,000, an increase in other research and development expenses of \$358,000 and an increase in stock based compensation of \$10,000.

For the year ended December 31, 2007, general and administrative expense was \$3,608,000 as compared to \$3,827,000 for the year ended December 31, 2006. This decrease of \$219,000, or 5.7%, is primarily comprised of a decrease in stock based compensation of \$245,000 partially offset by an increase in other general and administrative expense of \$26,000.

For the year ended December 31, 2007, other income was \$112,000 as compared to \$305,000 for the year ended December 31, 2006. This decrease of \$193,000, or 63.3%, is primarily due to a decrease in interest income which resulted from lower average balances in interest bearing and short-term investment accounts.

Net loss for the year ended December 31, 2007 was \$12,032,000 as compared to \$9,695,000 for the year ended December 31, 2006. This increase of \$2,337,000, or 24.11%, is primarily due to an increase in in-license, milestone and related fees of \$1,995,000, an increase in other research and development expenses of \$358,000 and a decrease of \$193,000 in other income partially offset by a decrease in stock based compensation of \$235,000.

# **Liquidity and Capital Resources**

From inception to June 30, 2008, we incurred a deficit during the development stage of \$58 million primarily as a result of our net losses and preferred stock dividends. We expect to continue to incur additional losses through at least June 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 we have an immediate need for capital in order to sustain our operations into the fourth quarter of 2008 and will need additional equity or debt financing or will need to generate revenues through licensing of our products or entering into strategic alliances to be able to sustain its operations through 2008.

We have financed our operations since inception primarily through equity financing. During the six months ended June 30, 2008, we had a net decrease in cash and cash equivalents of \$73,000. This decrease resulted principally from the net proceeds from the Hedrin JV Agreement of \$2.8 million, partially offset by net cash used in operating activities of \$2.9 million. Total liquid resources as of June 30, 2008 were \$0.5 million compared to \$0.6 million at December 31, 2007.

# Liquidity

As of June 30, 2008, we had a working capital deficit of \$755,000 as compared to a working capital deficit of \$1,006,000 at December 31, 2007. This \$251,000 reduction in the working capital deficit is primarily due to a decrease in accounts payable and accrued expenses of \$404,000 offset decreases in cash of \$73,000 and prepaid expenses and other current assets of \$80,000.

#### 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 our 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 June 30, 2008 and ending March 30, 2012.

Pursuant to these subscription agreements, we 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.

We 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

We and Nordic Biotech Venture Fund II K/S, or Nordic, entered into a joint venture agreement on January 31, 2008, which was amended on February 18, 2008 and on June 9, 2008. Pursuant the joint venture agreement, in February 2008, (i) Nordic contributed cash in the amount of \$2.5 million to Hedrin Pharmaceuticals K/S, a newly formed Danish limited partnership, or the Hedrin JV, in exchange for 50% of the equity interests in the Hedrin JV, and (ii) we contributed certain assets to North American rights (under license) to our Hedrin product to the Hedrin JV in exchange for \$2.0 million in cash and 50% of the equity interests in the Hedrin JV. On or around June 30, 2008, in accordance with the terms of the joint venture agreement, Nordic contributed an additional \$1.25 million in cash to the Hedrin JV, \$1.0 million of which was distributed to us and equity in the Hedrin JV was distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Pursuant to the joint venture agreement, upon the classification by the U.S. Food and Drug Administration, or the FDA, of Hedrin as a Class II or Class III medical device, Nordic will be required to contribute to the Hedrin JV an additional \$1.25 million in cash, \$0.5 million of which will be distributed to us and equity in the Hedrin JV will be distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Upon classification by the FDA of Hedrin as a Class II or Class III medical device, the Hedrin JV will have received a total of \$1.5 million cash to be applied toward the development and commercialization of Hedrin in North America. If classification of Hedrin by the FDA as a Class II or Class III medical device is not received by June 30, 2009, then Nordic will not be obligated to make the final milestone payment of \$1.25 million, the Hedrin JV will return to Nordic \$250,000 of the \$1.5 million Nordic contributed in June 2008 and Nordic will receive an additional 20% ownership of the joint venture and enhanced control over the joint venture's operations and other important decision-making powers.

The Hedrin JV will be 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 Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV will engage us to provide management services to the Hedrin JV in exchange for an annualized management fee, which for 2008, on an annualized basis, is \$527,000. As of June 30, 2008, we had recognized \$183,266 of other income from management fees earned from the Hedrin JV.

The profits of the Hedrin JV will be shared by us and Nordic in accordance with our respective equity interests in the Hedrin JV, of which we each currently hold 50%, except that Nordic is entitled to receive a minimum return each year from the Hedrin JV equal to 6% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Hedrin JV, before any distribution is made to us. If the Hedrin JV realizes a profit in excess of the Nordic minimum return in any year, then such excess shall first be distributed to us until our distribution and the Nordic minimum return are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. However, in the event of a liquidation of the Hedrin JV, Nordic's distribution in liquidation must equal the amount Nordic invested in the Hedrin JV (\$5 million if all of the milestones described above are met and \$3.5 million if they are not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV before any distribution is made to us. If the Hedrin JV's assets in liquidation exceed the Nordic liquidation preference amount, then any excess shall first be distributed to us until our distribution and the Nordic liquidation preference amount are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

Pursuant to the terms of the joint venture agreement, Nordic has the right to nominate one person for election or appointment to our board of directors. The Hedrin JV's board of directors consists of four members, two members appointed by us and two members 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. In the event that the final payment milestone described above is not achieved by March 30, 2009, then the Hedrin JV 's board of directors will increase to five

members, two appointed by us and three appointed by Nordic.

Pursuant to the joint venture agreement, Nordic has the right to put all or a portion of its interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the amount of Nordic's investment in the Hedrin JV divided by \$0.14, as adjusted from time to time for stock splits and other specified events, multiplied by a conversion factor, which is (i) 1.00 for so long as Nordic's distributions from the Hedrin JV are less than the amount of its investment, (ii) 1.25 for so long as Nordic's distributions from the Hedrin JV are less than two times the amount of its investment but greater than or equal to the amount of its investment amount, (iii) 1.50 for so long as Nordic's distributions from the Hedrin JV are less than three times the amount of its investment but greater than or equal to two times the amount of its investment amount, (iv) 2.00 for so long as Nordic's distributions from the Hedrin JV are less than four times the amount of its investment but greater than or equal to three times the amount of its investment amount and (v) 3.00 for so long as Nordic's distributions from Hedrin JV are greater than or equal to four times the amount of its investment. The put right expires upon the earlier to occur of (i) February 25, 2018 and (ii) 30 days after the date when Nordic's distributions from the Hedrin JV exceed five times the amount Nordic has invested in the Hedrin JV (or 10 days after such date if we have provided Nordic notice thereof).

Pursuant to the joint venture agreement, we have the right to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the portion of Nordic's investment in the Hedrin JV that we call by the dollar amount of Nordic's investment as of such date in the Hedrin JV, divided by \$0.14, as adjusted from time to time for stock splits and other specified events. The call right is only exercisable by us if the price of our common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 25% of the call right. During the second 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 50% of the call right on a cumulative basis. During the third consecutive 30 trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 75% of the call right on a cumulative basis. During the fourth consecutive 30 days in which our common stock closes at or above \$1.40 per share, we may exercise up to 100% of the call right on a cumulative basis. Nordic may refuse the call, either by paying \$1.5 million multiplied by the percentage of Nordic's investment being called or forfeiting an equivalent portion of the put right, calculated on a pro rata basis for the percentage of the Nordic equity interest called by us. The call right expires on February 25, 2013.

For purposes of Nordic's right to put, and our right to call, all or a portion of Nordic's equity interest in the Hedrin JV, the amount of Nordic's investment is currently \$3,750,000; provided, that if, by June 30, 2009, the FDA either does not formally classify Hedrin as a Class II or Class III medical device or formally designates Hedrin as a drug and refers regulation thereof to the FDA Center for Drug Evaluation and Research, the amount of Nordic's investment will be reduced to \$3,500,000 and if by June 30, 2009, the FDA formally classifies Hedrin as a Class II or Class III medical device then upon Nordic's payment of the final milestone payment, Nordic's investment will be increased to \$5,000,000.

In connection with our joint venture agreement, on February 25, 2008, Nordic paid us a non-refundable fee of \$150,000 in exchange for the right to receive a warrant to purchase up to 7,142,857 shares of our common stock at \$0.14 per share, as adjusted from time to time for stock splits and other specified events, if Nordic did not exercise all or part of its put right on or before April 30, 3008. The per share exercise price of the warrant was based on the volume weighted average price of our common stock for the period prior to the signing of the Hedrin JV Agreement. As of April 30, 2008, Nordic had not exercised all or any portion of its put right and we issued the warrant to Nordic.

In connection with the joint venture agreement, we and Nordic entered into a registration rights agreement, on February 25, 2008, as modified pursuant to a letter agreement, dated September 17, 2008, pursuant to which we agreed to file with the Securities and Exchange Commission, or the SEC, by no later than 10 calendar days following the date on which our Annual Report on Form 10-K for the year ended December 31, 2007 is required to be filed with the SEC, which was subsequently waived by Nordic until May 1, 2008, an initial registration statement registering the resale by Nordic of any shares of our common stock issuable to Nordic through the exercise of the warrant or the put right. We also have agreed to file with the SEC any additional registration statements which may be required no later than 45 days after the date we first know such additional registration statement is required; provided, however, that (i) in the case of the classification by the FDA of Hedrin as a Class II or Class III medical device described above and the payment in full by Nordic of the related final milestone payment of \$1.25 million, the registration statement with respect to the additional shares of our common stock relating to such additional investment must be filed within 45 days after achievement of such classification; and (ii) in the event we provide Nordic with notice of exercise of our right to call all or a portion of Nordic's equity interest in the Hedrin JV, a registration statement with respect to the shares of our common stock payable to Nordic in connection with such call right (after giving effect to any reduction in the number of such shares resulting from Nordic's refusal of all or a portion of such call in accordance with the terms of our joint venture agreement) must be filed within 16 days after delivery of such notice to Nordic . If we fail to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of the required filing date or in the case of the registration statement of which this prospectus forms a part, by October 17, 2008 or if we receive comments from the SEC with respect to such registration statement, November 17, 2008, or otherwise fail to diligently pursue registration with the SEC in accordance with the terms of the registration

rights agreement, we will be required to pay as partial liquidated damages and not as a penalty, to Nordic or its assigns, an amount equal to 0.5% of the amount invested in the Hedrin JV by Nordic pursuant to the joint venture agreement per month until the registration rights agreement is declared effective by the SEC; provided, however, that in no event shall the aggregate amount payable by us exceed 9% of the amount invested in the Hedrin JV by Nordic under the joint venture agreement.

# September 2008 Promissory Note and Warrant Issuance

On September 11, 2008, we issued secured 10% promissory notes to certain of our directors and officers and an employee for aggregate principal amount of \$70,000. Principal and interest on the notes are payable in cash on March 10, 2009 unless paid earlier by us. In connection with the issuance of the notes, we issued to the noteholders 5-year warrants to purchase an aggregate of 140,000 shares of our common stock at an exercise price of \$0.20 per share. We granted to the noteholders a continuing security interest in certain specific refunds, deposits and repayments due to us and expected to be repaid to us in the next several months.

## **American Stock Exchange**

In September 2007, we received notice from the staff of 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 six 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.

During 2007, we entered into an agreement with Therapeutics, Inc. for the conduct of a Phase 2a clinical trial of Topical PTH (1-34). The amount of the agreement is approximately \$845,000. The remaining financial commitment at June 30, 2008 related to the conduct of the clinical trial is approximately \$100,000. This clinical trial is expected to conclude in the second quarter of 2008.

Swiss Pharma Contract LTD, or Swiss Pharma, a clinical site that we used in one of its obesity trials, gave notice to us that Swiss Pharma believes it is entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. While the contract between us and Swiss Pharma provides for additional payments if certain conditions are met, Swiss Parma has not specified which conditions they believe have been achieved and we do not believe that Swiss Pharma is entitled to additional payments and has not accrued any of these costs as of December 31, 2007. The contract between us and Swiss Pharma provides for arbitration in the event of a dispute, such as this claim for an additional payment. On March 10, 2008, Swiss Pharma filed for arbitration with the Swiss Chamber of Commerce. As we do not believe that Swiss Pharma is entitled to additional payments, we intend to defend our position in arbitration. On April 2, 2008, we filed our statement of defense and counterclaim for recovery of costs incurred by us as a result of Swiss Pharma's failure to meet agreed upon deadlines under our contract. On June 3, 2008, a hearing was held before the arbitrator. On September 5, 2008, the arbitrator 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 we 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. We previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice and therefore, will recognize expense for the difference between the award of \$646,000 and the previously recognized liability of \$104,000, or \$542,000, in the quarter ending September 30, 2008. We will also continue to accrue interest at the rate of 5% per annum on the \$371,000. We disagree with the result of the arbitration and are exploring our post-award options, including potential appellate remedies in Switzerland, and defense of any actions which may be taken to enforce the arbitration award. We do not have sufficient cash or other current assets to satisfy the arbitrator's award.

In February 2007, a former employee of our company alleged an ownership interest in two of our provisional patent applications covering our discontinued product development program for Oleoyl-estrone. Also, without articulating precise legal claims, the former employee contends that we 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 our provisional patent applications. The former employee is seeking an unspecified amount in damages. We refute the former employee's contentions and intend to vigorously defend ourself should the former employee file claims against us. 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 with Thornton & Ross Ltd, or T&R, and Kerris, S.A., or Kerris. Pursuant to the Hedrin license agreement, we acquired an exclusive North American license to

certain patent rights and other intellectual property relating to  $Hedrin^{TM}$  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.

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

Further, we agreed to make future milestone payments to T&R and Kerris 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 T&R and Kerris and the proceeds resulting from such sublicenses will be shared with T&R and Kerris.

In February 2008, we entered into the Hedrin joint venture 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 joint venture 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 June 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, we 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. We intend 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 June 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 June 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**

We have 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 one year for one of the employees, and 9 months for the second employee, and have a total remaining obligation under these agreements of \$589,469 as of June 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 June 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 available to us at June 30, 2008, management believes that we have an immediate need for capital in order to sustain our operations and will need additional equity or debt financing or will need to generate revenues through licensing of our products or entering into strategic alliances to be able to sustain its operations through 2008. Furthermore, we will need additional financing thereafter until we can achieve profitability, if ever.

We currently do not have sufficient capital to fund our anticipated expenditures beyond September 30, 2008 and need to raise additional capital immediately, and we will need to raise additional capital in order to complete the anticipated development programs for each of our research and development projects. If we are unable to raise such additional capital, we may have to sublicense our rights to a third party as a means of continuing development, or, although less likely, we may be required to abandon further development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

# **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 joint venture agreement. The Hedrin JV is now responsible for all obligations to T&R and Kerris 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 June 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 six months ended June 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.

The Hedrin JV has been engaged in an ongoing dialogue with the U.S. Food and Drug Administration ("FDA") regarding the regulatory process for Hedrin. In June 2008, the FDA directed Hedrin to the Center for Devices and Radiological Health (CDRH) division of the FDA for review as a device. Subsequent to that the Hedrin JV submitted additional materials to CDRH, including information on the clinical trials completed on Hedrin to date, and is engaged in discussions with CDRH to determine the final device regulatory pathway as well as the sufficiency of the submitted clinical data.

# *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 desiged 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 June 30, 2008, we have incurred \$6,354,000 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 six months ended June 30, 2008, we incurred \$1,232,000 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, we 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. We intend 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 pruritus.

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 pruritus, 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 T&R 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 pruritus 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 June 30, 2008, we have incurred \$1,098,000 for the development of Altoderm. We incurred \$86,000 of such costs during the six months ended June 30, 2008.

### Altolyn

We are developing Altolyn for the treatment of mastocystosis. 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®, 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 June 30, 2008, we have incurred \$826,000 for the development of Altolyn. We incurred \$36,000 of such costs during the six months ended June 30, 2008.

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

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

#### **Critical Accounting Policies**

In December 2001, the SEC requested that all registrants discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

# Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

### Research and development expenses

All research and development costs are expensed as incurred and include costs of consultants who conduct research and development on behalf of us and our subsidiaries. Costs related to the acquisition of technology rights and patents for which development work is still in process are expensed as incurred and considered a component of research and development costs.

We often contract with third parties to facilitate, coordinate and perform agreed upon research and development of a new drug. To help ensure that research and development costs are expensed as incurred, we records monthly accruals for clinical trials and preclinical 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 expensed, or an accrued liability, when the amounts paid are less than the related research and development costs expensed.

# **Share-Based Compensation**

We have stockholder-approved stock incentive plans for employees, directors, officers and consultants. Prior to January 1, 2006, we accounted for the employee, director and officer plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board ("APB") Opinion No.25, "Accounting for Stock Issued to Employees" and related interpretations, as permitted by Statement of Financial Accounting Standards ("SFAS" or "Statement") No. 123, "Accounting for Stock-Based Compensation."

Effective January 1, 2006, we adopted SFAS No. 123(R), "Share-Based Payment," ("Statement 123(R)") for employee options using the modified prospective transition method. Statement 123(R) revised Statement 123 to eliminate the option to use the intrinsic value method and required us to expense the fair value of all employee options over the vesting period. Under the modified prospective transition method, we recognized compensation cost for the years ended December 31,2007 and 2006 which 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, based on the grant date fair value estimated in accordance with Statement 123(R). In accordance with the modified prospective method, we have not restated prior period results.

## New Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles ("GAAP") in the United States of America, and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements under GAAP and is effective for fiscal years beginning after November 15, 2007. We will adopt SFAS 157 as of January 1, 2008. The effects of adoption will be determined by the types of instruments carried at fair value in our financial statements at the time of adoption, as well as the method utilized to determine

their fair values prior to adoption. Based on our current use of fair value measurements, SFAS 157 is not expected to have a material effect on its results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities," ("SFAS 159"), which provides companies with an option to report selected financial assets and liabilities at fair value. SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities and highlights the effect of a company's choice to use fair value on its earnings. It also requires a company to display the fair value of those assets and liabilities for which it has chosen to use fair value on the face of the balance sheet. SFAS 159 will be effective beginning January 1, 2008 and is not expected to have a material impact on our consolidated financial statements.

In June 2007, the FASB issued EITF No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for use in Future Research and Development Activities" ("EITF No. 07-3"). EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. Entities should continue to evaluate whether they expect the goods to be delivered or services to be rendered. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. The provisions of EITF No. 07-3 will be effective for us on a prospective basis beginning January 1, 2008, evaluated on a contract by contract basis and is not expected to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), a revised version of SFAS No. 141, "Business Combinations." The revision is intended to simplify existing guidance and converge rulemaking under U.S. generally accepted accounting principles with international accounting standards. This statement 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. We currently are evaluating the impact of the provisions of the revision on its consolidated results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements" (SFAS 160), which will require noncontrolling interests (previously referred to as minority interests) to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. This statement applies to the accounting for noncontrolling interests and transactions with noncontrolling interest holders in consolidated financial statements. SFAS 160 will be applied prospectively to all noncontrolling interests, including any that arose before the effective date except that comparative period information must be recast to classify noncontrolling interests in equity, attribute net income and other comprehensive income to noncontrolling interests, and provide other disclosures required by Statement 160. SFAS 160 is effective for periods beginning on or after December 15, 2008. We are currently evaluating the impact that SFAS 160 will have on our consolidated financial statements.

The FASB and the SEC had issued certain other accounting pronouncements as of December 31, 2007 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected its financial accounting measures or disclosures had they been in effect during the years ended December 31, 2007 and 2006 and for the period from August 6, 2001 (inception) to December 31, 2007 or that will have a significant effect at the time they become effective.

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 us as of January 1, 2009. We do not believe that SFAS 161 will have any impact on its consolidated financial statements.

## **BUSINESS**

#### Overview

We are a clinical stage specialty pharmaceutical 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 in development: Hedrin<sup>TM</sup>, a novel, non-insecticide treatment for pediculosis (head lice); Topical PTH (1-34) for the treatment of psoriasis; Altoderm<sup>TM</sup> (topical cromolyn sodium) for the treatment of pruritus associated with dermatologic conditions including atopic dermatitis; and Altolyn<sup>TM</sup> (oral tablet cromolyn sodium) for the treatment of mastocytosis. We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

Our executive offices are located at 48 Wall Street, New York, NY 10005 USA. Our telephone number is (212) 582-3950 and our internet website address is <a href="https://www.manhattanpharma.com">www.manhattanpharma.com</a>.

## **Corporate History – Merger Transaction(s)**

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." From an accounting perspective, the accounting acquirer is considered to be Manhattan Research Development, Inc. and accordingly, the historical financial statements are those of Manhattan Research Development, Inc.

During 2005 we merged with Tarpan Therapeutics, Inc., or 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 10,731,000 shares of our common stock, representing approximately 20% of our then outstanding common shares. This transaction was accounted for as a purchase of Tarpan by us.

#### **Our Research and Development Programs**

#### **Hedrin**<sup>TM</sup>

In June 2007, we entered into an exclusive license agreement with Thornton & Ross Ltd., or T&R, and Kerris, S.A., or Kerris, for a product candidate called Hedrin. We 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, and at the same time, we also entered into a supply agreement with T&R pursuant to which T&R will be our exclusive supplier of Hedrin product.

In February 2008, we entered into a joint venture agreement with Nordic Venture Fund II K/S, or Nordic, to develop and commercialize Hedrin, which agreement was amended in February and June 2008. A 50/50 joint venture entity was formed that now owns, will develop and will secure a commercialization partner for the Hedrin product in North America, which we refer to in this prospectus as the Hedrin JV. We will manage the day-to-day operations of the Hedrin JV. The Hedrin JV has been independently funded and will be responsible for all costs associated with developing the Hedrin product, including any necessary U.S. clinical trials, patent costs, and future milestones owed to the original licensor, T&R.

## Pediculosis (Head lice)

Head lice (*Pediculus humanus capitis*) are small parasitic insects that live mainly on the human scalp and neck hair. Head lice are not known to transmit disease, but they are highly contagious and are acquired by direct head-to-head contact with an infested person's hair, and may also be transferred with shared combs, hats, and other hair accessories. They can also live on bedding or upholstered furniture for a brief period. Head lice are seen across the socioeconomic spectrum and are unrelated to personal cleanliness or hygiene. Children are more frequently infested than are adults, and Caucasians more frequently than other ethnic groups. Lice are most commonly found on the scalp, behind the ears, and near the neckline at the back of the neck. Common symptoms include a tickling feeling of something moving in the hair, itching, irritability caused by poor sleep, and sores on the head caused by scratching. According to our internal analysis, a majority of the currently available prescription and over-the-counter, or OTC, head lice treatments are chemical insecticides.

## Mechanism of Action

Hedrin is a novel, non-insecticide combination of silicones (dimethicone and cyclomethicone) that acts as a pediculicidal (lice killing) agent by disrupting the insect's mechanism for managing fluid and breathing. In contrast with most currently available lice treatments, Hedrin contains no chemical insecticides. Because Hedrin kills lice by preventing the louse from excreting waste fluid and by asphyxiation (smothering), rather than by acting on the central nervous system, the insects have not build up resistance to the treatment. Recent studies have indicated that resistance to chemical insecticides may be increasing and therefore contributing to insecticide treatment failure. Manhattan Pharmaceuticals believes there is significant market potential for convenient, non-insecticide treatment alternatives. Both silicones in this proprietary formulation of Hedrin are used extensively in cosmetics and toiletries.

## Clinical Development

To date, Hedrin has been clinically studied in 326 subjects and is currently marketed as a medical device in Western Europe and as a pharmaceutical in the United Kingdom.

In a randomized, controlled, equivalence, clinical study (conducted in Europe), Hedrin was administered to 253 adult and child subjects with head lice 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 has become resistant to malathion, and we believe this resistance may have influenced the study results. To date, there have been no reports of malathion resistance in the U.S. 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 the U.S., we, through the Hedrin JV, are pursuing the development of Hedrin as a medical device and have submitted an initial regulatory package to the FDA, Center for Devices and Radiological Health. We expect that the Hedron JV will be required to complete at least one clinical trial with this product candidate.

## Market and Competition

In Europe, Hedrin has been launched in 21 countries and has achieved annual sales through its licensees of approximately \$45 million at in-market public prices, and is the market leader in the United Kingdom with \$11 million in sales (23% market share) and France with a 21% market share. These figures do not include sales in Germany, Spain and Greece where Hedrin was launched in mid-late 2007.

According to the American Academy of Pediatrics an estimated 6-12 million Americans are infested with head lice each year, with pre-school and elementary children and their families affected most often. The total U.S. head lice market is estimated to be over \$200 million with prescription and over-the-counter (OTC) therapies comprising approximately 50% of that market. The remaining 50% of the market is comprised of alternative therapies such as tea tree oils, mineral oils, and "nit picking", or physical combing to remove lice.

The prescription and OTC segment of the market is dominated by 4-5 name brand products and numerous, low cost generics and store brand equivalents. The active ingredients in these pharmacological therapies are chemical insecticides. The most frequently prescribed insecticide treatments are Kwell (lindane) and Ovide (malathion), and the most frequently purchased OTC brands are Rid (pyrethrin), Nix (permethrin), and Pronto (pyrethrin). Lindane has been banned in 52 countries worldwide and has now been banned in the state of California due to its toxicity. European formulations of Malathion have experienced widespread resistance. Resistance to U.S. formulations of malathion have not been widely reported, but given the European experience, we believe it may eventually develop with continued use. Head lice resistance to pyrethrin and permethrin has been reported in the U.S. and treatment failures are common.

See also "Management's Discussion and Analysis of Financial Condition and Results of Operations- Liquidity and Capital Resources- Research and Development Projects- Hedrin."

## *Topical PTH (1-34)*

As a result of our merger with Tarpan Therapeutics in 2005, we hold an exclusive, worldwide license to develop and commercialize Topical PTH (1-34) for the treatment of psoriasis. Tarpan acquired the exclusive, worldwide rights pursuant to a 2004 license agreement with IGI, Inc. Topical PTH (1-34) has been tested in a Phase 1/2 clinical study conducted under a physician investigational new drug application, or P-IND.

In July 2008, we 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.

#### **Psoriasis**

Psoriasis is a common, chronic, immune-mediated disease that results in the over-production of skin cells. In healthy skin, immature skin cells migrate from the lowest layer of the epidermis to the skin's surface over a period of 28-30

days. In psoriasis, these cells reproduce at an extremely accelerated rate and advance to the surface in only 7 days. This results in a build up of excess, poorly differentiated skin cells that accumulate in dry, thick patches known as plaques. These plaques can appear anywhere on the body resulting in skin irritation and disability.

## Mechanism of Action

It is believed that Topical PTH (1-34) is an agonist that mimics a natural protein responsible for regulating the growth of skin cells. The presence of this natural protein, PTHrp, is significantly reduced in the skin of psoriasis patients leading to skin cell hyperproliferation, poor differentiation of skin cells, and ultimately, the accumulation of dry thick patches of skin (plaques). Acting in place of the absent PTHrp, it is also believed that Topical PTH (1-34) is able to help restore skin cells' normal rate of development, migration and turnover, reducing cell accumulation and the formation of plaques.

### Clinical Development

In 2003, researchers, led by Michael Holick, MD, PhD, Professor of Medicine, Physiology, and Biophysics at Boston University Medical Center, reported positive results from a US Phase 1 and 2 clinical trial conducted under a P-IND 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 receiving Topical PTH (1-34) in an open label extension study in which the Psoriasis Area and Severity Index (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 well tolerated and efficacious for the treatment of 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 believed that it may have an important clinical advantage over current topical psoriasis treatments. A Phase 2a clinical study testing Topical PTH (1-34) under a P-IND was initiated in December 2005 under the auspices of Boston University. In April 2006, and prior to dosing subjects, we reported a delay in our Phase 2a clinical study of Topical PTH (1-34) due to a formulation issue. We believe 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). In July 2008, we announced top-line results from its Phase 2a clinical study of topical PTH (1-34) for the treatment of psoriasis, as described above.

## Market and Competition

According to the National Psoriasis Foundation nearly 2% of the worldwide population, including approximately 4.5 million Americans, suffers from psoriasis. In the U.S. psoriasis patients are responsible for nearly 2.4 million visits to dermatologists each year at an annual cost of nearly \$3 billion. We estimate the U.S. topical psoriasis therapeutics market to be approximately \$400-500 million, with the market throughout the rest of the world in the same range.

The efficacy and safety profile of Topical PTH (1-34) potentially make it an attractive alternative to existing topical treatments, photo therapies and systemic treatments such as methotrexate and biologics for the treatment of psoriasis. We are developing Topical PTH (1-34) as a monotherapy and for use in combination with currently available therapies. Some of Topical PTH (1-34)'s competitors would include, but are not limited to over-the-counter, or "OTC,"

prescription topical treatments, and laser treatment. Treatments such as phototherapy, methotrexate, cyclosporine, Remicade® (Johnson & Johnson), Enbrel® (Amgen), Amiveve® (Astellas), and Raptiva® (Genentech) are generally used for more severe patients due to their harsh side effect profiles.

There are a number of treatments available today for psoriasis, including topicals and steroids. Topical treatments include numerous OTC ointments that help to reduce inflammation, soothe skin and enhance the efficacy of other therapies. Steroids are also prescribed as an adjunct therapy for pain and anti-inflammation. One of the most frequently prescribed topical treatments is Dovonex® (calcipotriene), which is an active vitamin D3 analogue. Approximately 60% of patients show some response to Dovonex® in the first few months of treatment, however, 60% of these patients become resistant to treatment in 6-12 months. Dovonex® sales in the US in 2006 were \$147 million.

See also "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Research and Development Projects – Topical PTH (1-34)."

### **Altoderm**<sup>TM</sup>

In April 2007, we entered into a license agreement with T&R, pursuant to which we acquired exclusive rights to develop and commercialize Altoderm in North America. Altoderm is a novel, proprietary formulation of topical cromolyn sodium and is designed to enhance the absorption of cromolyn sodium into the skin in order to treat pruritus (itch) associated with dermatologic conditions including atopic dermatitis (eczema).

### Atopic Dermatitis (Eczema)

Atopic dermatitis, also know as eczema, is a chronic disease of the skin that is believed to be caused by a combination of hereditary and environmental factors. The main symptoms of atopic dermatitis include dry, itchy skin leading to rashes on the face, hands, feet, along with inside the elbows and behind the knees. Scratching results in redness, swelling, cracking, "weeping" clear fluid, and crusting or scaling.

### Mechanism of Action

Altoderm is a topical formulation of cromolyn sodium, a non-steroidal, anti-inflammatory agent that is categorized as a mast cell stabilizer. Cromolyn sodium has been shown to block allergic reactions by inhibiting the release of inflammatory mediators, including histamine and leukotrienes. Elevated levels of these agents result in local and systemic inflammation that, in turn, leads to conditions such as atopic dermatitis. By reducing the release of inflammatory agents by mast cells, we believe that Altoderm may effectively treat patients suffering from pruritus associated with atopic dermatitis, and possibly other dermatologic conditions. Cromolyn sodium has been used worldwide for over 35 years to treat a number of allergic conditions includin asthma, allergic rhinitis (nasal allergies), allergic conjunctivitis (eye allergies), and internal allergic conditions such as mastocytosis.

### Clinical Development

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 pruritus.

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 pruritus, 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. In this study, subjects treated with vehicle alone in the blinded portion of the study were switched to Altoderm for the open label portion of the study. 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 T&R believe there is significant potential for Altoderm and will continue development of this product candidate.

On March 6, 2008, we announced that we 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 pruritus associated with dermatologic conditions including atopic dermatitis can be pursued.

### Market and Competition

According to the National Institutes of Health, an estimated 10-20% of all infants and young children and 1-3% of adults have atopic dermatitis (eczema). This translates to approximately 15 million Americans suffering from the disease. Insurance companies spend more than \$1 billion annually on the condition.

Topical steroids, topical immunomodulators, systemic antihistamines, and moisturizing agents are currently the primary pharmaceutical treatments for atopic dermatitis. However, these products are not meeting the needs of patients due to unwanted side effects including skin thinning, acne, hypopigmentation, and secondary infection, among others, and limited evidence to support their long term safety. Based on these limitations of current atopic dermatitis treatments, there is a significant market opportunity for new, effective therapies.

See also "Management's Discussion and Analysis of Financial Condition and Results of Operations- Liquidity and Capital Resources- Research and Development Projects- Altoderm."

### Altolyn<sup>TM</sup>

In April 2007 we entered into a license agreement with T&R, pursuant to which we acquired exclusive rights to develop and commercialize Altolyn in North America. Altolyn is a novel, proprietary oral tablet formulation of cromolyn sodium designed to treat mastocytosis and possibly other gastrointestinal disorders such as food allergy and symptoms of irritable bowel syndrome.

### Mastocytosis

Mastocytosis is a rare disorder that occurs in both children and adults. It is caused by the presence of too many mast cells in the body. Mast cells are found in skin, linings of the stomach and intestine, and connective tissue (such as cartilage and tendons). Mast cells play an important role in helping the immune systems defend these tissues from disease. They release chemical "alarms" such as histamine and cytokines to attract other key players of the immune defense system to sites in the body where they might be needed. People with mastocytosis experience abdominal

discomfort, nausea and vomiting, ulcers, diarrhea, and skin lesions.

## Mechanism of Action

Altolyn is a novel oral tablet formulation of cromolyn sodium that has been formulated using site specific drug delivery technology. This unique formulation targets release of the drug in the upper region of the small intestine. Cromolyn sodium, which has been used for more than 35 years to treat a variety of allergic conditions, is a mast cell stabilizer that reduces mast cell activation and decreases the release of inflammatory mediators.

### Nonclinical Development

On March 6, 2008, we announced we had 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®, the oral liquid formulation of cromolyn sodium currently approved in the U.S. to treat mastocytosis. Section 505(b)(2) of the Food, Drug and Cosmetic Act allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by FDA in the approval of other drugs. 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 Good Manufacturing Process ("cGMP") 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.

See also "Management's Discussion and Analysis of Financial Condition and Results of Operations- Liquidity and Capital Resources- Research and Development Projects- Altolyn."

### Oleoyl-estrone

On July 9, 2007, we announced the results of our two Phase 2a clinical trials of oral Oleoyl-estrone ("OE"). The results of both randomized, double-blind, placebo controlled studies, one in common obesity and the other in morbid obesity, demonstrated no statistically or clinically meaningful placebo adjusted weight loss for any of the treatment arms evaluated. Based on these results, we discontinued its OE programs in both common obesity and morbid obesity.

## **Propofol Lingual Spray**

On July 9, 2007, we announced that it discontinued development of Propofol Lingual Spray for pre-procedural sedation.

### **Intellectual Property and License Agreements**

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge and experience we call "know-how". To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We currently do not directly own the rights to any issued patents. We license the exclusive rights to a total of four issued patents relating to our current product candidates, which expire from 2013 to 2022. Altoderm<sup>TM</sup> and Altolyn<sup>TM</sup> are the trademarks for our topical cromolyn sodium and for our oral cromolyn sodium product candidates, both of which trademarks we license from T&R, from which we have licensed all of our rights to Altoderm and Altolyn. T&R has applied for registration for the Altoderm and Altolyn trademarks. All other trademarks and tradenames mentioned in this prospectus are the property of their respective owners.

### Hedrin

On June 26, 2007, we entered into an exclusive license the Hedrin agreement with T&R and Kerris. Pursuant to our license agreement with T&R and Kerris, 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"):

U.S. Patent Application No. 2007/0142330, entitled, "Method and composition for the control of arthropods." Jayne Ansell, Inventor. Application filed February 12, 2007. This application is a divisional of U.S. application Ser. No. 10/097,615, filed Mar. 15, 2002, which is a continuation of International Application No. PCT/GB00/03540, which designated the United States and was filed on Sep. 14, 2000. This application has not yet issued as a patent. Any patent that issues will expire on September14, 2020.

This patent application has numerous, detailed and specific claims related to the use of Hedrin (novel formulation of silicon derivatives) in controlling and repelling arthropods such as insects and arachnids, and in particular control and eradication of head lice and their ova.

In addition, on June 26, 2007, we entered into the Hedrin supply agreement with T&R pursuant to which T&R will be our exclusive supplier of the Hedrin product.

In consideration for the license, we issued to T&R and Kerris, whom we refer to jointly herein as the Licensor, a combined total of 150,000 shares of its common stock valued at \$120,000. In addition, we also made a cash payment of \$600,000 to the Licensor. 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 FDA of 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 a New Drug Application (NDA), or its equivalent, 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.

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

We also agreed to pay royalties to the Licensor of 8% (or, under certain circumstances, 4%) on net sales of licensed products. Our exclusivity under the Hedrin 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 Agreement with the consent of Licensor and the proceeds resulting from such sublicenses will be shared with the Licensor.

Pursuant to our Hedrin supply agreement, we have 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 Supply Agreement, we may obtain product from an alternative supplier subject to certain conditions. The term of the Supply Agreement ends upon termination of the Hedrin Agreement.

On February 25, 2008, we assigned and transferred our rights in Hedrin to the Hedrin JV. The Hedrin JV is now responsible for all of our obligations under our Hedrin license agreement and our Hedrin supply agreement.

## Topical PTH (1-34) License Agreement.

In connection with our April 2005 acquisition of Tarpan Therapeutics, Inc., we acquired Tarpan's rights under an April 2004 sublicense agreement with IGI, Inc. Pursuant to this agreement we now have worldwide, exclusive license rights to the U.S. and foreign patents and patent applications for all topical uses of Topical PTH(1-34) for the treatment of hyperproliferative skin disorders including psoriasis:

- 1. U.S. Patent No. 5,527,772, entitled "Regulation of cell proliferation and differentiation using peptides." M.F. Holick, Inventor. Application filed July, 28, 1994. Patent issued June 18, 1996. This patent expires June 18, 2013.
- 2. U.S. Patent No. 5,840,690, entitled "Regulation of cell proliferation and differentiation using peptides." M.F. Holick, Inventor. Application filed June 6, 1995. Patent issued November 24, 1998. This patent expires June 18, 2013.
- 3. U.S. Provisional application No. US60/940,509, entitled "Topical Compositions comprising a macromolecule and methods of using same." Application was filed on May 29, 2007.

These patents have numerous, detailed and specific claims relating to the topical use of Topical PTH (1-34)

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, 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 a 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% annual net sales. Through December 31, 2007 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. We may terminate the agreement in whole or as to any portion of the PTH patent rights upon 90 days' notice to IGI, Inc.

#### 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 pruritis (itch) associated with dermatologic conditions including atopic dermatitis:

1.U.S. Patent No. 7,109,246, entitled "Pharmaceutical compositions comprising an amphoteric surfactant an alkoxylated cetyl alcohol and a polar drug." Brian Hawtin, Inventor. Application filed May 20, 1999. Patent issued

September 19, 2006. This patent expires on May 20, 2019.

2. U.S. Application Publication No. 2007/0036860, entitled "Treatment of allergic conditions." Alexander James Wigmore, Inventor. Any patent that issues will expire on November 9, 2019. This patent covers both Altoderm and Altolyn.

These patents have numerous, detailed and specific claims related to the use of Altoderm (composition of topically administered cromolyn sodium) for treating atopic dermatitis (eczema).

In accordance with the terms of our 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. 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 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; \$500,000 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 acceptance for filing of a 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 December 31, 2007, 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 our Altolyn license agreement, we acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altolyn, an oral tablet formulation product candidate using sodium cromolyn for the treatment of mastocytosis, food allergies, and inflammatory bowel disorder.

- 1. U.S. Patent No. 7,258,872, entitled "Chromone enteric release formulation." Alexander James Wigmore, Inventor. Application filed November 9, 1999, claiming the benefit of a GB application filed November 11, 1998. Patent issued August 21, 2007. The expected date of expiration, which was November 9, 2019, has been extended by 793 days (expiration date Jan 10, 2022).
- 2. U.S. Application Publication No. 2007/0036860, entitled "Treatment of allergic conditions." Alexander James Wigmore, Inventor. Application filed October 13, 2006, claiming the benefit of a prior U.S. application, which claimed the benefit of a PCT application filed November 9, 1999. This application has not yet issued as a patent. Any patent that issues is expected to expire on November 9, 2019. This patent covers both Altoderm and Altolyn.

These patents have numerous, detailed and specific claims related to Altolyn (as an oral tablet drug delivery composition), and the pending application discloses and may be used to claim the use of Altolyn (composition of orally administered sodium cromolyn) for the treatment of allergic conditions, specifically food allergies.

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. 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 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 a 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 December 31, 2007, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

### **Oleoyl-estrone**

On July 9, 2007, we announced the results of our two Phase 2a clinical trials of oral OE. The results of both randomized, double-blind, placebo controlled studies, one in common obesity and the other in morbid obesity, demonstrated no statistically or clinically meaningful placebo adjusted weight loss for any of the treatment arms evaluated. Based on these results, we discontinued its OE programs in both common obesity and morbid obesity.

## **Propofol Lingual Spray**

On July 9, 2007, we announced that we discontinued development of Propofol Lingual Spray for pre-procedural sedation.

## Manufacturing

We do not have any manufacturing capabilities. We are in contact with several contract cGMP manufacturers for the supply of Topical PTH(1-34), Hedrin, Altoderm and Altolyn that will be necessary to conduct human clinical trials.

## **Government Regulation**

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

*Drug Approval Process.* None of our drugs may be marketed in the U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

- · nonclinical laboratory tests, animal studies, and formulation studies,
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin,
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication,
- · submission to the FDA of an NDA,
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMPs, and

FDA review and approval of the NDA.

Nonclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) preliminarily evaluate the efficacy of the drug for specific indications. Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that Phase 1, Phase 2, or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as Special Protocol Assessment, or SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

Assuming successful completion of the required clinical testing, the results of the nonclinical and clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of a NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The agencies review the application and may deem it to be inadequate to support the registration and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, that the review time will be reduced.

Section 505(b)(2) of the FDCA allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by FDA in the approval of other drugs. This procedure potentially makes it easier for generic drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer. We intend to rely on Section 505(b)(2) to obtain approval for Altolyn.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before we can market our product candidates for additional indications, we must obtain additional approvals from FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements. Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

*Orphan Drug.* The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years. Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication.

**Non-United States Regulation.** Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate

application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union ("EU") members states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

Device Approval Process. The medical devices that we develop or market are subject to regulation by the FDA's Center for Devices and Radiological Health (CDRH). These medical devices must comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. The most comprehensive regulatory controls require that a clinical evaluation program be conducted before a device receives approval for commercial distribution. CDRH reviews and evaluates medical device pre-market approval (PMA) applications, product development protocols (PDPs), exemption requests for investigational devices (IDEs), and premarket notifications, or 510(k)s. In the U.S., permission to distribute a new device generally can be met in one of three ways.

The first process requires that a pre-market notification (510(k) Submission) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to PMA (i.e., the "predicate" device). An appropriate predicate device for a pre-market notification is one that (i) was legally marketed prior to May 28, 1976, (ii) was approved under a PMA but then subsequently reclassified from class III to class II or I, or (iii) has been found to be substantially equivalent and cleared for commercial distribution under a 510(k) Submission. Applicants must submit descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical trials must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue an order finding substantial equivalence before commercial distribution can occur. Changes to existing devices covered by a 510(k) Submission that do not raise new questions of safety or effectiveness can generally be made without additional 510(k) Submissions. More significant changes, such as new designs or materials, may require a separate 510(k) with data to support that the modified device remains substantially equivalent. First, the FDA determines that the proposed medical device can be marketed in the United States because it is substantially equivalent to an existing medical device already in the United States market and issues what is known as a 510(k) pre-market notification clearance. Second, the FDA may require that the new device satisfy a more in depth approval process, known as pre-market approval, or PMA. Both the 510(k) clearance and the PMA processes may require the presentation of a substantial volume of clinical data, as well as a substantial review, thereby delaying the introduction of the new device into the market. Moreover, the PMA process requires extensive clinical studies, manufacturing information (including demonstration of compliance with quality systems requirements), and possible review by a panel of experts outside the FDA.

The second process requires the submission of an application for PMA to the FDA to demonstrate that the device is safe and effective for its intended use as manufactured. This approval process applies to certain class III devices. In this case, two steps of FDA approval are generally required before marketing in the U.S. can begin. First, we must comply with the applicable IDE regulations in connection with any human clinical investigation of the device in the U.S. Second, the FDA must review our PMA application, which contains, among other things, clinical information acquired under the IDE. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose. FDA review of a PMA application could take significantly longer than that for a 510(k) application, thereby further delaying the introduction of the new medical device into the market. Finally, even if the FDA approves the new device, it may impose restrictions on our ability to market the device.

The third process requires that an application for a Humanitarian Device Exemption (HDE) be made to the FDA for the use of a Humanitarian Use Device (HUD). A HUD is intended to benefit patients by treating or diagnosing a disease or condition that affects, or is manifested in, fewer than 4,000 individuals in the U.S. per year. The application submitted to the FDA for an HDE is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements of a PMA. This approval process demonstrates there is no comparable device available to treat or diagnose the condition, the device will not expose patients to unreasonable or significant risk, and the benefits to health from use outweigh the risks. The HUD provision of the regulation provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting small patient populations.

The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations.

**Post-Approval Requirements.** Medical device manufacturers are subject to periodic inspections by the FDA and state agencies. If the FDA believes that a company is not in compliance with applicable laws or regulations, it can take any of the following actions: issue a warning or other letter notifying the particular manufacturer of improper conduct; impose civil penalties; detain or seize products; issue a recall; ask a court to seize products; enjoin future violations; withdraw clearances or approvals; or assess civil and criminal penalties against us, our officers or our employees.

In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and/or criminal prosecution. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products or the withdrawal of product approval by the FDA could have a material adverse effect on our business, financial condition or results of operations.

Medical device manufacturers are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation (QSR) requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require medical device manufacturers to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, medical device manufactures are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications.

Non-United States Regulation. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

In the European Union, we are required to comply with the Medical Devices Directive and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent notified body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We are also required to comply with other foreign regulations such as the requirement that we obtain Ministry of Health, Labor and Welfare approval before we can launch new products in Japan. The time required to obtain these foreign approvals to market our products may vary from U.S.

approvals, and requirements for these approvals may differ from those required by the FDA.

We cannot assure you that we will or our collaborators will be able to meet the FDA's requirements or receive FDA clearance for our products. Moreover, even if we are exempt from approval or even if we receive clearance, the FDA may impose restrictions on our marketing efforts. Finally, delays in the approval process may cause us to introduce our products into the market later than anticipated. Any failure to obtain regulatory approval, restrictions on our ability to market our products, or delay in the introduction of our products to the market could have a serious adverse effect on our business, financial condition and results of operations.

Medical device laws and regulations are also in effect in many of the countries in which we may do business outside the United States. These laws and regulations range from comprehensive device approval requirements for our medical device product to requests for product data or certifications. The number and scope of these requirements are increasing. We may not be able to obtain regulatory approvals in such countries and we may be required to incur significant costs in obtaining or maintaining our foreign regulatory approvals. In addition, the export of certain of our products which have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Any failure to obtain product approvals in a timely fashion or to comply with state or foreign medical device laws and regulations may have a serious adverse effect on our business, financial condition or results of operations.

### **Employees**

As of September 15, 2008, we had 1 part time and 3 full time employees, all of whom are devoted to business development, administration and finance, including our senior management. None of our employees is covered by a collective bargaining unit. We believe our relationship with our employees is satisfactory.

## **Properties**

Our executive offices are located at 48 Wall Street, New York, New York 10005. We currently occupy this space pursuant to a written lease that expires on September 30, 2009 under which we pay rent of approximately \$7,000 per month. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

### **Legal Proceedings**

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Except for the proceedings described below, we are not aware of any pending or threatened legal proceeding that, if determined in a manner adverse to us, could have a material adverse effect on our business and operations.

Swiss Pharma Contract LTD, or Swiss Pharma, a clinical site that we used in one of its obesity trials, gave notice to us that Swiss Pharma believes it is entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. We do not believe that Swiss Pharma is entitled to additional payments and have not accrued any of these costs as of March 31, 2008. The contract between us and Swiss Pharma provides for arbitration in the event of a dispute, such as this claim for an additional payment. On March 10, 2008, Swiss Pharma filed for arbitration with the Swiss Chamber of Commerce. As we do not believe that Swiss Pharma is entitled to additional payments, we intend to defend our position in arbitration. On April 2, 2008, we filed our statement of defense and counterclaim for recovery of costs incurred by us as a result of Swiss Pharma's failure to meet agreed upon deadlines under our contract. On June 3, 2008, a hearing was held before the arbitrator. On September 5, 2008, the arbitrator 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 we 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. We previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice and therefore, will recognize expense for the difference between the award of \$646,000 and the previously recognized liability of \$104,000, or \$542,000, in the quarter ending September 30, 2008. We will also continue to accrue interest at the rate of 5% per annum on the \$371,000. We disagree with the result of the arbitration and are exploring our post-award options, including potential appellate remedies in Switzerland, and defense of any actions which may be taken to enforce the arbitration award. We do not have sufficient cash or other current assets to satisfy the arbitrator's award.

In February 2007, a former employee of ours alleged an ownership interest in two of our provisional patent applications covering our discontinued product development program for Oleoyl-estrone. Also, without articulating precise legal claims, the former employee contends that we 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 our provisional patent applications. The former employee is seeking an unspecified amount in damages. We refute the former employee's contentions and intend to vigorously defend ourselves should the former employee file claims against us. There have been no further developments with respect to these contentions.

### **MANAGEMENT**

#### **Directors**

The name and age of each of our six directors as of September 15, 2008, his position with us, his principal occupation, and the period during which such person has served as a director of our company are set forth below. All directors hold office until the next annual meeting of shareholders or until their respective successors are elected and qualified.

Name	Age	Position(s) Held	
		President, Chief Executive Officer and	
Douglas Abel	47	Director	2005
Neil Herskowitz	51	Director	2004
Malcolm			
Hoenlein	64	Director	2004
Timothy			
McInerney	47	Director	2004
Richard I.			
Steinhart	51	Director	2004
Michael Weiser,			
M.D.	45	Director	2003

**Douglas Abel** has been our President and Chief Executive Officer and a director of our company since April 2005. Mr. Abel was President and CEO of Tarpan Therapeutics, Inc., a privately-held biopharmaceutical company, from November 2004 until April 2005, when Tarpan was acquired by us. Prior to becoming President and CEO of Tarpan, Mr. Abel served as Vice President of the Dermatology Business Unit at Biogen Idec where he worked from August 2000 to November 2004. While at Biogen, he led more than 100 employees to support the launch of AMEVIVE®. Before that, Mr. Abel was at Allergan Pharmaceuticals from December 1987 to August of 2000, with his most recent position being Director of BOTOX® Marketing. Mr. Abel received his A.B. in chemistry from Lafayette College and an M.B.A. from Temple University.

*Neil Herskowitz* was appointed to our Board of Directors in July 2004. He has served as the Managing Member of ReGen Partners LLC, an investment fund located in New York, and as the President of its affiliate, Riverside Contracting LLC since June 1998. Mr. Herskowitz currently serves as a director of Innovive Pharmaceuticals (OTCBB: IVPH) a publicly traded pharmaceutical development company. He also serves on the board of directors of Starting Point Services for Children, a not-for-profit corporation, and of Vacation Village, a 220-unit development in Sullivan County, New York. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978.

*Malcolm Hoenlein* was appointed to our Board of Directors in July 2004. Since January 2001, he is also a director of Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX). Mr. Hoenlein currently serves as the Executive Vice Chairman of the Conference of Presidents of Major American Jewish Organizations, a position he has held since 1986. He also serves as a director of Bank Leumi. Mr. Hoenlein received his B.A. from Temple University and his M.A. from the University of Pennsylvania.

*Timothy McInerney* has been a director of our company since July 2004. Mr. McInerney serves as a partner at Riverbank Capital Securities, Inc., a position he has held since June 2007. Mr. McInerney currently serves on the board of directors of ZIOPHARM Oncology Inc. (NASDAQ: ZIOP). From 1992 to March 2007, Mr. McInerney was a Managing Director of Paramount BioCapital, Inc. where he oversaw the overall distribution of Paramount's private equity product. Prior to 1992, Mr. McInerney was a research analyst focusing on the biotechnology industry at Ladenburg, Thalman & Co. Prior to that, Mr. McInerney held equity sales positions at Bear, Stearns & Co. and Shearson Lehman Brothers, Inc. Mr. McInerney also worked in sales and marketing for Bristol-Myers Squibb. He

received his B.S. in pharmacy from St. John's University at New York. He also completed a post-graduate residency at the New York University Medical Center in drug information systems.

Richard I. Steinhart has been a director of our company since July 2004. Since April 2006, Mr. Steinhart has served as Chief Financial Officer of Electro-Optical Sciences, Inc., a publicly-held medical device company. From May 1992 to April 2006, Mr. Steinhart was principal of Forest Street Capital, a boutique investment banking, venture capital, and management consulting firm. Prior to Forest Street Capital, from May 1991 to May 1992, he was the Vice President and Chief Financial Officer of Emisphere Technologies, Inc., a publicly held biopharmaceutical company that is working to develop and commercialize a proprietary oral drug delivery system. Prior to joining Emisphere Technologies, Mr. Steinhart spent seven years at CW Group, Inc., a venture capital firm focused on medical and healthcare investments, where he was a General Partner and Chief Financial Officer. Mr. Steinhart has previously served as a director of a number of privately-held companies, including ARRIS Pharmaceuticals, Inc., a biotechnology company involved with rational drug design; Membrex, Inc., a laboratory equipment manufacturing company; and Photest, Inc., a diagnostics company. He began his career working as a certified public accountant and continues to be a New York State Certified Public Accountant. Mr. Steinhart holds a Bachelors of Business Administration and Masters of Business Administration from Pace University.

Michael Weiser, M.D., Ph.D., has served as a director of our company since February 2003. Dr. Weiser currently serves as founder and co-chairman of Actin Biomed, a position he has held since December 2006. Previously, he served as Director of Research of Paramount BioSciences, Inc. Dr. Weiser completed his Ph.D. in Molecular Neurobiology at Cornell University Medical College and received his M.D. from New York University School of Medicine, where he also completed a Postdoctoral Fellowship in the Department of Physiology and Neuroscience. Dr. Weiser currently serves on the boards of directors of Hana Biosciences, Inc. (NASDAQ: HNAB), Chelsea Therapeutics International Ltd. (NASDAQ: CHTP), Emisphere Technologies Inc. (NASDAQ: EMIS), ZIOPHARM Oncology Inc. (NASDAQ: ZIOP), and VioQuest Pharmaceuticals Inc. (OTCBB: VQPH), as well as several other privately held biotechnology companies.

There are no family relationships among any of our executive officers, directors and key employees.

### **Independence of the Board of Directors**

Our common stock has not been listed on a national securities exchange since we voluntarily de-listed our shares from the American Stock Exchange, or AMEX, effective March 26, 2008 and therefore, we are not subject to any corporate governance requirements regarding independence of board or committee members. However, we have chosen the definition of independence contained in the AMEX rules as a benchmark to evaluate the independence of its directors. Under the AMEX listing standards, an "independent director" of a company means a person who is not an officer or employee of the company or its subsidiaries and who the board of directors has affirmatively determined does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. After review of all relevant transactions or relationships between each director, or any of his family members, and our company, our senior management and our independent registered public accounting firm, the Board has determined that all of our directors are independent directors within the meaning of the applicable AMEX listing standard, except for Mr. Abel, our President and Chief Executive Officer.

### **Board Committees**

The Board of Directors has three standing committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The following table provides membership for each of the Board committees:

Name of Committee Membership

Audit Messrs. Herskowitz, Hoenlein and Steinhart (Chair)

Compensation

Messrs. Herskowitz, Hoenlein, Steinhart and Weiser

(Chair)

Nominating and Governance Messrs. Herskowitz, Hoenlein and Steinhart (Chair)

### Audit Committee

The Audit Committee oversees our accounting and financial reporting process. For these purposes, the Audit Committee performs several functions. For example, the Committee evaluates and assesses the qualifications of the independent registered public accounting firm; determines the engagement of the independent registered public accounting firm; reviews and approves the retention of the independent registered public accounting firm to perform any non-audit services; reviews the financial statements to be included in our Annual Report on Form 10-K; and discusses with management and the independent registered public accounting firm the results of the annual audit and the results of our quarterly financial statements. The Board of Directors adopted a written Audit Committee Charter, a copy of which can be found on our company website at <a href="https://www.manhattanpharma.com">www.manhattanpharma.com</a>.

Our Board of Directors has reviewed the definition of independence for Audit Committee members and has determined that each member of our Audit Committee is independent (as independence for audit committee members is currently defined under applicable SEC rules and the relevant AMEX listing standards. The Board has further determined that Mr. Steinhart qualifies as an "audit committee financial expert," as defined by applicable rules of the SEC.

## Compensation Committee

The Compensation Committee of the Board of Directors oversees our compensation policies, plans and programs. The Compensation Committee reviews and approves corporate performance goals and objectives relevant to the compensation of our executive officers and other senior management; reviews and recommends to the Board the compensation and other terms of employment of our Chief Executive Officer and our other executive officers; administers our equity incentive and stock option plans; and makes recommendations to the Board concerning the issuance of awards pursuant to those plans. All current members of the Compensation Committee, except for Dr. Weiser who serves as Chair of the Compensation Committee, are independent (as independence is currently defined under applicable AMEX listing standards). The Board of Directors has adopted a written charter of the Compensation Committee, a copy of which can be found on our company website at <a href="https://www.manhattanpharma.com">www.manhattanpharma.com</a>.

# Nominating and Governance Committee

The Nominating and Governance Committee considers and recommends to the Board persons to be nominated for election by the stockholders as directors. In addition to nominees recommended by directors, the Nominating and Governance Committee will consider nominees recommended by stockholders if submitted in writing to our Secretary at the address of Company's principal offices. The Board believes that any candidate for director, whether recommended by stockholders or by the Board, should be considered on the basis of all factors relevant to the needs of our company and the credentials of the candidate at the time the candidate is proposed. Such factors include relevant business and industry experience and demonstrated character and judgment. All current members of the Nominating and Corporate Governance Committee are independent (as independence is currently defined under applicable AMEX listing standards). The Board of Directors adopted a written charter of the Nominating and Governance Committee, a copy of which can be found on our company website at www.manhattanpharma.com.

### **Communication with the Board of Directors**

Although we have not adopted a formal process for stockholder communications with our Board of Directors, we believe stockholders should have the ability to communicate directly with the Board so that their views can be heard by the Board or individual directors, as applicable, and that appropriate and timely responses are provided to stockholders. All communications regarding general matters should be directed to our Secretary at the address below and should prominently indicate on the outside of the envelope that it is intended for the complete Board of Directors

or for any particular director(s). If no designation is made, the communication will be forwarded to the entire board. Stockholder communications to the Board should be sent to: Corporate Secretary, Attention: Board of Directors (or name(s) of particular directors), Manhattan Pharmaceuticals, Inc., 48 Wall Street, New York, NY 10005.

### **Code of Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees of our company. A copy of our Code of Business Conduct and Ethics is available on our company's website at <a href="https://www.manhattanpharma.com">www.manhattanpharma.com</a>. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the code to an executive officer or director, we will promptly disclose the nature of the amendment or waiver by filing with the SEC a current report on Form 8-K.

#### **Executive Officers**

Set forth below are the names, ages and titles of all of our executive officers as of September 15, 2008. All directors hold office until the next annual meeting of stockholders or until their respective successors are elected and qualified.

Name	Age	Position
Douglas Abel	47	President & Chief Executive Officer and
		Director
Michael G. McGuinness	54	Chief Operating and Financial Officer &
		Secretary

The biographies of our executive officers are set forth below.

**Douglas Abel** has been President and Chief Executive Officer and a director of our company since April 2005. His complete biography is set forth above under the caption "Management - Directors."

*Michael G. McGuinness* has been our Chief Financial Officer and Secretary since July 2006. Mr. McGuinness was appointed Chief Operating Officer on April 1, 2008. Prior to joining Manhattan, Mr. McGuinness served as chief financial officer of Vyteris Holdings (Nevada), Inc. (OTCBB: VYHN), a product-based drug delivery company, from September 2001 to April 2006, and from 1998 to 2001 he was chief financial officer of EpiGenesis Pharmaceuticals, a privately-held biotechnology company. Mr. McGuinness received a BBA in public accounting from Hofstra University.

None of our executive officers is related to any other executive officer or to any of our directors.

### **Summary Compensation of Executive Officers**

The following table sets forth all of the compensation awarded to, earned by or paid to (i) each individual serving as our principal executive officer during our last completed fiscal year and (ii) the two most highly compensated executive officers, other than the principal executive officer, that served as an executive officer at the conclusion of the fiscal year ended December 31, 2007 and who received total compensation in excess of \$100,000 during such fiscal year (collectively, the "named executives").

Name and Principal Position	Year	Salary	Bonus	Non- Option Incent Awards Comp	_	red isatio <b>A</b> l		Total
Douglas Abel Chief Executive Officer and President		345,000 \$	180,000(3)\$ 150,000 \$	(5)		Ü	42,333 <sup>(4)</sup> \$ 116,776 \$	1,477,557 1,748,841
Alan G. Harris (1) Chief Medical Officer		288,333 \$ 252,083 \$		292,530 <sup>(5)</sup> \$ 98,837 \$	0 \$ 0 \$	0 \$ 0 \$	9,000 <sup>(6)</sup> 8,800 \$	589,863 467,220
Michael McGuinness <sup>(2)</sup> Chief Operating and Financial Officer, Secretary	2007 \$ 2006 \$		100,000(3)\$ 60,000 \$	(3)	0 \$ 0 \$	0 \$ 0 \$	9,000(6)\$	442,861 181,851

<sup>(1)</sup> Dr. Harris was appointed our Chief Medical Officer on February 1, 2006. Dr. Harris' employment with us ended effective December 31, 2007.

- (3) The Company has accrued for such bonuses but has not paid such bonuses. Payment of such bonuses are contingent upon our raising additional financing and shall be paid as follows: (i) 50% will be paid when we have consummated a financing transaction with gross proceeds (net of commissions) to the Company of at least \$1,000,000 and (ii) the remaining 50% will be paid when we have consummated a financing transaction with gross proceeds (net of commissions) to us of at least \$2.5 million (cumulative, including the \$1 million financing transaction referred to above).
- (4) For 2007 represents a payment in the amount of \$33,333, which represents the approximate amount of additional expense incurred by Mr. Abel relating to his commuting between Boston and New York and a tax "gross up" to cover the additional tax liability to Mr. Abel from such payment, and a matching contributions by us pursuant to our company's 401(k) retirement plan of \$9,000. For 2006 represents a payment in the amount of \$83,333, which represents the approximate amount of additional expense incurred by Mr. Abel relating to his commuting between Boston and New York and a tax "gross up" to cover the additional tax liability to Mr. Abel from such payment, reimbursement of certain commuting expenses of \$24,643 and a matching contributions by us pursuant to our company's 401(k) retirement plan of \$8,800.
- (5) Represents the amount of share-based costs recognized by us during 2007 under SFAS No. 123(R). See Note 3 to our Consolidated Financial Statements included in our annual report for 2007 on Form 10-K and for 2006 on Form 10-KSB for the assumptions made in the valuation.
  - (6) Represents matching contributions by us pursuant to our company's 401(k) retirement plan.

<sup>(2)</sup>Mr. McGuinness was appointed our Chief Financial Officer on July 10, 2006 and Chief Operating Officer on April 1, 2008.

## **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information regarding the unexercised options held by each of our named executive officers as of December 31, 2007.

	Option Awards							
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	-	ion Exercise Price (\$)	Option Expiration Date			
				,	•			
Douglas Abel	2,923,900	0	\$	1.50	04/01/2015			
	0	250,000	\$	0.95	04/25/2017			
Alan Harris	300,000	0	\$	1.35	12/31/2009			
	100,000	0	\$	0.95	12/31/2009			
Michael McGuinness	73,333	146,667	\$	0.70	07/10/2016			
	20,000	40,000	\$	1.35	07/10/2016			
	0	320,000	\$	0.95	04/25/2017			

### **Employment Agreements**

**Douglas Abel.** We entered into an employment agreement and an extension to that employment agreement with Mr. Abel dated April 1, 2005, whereby Mr. Abel agreed to serve as our President and Chief Executive Officer for a period of four years in exchange for (i) an annual base salary of \$300,000, subject to a retroactive increase in the amount of \$25,000 upon our completing a financing transaction of at least \$5,000,000, (ii) a signing bonus in the amount of \$200,000, which was payable in two installments during the first year of the agreement, (iii) a discretionary performance-based bonus in an amount equal to up to 50% of Mr. Abel's base salary, and (iv) an option to purchase 2,923,900 shares of our common stock at \$1.50 per share with three-year annual vesting, purchasable for a 10-year term. In accordance with the terms of his employment agreement and as a result of our private placement financing that we completed in August 2005, Mr. Abel's salary was increased to \$325,000 retroactive to April 1, 2005. The employment agreement contains customary provisions relating to confidentiality, work-product assignment, non-competition and non-solicitation. In the event Mr. Abel's employment is terminated by us (other than for cause) during the term of the agreement, including a termination upon a change of control (as defined in the agreement), we are required to pay a severance payment ranging from between 6 and 12 month of base salary, depending upon the circumstances of such termination.

Alan G. Harris. We entered into an employment agreement with Dr. Harris dated January 26, 2006, whereby Dr. Harris agreed to serve as our Chief Medical Officer for a period of three years commencing on February 1, 2006. Mr. Harris' employment with Company ended on December 31, 2007. The employment agreement provided that, in exchange for his services, Dr. Harris would receive (i) an annual base salary of \$275,000; (ii) a guaranteed cash bonus of \$50,000; (iii) an annual milestone bonus on each anniversary of the employment agreement during the term of the agreement in an amount up to 30% of his annual base salary, at the discretion of our chief executive officer and the Board; and (iv) an option to purchase 300,000 shares of our common stock at an exercise price equal to the last closing sale price of our common stock on February 1, 2006, such options to vest in equal amounts over three years and be exercisable for a 10-year term. In the event Dr. Harris' employment is terminated by us upon a change of control and the fair market value of our common stock, as determined in the good faith discretion of the Board, is less than \$40,000,000 on the date of the change of control, Dr. Harris shall continue to receive his base salary and benefits for a period of three months from the date of termination. In the event such termination is for a reason other than for cause or pursuant to a change of control, Dr. Harris shall be entitled to receive his base salary for a period of six

months from the date of termination.

Dr. Harris executed a Separation and Release Agreement (the "Separation Agreement") with us which provides for, among other things, (i) the termination of Dr. Harris's employment effective December 31, 2007; (ii) continuation of his base salary through February 29, 2008 in accordance with our standard payroll practices; (iii) the amendment of certain outstanding option grants to provide for the immediate vesting of the unvested portion of the grant issued on February 1, 2006 and the immediate vesting of one-third of the options granted on April 25, 2007 and to extend the expiration date of such option grants; and (iv) the waiver of our right to enforce the covenants against competition contained in Section 6(a) of his employment agreement. The Separation Agreement further provides for mutual general releases.

Michael G. McGuinness. Mr. McGuinness' employment with us is governed by an employment agreement dated July 7, 2006. The agreement provides for an initial three-year term of employment ending July 2009, subject to additional one-year renewal periods upon the mutual agreement of the parties. Pursuant to the agreement, Mr. McGuinness is entitled to an annual base salary of \$205,000 and an annual bonus, payable in the discretion of our Board, of up to 30 percent of his annual base salary. Mr. McGuinness is also entitled to certain other fringe benefits that are made available to our senior executives from time to time, including medical and dental insurance and participation in our 401(k) plan.

In addition, in accordance with the terms of the employment agreement, we issued to Mr. McGuinness two 10-year stock options pursuant to our 2003 Stock Option Plan. The first option relates to 220,000 shares of common stock and is exercisable at a price of \$0.70, the closing price of our common stock on the date of his employment agreement. The second option relates to 60,000 shares and is exercisable at a price of \$1.35 per share. Both options vest in three annual installments commencing July 10, 2007. To the extent Mr. McGuinness' employment with us is terminated prior to the end of such 10-year term, the options shall remain exercisable for a period of 90 days.

Mr. McGuinness' employment agreement further provides that in the event we terminate his employment with us other than as a result of death, for "cause," "disability" or upon a "change of control" (as those terms are defined in the agreement), then (1) Mr. McGuinness will continue receiving his base salary and fringe benefits for a period of six months following such termination, provided, that our obligation to pay such compensation shall be offset by any amounts received by Mr. McGuinness from subsequent employment during such 6-month period, and (2) the vesting of the stock options issued to Mr. McGuinness in accordance with the employment agreement will accelerate and be deemed vested as of the date of termination and will remain exercisable for a period of 90 days following such termination. In the event we terminate Mr. McGuinness' employment during the term of the agreement upon a "change of control" and, if at the time of such termination, the aggregate value of our outstanding common stock is less than \$80 million, then (i) Mr. McGuinness will continue receiving his base salary and fringe benefits for a period of six months following such termination and (ii) the portions of the stock options issued in accordance with the employment agreement that have vested as of the date of such termination or that are scheduled to vest in the calendar year of such termination will be deemed vested and will remain exercisable for a period of 90 days following such termination.

### **Compensation of Directors**

Non-employee directors are eligible to participate in our Non-employee Director Compensation Arrangement, which was adopted on January 30, 2007. Under the arrangement, non-employee directors are granted an option to purchase 50,000 shares of common stock upon their initial election or appointment to the board. Thereafter on an annual basis, non-employee directors are entitled to an option to purchase 50,000 shares of common stock. Each non-employee director is entitled to a retainer of \$20,000 per year, payable on a quarterly basis. In addition, each such director shall be entitled to a fee of \$1,000 for each meeting of the Board attended in person, or \$500 for attending a meeting by telephone or other electronic means. Each non-employee director in person, or \$500 for attending a committee meeting by telephone or other electronic means. Each non-employee director is also entitled to reimbursement for reasonable out-of-pocket expenses incurred in connection with the performance of his service as a director, including without limitation, travel related expenses incurred in connection with attendance at Board or Board committee meetings.

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2007:

	Fee	s Earned or			
		Paid in	Option	All Other	
Name		Cash	Awards (1)	Compensation	Total
Neil Herskowitz	\$	27,500	\$ 7,948(3)	\$ 0	\$ 35,448
Malcolm Hoenlein	\$	25,000	\$ 7,948(4)	\$ 0	\$ 32,948
Timothy McInerney	\$	24,000	\$ 7,948 <sup>(5)</sup>	\$ 0	\$ 31,948
Joan Pons Gimbert (2)	\$	12,000	\$ 7,948(6)	\$ 0	\$ 19,948
Richard I. Steinhart	\$	27,000	\$ 7,948 <sup>(7)</sup>	\$ 0	\$ 34,948
Michael Weiser	\$	24,500	\$ 7,948(8)	\$ 0	\$ 32,448

- (1) Represents the amount of share-based costs recognized by us during 2006 under SFAS No. 123(R). See Note 3 to our Consolidated Financial Statements included in our annual report for 2006 on Form 10-KSB for the assumptions made in the valuation.
  - (2) Joan Pons Gimbert resigned from the Board in July 2007.
- (3) As of September 15, 2008, Mr. Herskowitz had options to purchase an aggregate of 216,010 shares of our common stock.
- (4) As of September 15, 2008, Mr. Hoenlein had options to purchase an aggregate of 216,010 shares of our common stock.
- (5) As of September 15, 2008, Mr. McInerney had options to purchase an aggregate of 236,010 shares of our common stock.
- (6) As of September 15, 2008, Mr. Pons Gimbert had options to purchase an aggregate of 133,334 shares of our common stock.
- (7) As of September 15, 2008, Mr. Steinhart had options to purchase an aggregate of 216,010 shares of our common stock.
- (8) As of September 15, 2008, Mr. Weiser had options to purchase an aggregate of 230,000 shares of our common stock.

### **Compensation Committee Interlocks and Insider Participation**

There were no interlocks or other relationships with other entities among our executive officers and directors that are required to be disclosed under applicable SEC regulations relating to compensation committee interlocks and insider participation.

# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding ownership of shares of our common stock, as of September 15, 2008:

- o by each person known by us to be the beneficial owner of 5% or more of our common stock;
- o by each of our directors and executive officers; and
- o by all of our directors and executive officers as a group.

Except as otherwise indicated, each person and each group shown in the table has sole voting and investment power with respect to the shares of common stock indicated. For purposes of the table below, in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended, a person is deemed to be the beneficial owner, of any shares of our common stock over which he or she has or shares, directly or indirectly, voting or investment power or of which he or she has the right to acquire beneficial ownership at any time within 60 days. As used in this prospectus, "voting power" is the power to vote or direct the voting of shares and "investment power" includes the power to dispose or direct the disposition of shares. Common stock beneficially owned and percentage ownership as of September 15, 2008 was based on 70,624,232 shares outstanding. Unless otherwise indicated, the address of each beneficial owner is c/o Manhattan Pharmaceuticals, Inc., 48 Wall Street, New York, New York 10005.

	Number of	
	Shares	Percentage
	Beneficially	Beneficially
Name of Beneficial Owners, Officers and Directors	Owned (#)	Owned (%)
Douglas Abel (1)	3,519,566	4.8
Michael McGuinness (2)	694,000	1.0
Michael Weiser (3)	2,562,651	3.6
Timothy McInerney (4)	990,857	1.4
Neil Herskowitz (5)	347,128	*
Richard I. Steinhart <sup>(6)</sup>	154,967	*
Malcolm Hoenlien (7)	150,525	*
All directors and officers as a group <sup>(8)</sup> (7 persons)	8,419,694	11.1
Lester Lipschutz (9)		
1650 Arch Street, Philadelphia, PA 19103	8,941,873	12.7
Lindsay Rosenwald (10)		
787 Seventh Avenue		
New York, NY 10019	4,224,268	5.9
Nordic Biotech Venture Fund II K/S <sup>(11)</sup>		
Ostergrade 5, 3rd floor, DK-1100		
Copenhagen K, Denmark	33,928,571	32.5
Ostergrade 5, 3rd floor, DK-1100	33,928,571	32.5

<sup>\*</sup> Less than 1.0%

- (1) Includes 3,440,566 shares issuable upon exercise of vested portions of options and 24,000 shares issuable upon exercise of warrants.
- (2) Includes 660,000 shares issuable upon exercise of vested portions of options and 24,000 shares issuable upon exercise of warrants.
- (3) Includes 163,334 shares issuable upon the exercise of vested portions of options, and 151,754 shares issuable upon exercise of warrants.
- (4) Includes 183,334 shares issuable upon exercise of vested portions of options; and 139,863 shares issuable upon exercise of warrants.
- (5) Includes 149,344 shares issuable upon exercise of vested portions of options, and 43,444 shares issuance upon exercise of warrants; 77,288 shares held by Riverside Contracting, LLC, a limited liability company of which Mr. Herskowitz is a member holding 50% ownership and 44,168 shares held by ReGen Capital II, LLC, a limited liability company of which Mr. Herskowitz is a member holding 50% ownership.
- (6) Includes 149,344 shares issuable upon exercise of vested portions of options.
- (7) Includes 149,344 shares issuable upon exercise of vested portions of options.
- (8) Includes 4,895,246 shares issuable upon exercise of vested portions of options; 383,061 shares issuable upon the exercise of warrants; 77,288 shares held by Riverside Contracting, LLC, a limited liability company of which Mr. Herskowitz is a member holding 50% ownership and 44,168 shares held by ReGen Capital II, LLC, a limited liability company of which Mr. Herskowitz is a member holding 50% ownership.
- (9) Includes 8,941,873 shares of Common Stock held by separate trusts for the benefit of Dr. Rosenwald or his family with respect to which Mr. Lipschutz is either trustee or investment manager and in either case has investment and voting power. Mr. Lipschutz disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein, if any. The foregoing information is derived from a Schedule 13G filed on behalf of the reporting person on August 1, 2007
- (10) Includes 3,183,497 shares held directly by Dr. Rosenwald, 1,040,658 shares issuable upon the exercise of warrants, 80 shares held by the Dr. Rosenwald's wife, over which Dr. Rosenwald may be deemed to have sole voting and dispositive power, although he disclaims beneficial ownership of such shares except with regard to his pecuniary interest therein, if any, and 33 shares held by Dr. Rosenwald's children, over which Dr. Rosenwald may be deemed to have sole voting and dispositive power, although he disclaims beneficial ownership of such shares except with regard to his pecuniary interest therein, if any. The foregoing information is derived from a Schedule 13G/A filed on behalf of the reporting person on February 13, 2008.
- (11) Includes (i) 26,785,714 shares issuable upon exercise of Nordic's right to put all or a portion of Nordic Biotech Venture Fund II K/S' equity interest in Hedrin Pharmaceuticals K/S, a Danish limited partnership, of which we and Nordic are partners and (ii) 7,142,857 shares issuable upon exercise of an outstanding warrant held by Nordic. Does not include (i) 26,785,714 shares issuable upon exercise of our right to call all or a portion of Nordic's equity interest in Hedrin Pharmaceuticals K/S to the extent such shares are not issued upon exercise of Nordic's put right, which call right is subject to the satisfaction of certain conditions with respect to the closing price of our common stock and Nordic's right to refuse such call upon payment of cash or forfeiture of equity interests in Hedrin Pharmaceuticals K/S, or (ii) 8,928,572 additional shares which may

become issuable upon exercise of Nordic's right to put, or subject to the satisfaction of certain conditions and to certain exceptions discussed above, our right to call, all or a portion of selling securityholder's equity interest in Hedrin Pharmaceuticals K/S upon classification of Hedrin by the FDA, as a Class II or Class III medical device and selling securityholder's investment of an additional \$1.25 million in Hedrin Pharmaceuticals K/S. Florian Schonharting and Christian Hansen have voting and investment control over such securities.

#### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

#### Oleoylestrone Developments, SL

Pursuant to the terms of a license agreement dated February 15, 2002 between us and Oleoylestrone Developments, SL, or OED, which was terminated in November 2007, we had an exclusive, worldwide license to U.S. and foreign patents and patent applications relating to certain technologies. Although we were not obligated to pay royalties to OED, the license agreement required us to make certain performance-based milestone payments. As of April 15, 2008, OED held approximately 5.6% of our outstanding common stock. Additionally, Mr. Pons, a member of our board of directors, is the chief executive officer of OED.

We also entered into a consulting agreement with OED, which became effective in February 2002 and was terminated along with the termination of the license agreement in November 2007. Pursuant to our consulting agreement, we paid OED a fee of \$6,250 per month The fees associated with the consulting agreement were expensed as incurred. Pursuant the consulting agreement, OED agreed to appoint a member to serve as a member of our Scientific Advisory Board and to render consulting and advisory services to us. Such services included research, development and clinical testing of our technology as well as the reporting of the findings of such tests, assistance in the filing of patent applications and oversight and direction of efforts in regards to personnel for clinical development. For the periods ended December 31, 2007 and 2006 and from inception, fees paid to OED were \$68,750, \$325,000 and \$931,250, respectively.

#### Paramount BioCapital, Inc.

In February 2007, we engaged Paramount BioCapital, Inc., as our 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. At the time of the engagement, Timothy McInerney was an employee of Paramount BioCapital, Inc. or one of its affiliates. The sole shareholder of Paramount BioCapital, Inc. is Lindsay A. Rosenwald, M.D. Dr. Rosenwald beneficially owns more than 5 percent of our common stock. 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 total gross proceeds of approximately \$8.56 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 Neil Herskowitz, a director of Manhattan, at a per share price of \$0.90, the closing sale price of our 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, 2007 and ending March 30, 2012.

#### Private Placement

As described above, on March 30, 2007, we issued and sold in a private placement transaction an aggregate of 10,185,502 shares of our common stock. 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 Neil Herskowitz, a director of Manhattan, at a per share price of \$0.90, the closing sale price of our common stock on March 29, 2007. In addition to the shares of common stock, 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, 2007 and ending March 30, 2012. Accordingly, we received net proceeds of \$7.9 million from the sale of these shares and warrants. We engaged Paramount BioCapital, Inc., as our placement agent in connection with the private placement, as discussed above.

#### The Hedrin JV

We and Nordic entered into a joint venture agreement on January 31, 2008, which was amended on February 18, 2008 and on June 9, 2008. Pursuant the joint venture agreement, in February 2008, (i) Nordic contributed cash in the amount of \$2.5 million to Hedrin Pharmaceuticals K/S, a newly formed Danish limited partnership, or the Hedrin JV, in exchange for 50% of the equity interests in the Hedrin JV, and (ii) we contributed certain assets to North American rights (under license) to our Hedrin product to the Hedrin JV in exchange for \$2.0 million in cash and 50% of the equity interests in the Hedrin JV. On or around June 30, 2008, in accordance with the terms of the joint venture agreement, Nordic contributed an additional \$1.25 million in cash to the Hedrin JV, \$1.0 million of which was distributed to us and equity in the Hedrin JV was distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Pursuant to the joint venture agreement, upon the classification by the FDA of Hedrin as a Class II or Class III medical device, Nordic will be required to contribute to the Hedrin JV an additional \$1.25 million in cash, \$0.5 million of which will be distributed to us and equity in the Hedrin JV will be distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Upon classification by the FDA of Hedrin as a Class II or Class III medical device, the Hedrin JV will have received a total of \$1.5 million cash to be applied toward the development and commercialization of Hedrin in North America. If classification of Hedrin by the FDA as a Class II or Class III medical device is not received by June 30, 2009, then Nordic will not be obligated to make the final payment of \$1.25 million and Nordic will receive an additional 20% ownership of the joint venture and enhanced control over the joint venture's operations and other important decision-making.

The Hedrin JV will be 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 Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV will engage us to provide management services to the Hedrin JV in exchange for an annualized management fee, which for 2008, on an annualized basis, is \$527,000. The profits of the Hedrin JV will be shared by us and Nordic in accordance with our respective equity interests in the Hedrin JV, of which we each currently hold 50%, except that Nordic is entitled to receive a minimum return each year from the Hedrin JV equal to 6% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Hedrin JV, before any distribution is made to us. If the Hedrin JV realizes a profit in excess of the Nordic minimum return in any year, then such excess shall first be distributed to us until our distribution and the Nordic minimum return are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. However, in the event of a liquidation of the Hedrin JV, Nordic's distribution in liquidation must equal to the amount Nordic invested in the Hedrin JV (\$5 million if all of the milestones described above are met and \$3.5 million if they are not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV before any distribution is made to us. If the Hedrin JV's assets in liquidation exceed the Nordic liquidation preference amount, then any excess shall first be distributed to us until our distribution and the Nordic liquidation preference amount are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

Pursuant to the terms of the joint venture agreement, Nordic has the right to nominate one person for election or appointment to our board of directors. The Hedrin JV's board of directors will consist of four members, two members appointed by us and two members 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. In the event that the final payment milestone described above is not achieved by March 30, 2009, then the Hedrin JV 's board of directors will increase to five members, two appointed by us and three appointed by Nordic.

Pursuant to the joint venture agreement, Nordic has the right to put all or a portion of its interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the amount of Nordic's investment in the Hedrin JV divided by \$0.14, as adjusted from time to time for stock splits and other specified events, multiplied by a conversion

factor, which is (i) 1.00 for so long as Nordic's distributions from the Hedrin JV are less than the amount of its investment, (ii) 1.25 for so long as Nordic's distributions from the Hedrin JV are less than two times the amount of its investment but greater than or equal to the amount of its investment amount, (iii) 1.50 for so long as Nordic's distributions from the Hedrin JV are less than three times the amount of its investment but greater than or equal to two times the amount of its investment amount, (iv) 2.00 for so long as Nordic's distributions from the Hedrin JV are less than four times the amount of its investment but greater than or equal to three times the amount of its investment amount and (v) 3.00 for so long as Nordic's distributions from Hedrin JV are greater than or equal to four times the amount of its investment. The put right expires upon the earlier to occur of (i) February 25, 2018 and (ii) 30 days after the date when Nordic's distributions from the Hedrin JV exceed five times the amount Nordic has invested in the Hedrin JV (or 10 days after such date if we have provided Nordic notice thereof).

Pursuant to the joint venture agreement, we have the right to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the portion of Nordic's investment in the Hedrin JV that we call by the dollar amount of Nordic's investment as of such date in the Hedrin JV, divided by \$0.14, as adjusted from time to time for stock splits and other specified events. The call right is only exercisable by us if the price of our common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 25% of the call right. During the second 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 50% of the call right on a cumulative basis. During the third consecutive 30 trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 75% of the call right on a cumulative basis. During the fourth consecutive 30 days in which our common stock closes at or above \$1.40 per share, we may exercise up to 100% of the call right on a cumulative basis. Nordic may refuse the call, either by paying \$1.5 million multiplied by the percentage of Nordic's investment being called or forfeiting an equivalent portion of the put right, calculated on a pro rata basis for the percentage of the Nordic equity interest called by us. The call right expires on February 25, 2013.

For purposes of Nordic's right to put, and our right to call, all or a portion of Nordic's equity interest in the Hedrin JV, the amount of Nordic's investment is currently \$3,750,000; provided, that if, by June 30, 2009, the FDA either does not formally classify Hedrin as a Class II or Class III medical device or formally designates Hedrin as a drug and refers regulation thereof to the FDA Center for Drug Evaluation and Research, the amount of Nordic's investment will be reduced to \$3,500,000 and if by June 30, 2009, the FDA formally classifies Hedrin as a Class II or Class III medical device then upon Nordic's payment of the final milestone payment, Nordic's investment will be increased to \$5,000,000.

In connection with our joint venture agreement, on February 25, 2008, Nordic paid us a non-refundable fee of \$150,000 in exchange for the right to receive a warrant to purchase up to 7,142,857 shares of our common stock at \$0.14 per share, as adjusted from time to time for stock splits and other specified events, if Nordic did not exercise all or part of its put right on or before April 30, 3008. As of April 30, 2008, Nordic had not exercised all or any portion of its put right and we issued the warrant to Nordic.

#### Issuance of Secured Promissory Notes and Warrants

On September 11, 2008, we issued a secured promissory note in the principal amount of \$12,000 to each of Douglas Abel, our President and Chief Executive Officer and a director of our company; Michael Weiser, a director of our company; Timothy McInerny, a director of our company; Neil Herskowitz, a director of our company, and Michael McGuiness, our Chief Financial Officer and Chief Operating Officer. Principal and interest on the notes are payable in cash on March 10, 2009 unless paid earlier by us. In connection with the issuance of the notes, we issued to each noteholder a 5-year warrant to purchase 24,000 shares of our common stock at an exercise price of \$0.20 per share. We granted to the noteholders a continuing security interest in certain specific refunds, deposits and repayments due to us and expected to be repaid to us in the next several months.

We believe that all of the transactions set forth above were made on terms no less favorable to us than could have been obtained from unaffiliated third parties. All such transactions have been reviewed by the audit committee of our Board of Directors and approved by them. All future transactions between us and our officers, directors and principal shareholders and their affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by our audit committee or another independent committee of our Board of Directors.

#### DESCRIPTION OF SECURITIES TO BE REGISTERED

#### General

Our certificate of incorporation, as amended and restated to date, authorizes the issuance of up to 150,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of "blank check" preferred stock, par value \$0.001 per share. In June 2008, our stockholders approved an amendment to our certification of incorporation to increase the total number of shares of our common stock authorized to be issued to 300,000,000.

As of August 28, 2008, there were 70,624,232 shares of our common stock and no shares of preferred stock issued and outstanding. As of such date, warrants to purchase up to 15,826,710 shares of our common stock and options to purchase up to 10,766,336 shares of our common stock were issued and outstanding.

#### Common Stock

*Voting*. The holders of our common stock are entitled to one vote for each outstanding share of common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. Stockholders are not entitled to vote cumulatively for the election of directors.

*Dividend Rights.* Subject to the dividend rights of the holders of any outstanding series of preferred stock, holders of our common stock are entitled to receive ratably such dividends and other distributions of cash or any other right or property as may be declared by our board of directors out of our assets or funds legally available for such dividends or distributions.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of our common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities. If we have any preferred stock outstanding at such time, holders of the preferred stock may be entitled to distribution and/or liquidation preferences. In either such case, we must pay the applicable distribution to the holders of its preferred stock (if any) before it may pay distributions to the holders of common stock.

*Conversion, Redemption and Preemptive Rights.* Holders of our common stock have no conversion, redemption, preemptive, subscription or similar rights.

#### **Preferred Stock**

We are authorized to issue up to 10,000,000 shares of preferred stock, none of which are outstanding, with the Board of Directors having the right to determine the designations, rights, preferences and powers of each series of preferred stock. Accordingly, the Board of Directors is empowered, without shareholder approval, to issue preferred stock with voting, dividend, conversion, redemption, liquidation or other rights which may be superior to the rights of the holders of common stock and could adversely affect the voting power and other equity interests of the holders of common stock.

#### **Warrants and Rights Granted in Connection with Joint Venture**

Put or Call Right

Pursuant to our joint venture agreement with Nordic Biotech Venture Fund II K/S, or Nordic, which was entered into in January 31, 2008 and amended on February 18, 2008, Nordic has the right to put all or a portion of its interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the amount of Nordic's investment in

the Hedrin JV divided by \$0.14, as adjusted from time to time for stock splits and other specified events, multiplied by a conversion factor, which is (i) 1.00 for so long as Nordic's distributions from the Hedrin JV are less than the amount of its investment, (ii) 1.25 for so long as Nordic's distributions from the Hedrin JV are less than two times the amount of its investment but greater than or equal to the amount of its investment but greater than or equal to two times the amount of its investment amount, (iv) 2.00 for so long as Nordic's distributions from the Hedrin JV are less than four times the amount of its investment but greater than or equal to three times the amount of its investment amount and (v) 3.00 for so long as Nordic's distributions from Hedrin JV are greater than or equal to four times the amount of its investment. The put right expires upon the earlier to occur of (i) February 25, 2018 and (ii) 30 days after the date when Nordic's distributions from the Hedrin JV exceed five times the amount Nordic has invested in the Hedrin JV (or 10 days after such date if we have provided Nordic notice thereof).

Pursuant to the joint venture agreement, we have the right to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the portion of Nordic's investment in the Hedrin JV that we call by the dollar amount of Nordic's investment as of such date in the Hedrin JV, divided by \$0.14, as adjusted from time to time for stock splits and other specified events. The call right is only exercisable by us if the price of our common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 25% of the call right. During the second 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 50% of the call right on a cumulative basis. During the third consecutive 30 trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 75% of the call right on a cumulative basis. During the fourth consecutive 30 days in which our common stock closes at or above \$1.40 per share, we may exercise up to 100% of the call right on a cumulative basis. Nordic may refuse the call, either by paying \$1.5 million multiplied by the percentage of Nordic's investment being called or forfeiting an equivalent portion of the put right, calculated on a pro rata basis for the percentage of the Nordic equity interest called by us. The call right expires on February 25, 2013.

#### Warrant

In connection with our joint venture agreement with Nordic Biotech Venture Fund II K/S, on February 25, 2008, Nordic paid us a non-refundable fee of \$150,000 in exchange for the right to receive a warrant to purchase up to 7,142,857 shares of our common stock at \$0.14 per share, as adjusted from time to time for stock splits and other specified events, if Nordic did not exercise all or part of its put right on or before April 30, 3008. As of April 30, 2008, Nordic had not exercised all or any portion of its put right and we issued the warrant to Nordic.

The warrant entitles the holder to purchase up to 7,142,857 shares of our common stock at an exercise price of \$0.14 per share for a period of five (5) years commencing on the date of issuance. The warrant may be exercised in whole or in part from time to time during the exercise period (i) by the surrender of the warrant certificate to us, together with the payment of the purchase price for the shares to be purchased or (ii) on a cashless basis, by the surrender of the warrant certificate to us and the cancellation of a portion of the warrant in payment of the purchase price for the shares to be purchased.

The holder of the warrant is protected against dilution of the equity interest represented by the underlying shares of our common stock upon the occurrence of certain events, including, but not limited to, issuance of stock dividends or stock splits. In addition, the warrant contains certain weighted average anti-dilution protections in the event that we issue shares of common stock or securities convertible into shares of common stock at less than the then-current exercise price per share, subject to exceptions for, among other things, issuance of (i) options pursuant to existing stock option plans or stock option plans approved by our outside directors, (ii) securities upon the exercise, exchange or conversion of outstanding securities, (iii) securities issued pursuant to acquisition or strategic transactions approved by the majority of disinterested directors and (iv) less than 50,000 shares, subject to adjustment for stock splits, combinations and the like, in the aggregate which do not meet any of the foregoing conditions.

#### Registration Rights

In connection with the joint venture agreement, we and Nordic entered into a registration rights agreement, on February 25, 2008, as modified pursuant to a letter agreement, dated September 17, 2008, pursuant to which we agreed to file with the Securities and Exchange Commission, or the SEC, by no later than 10 calendar days following the date on which our Annual Report on Form 10-K for the year ended December 31, 2007 is required to be filed with the SEC, which was subsequently waived by Nordic until May 1, 2008, an initial registration statement registering the resale by Nordic of any shares of our common stock issuable to Nordic through the exercise of the warrant or the put right. We also have agreed to file with the SEC any additional registration statements which may be required no later than 45 days after the date we first know such additional registration statement is required; provided, however, that (i) in the case of the classification by the FDA of Hedrin as a Class II or Class III medical device described above and the payment in full by Nordic of the related final milestone payment of \$1.25 million, the registration statement with respect to the additional shares of our common stock relating to such additional investment must be filed within 45 days after achievement of such classification; and (ii) in the event we provide Nordic with notice of exercise of our right to call all or a portion of Nordic's equity interest in the Hedrin JV, a registration statement with respect to the shares of our common stock payable to Nordic in connection with such call right (after giving effect to any reduction in the number of such shares resulting from Nordic's refusal of all or a portion of such call in accordance with the terms of our joint venture agreement) must be filed within 16 days after delivery of such notice to Nordic. If we fail to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of the required filing date or in the case of the registration statement of which this prospectus forms a part, by October 17, 2008 or if we receive comments from the SEC with respect to such registration statement, November 17, 2008, or otherwise fail to diligently pursue registration with the SEC in accordance with the terms of the registration rights agreement, we will be required to pay as partial liquidated damages and not as a penalty, to Nordic or its assigns, an amount equal to 0.5% of the amount invested in the Hedrin JV by Nordic pursuant to the joint venture agreement per month until the registration rights agreement is declared effective by the SEC; provided, however, that in no event shall the aggregate amount payable by us exceed 9% of the amount invested in the Hedrin JV by Nordic under the joint venture agreement.

#### **Limitations on Directors' Liability**

As permitted by Delaware law, our certificate of incorporation provides the personal liability of our directors to us or our stockholders for monetary damages for breach of certain fiduciary duties as a director is eliminated. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of certain fiduciary duties as a director, except that a director will be personally liable for:

- · any breach of his or her duty of loyalty to us or our stockholders;
- acts or omissions not in good faith which involve intentional misconduct or a knowing violation of law;
- the payment of dividends or the redemption or purchase of stock in violation of Delaware law; or
- · any transaction from which the director derived an improper personal benefit.

This provision does not affect a director's liability under the federal securities laws. To the extent that the our directors, officers and controlling persons are indemnified under the provisions contained in our certificate of incorporation, Delaware law or contractual arrangements against liabilities arising under the Securities Act, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is

therefore unenforceable.

#### **Delaware Takeover Statute**

As a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law which contains specific provisions regarding "business combinations" between corporations organized under the laws of the State of Delaware and "interested stockholders." These provisions prohibit us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to such date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

For purposes of these provisions, a "business combination" includes mergers, consolidations, exchanges, asset sales, leases and other transactions resulting in a financial benefit to the interested stockholder and an "interested stockholder" is any person or entity that beneficially owns 15% or more of our outstanding voting stock and any person or entity affiliated with or controlled by that person or entity.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer. Its address 17 Battery Place, New York, NY 10004 and its telephone number is 212-509-4000.

#### Listing

Our common stock is listed on the Over the Counter Bulletin Board under the symbol "MHAN."

#### SHARES ELIGIBLE FOR FUTURE SALE

We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding warrants, in the public market after this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

As of June 30, 2008, 70,624,232 shares of our common stock were outstanding. All of these shares are freely tradable without restriction or further registration under the Securities Act, except for any shares held by our affiliates, as that term in is defined in Rule 144 under the Securities Act.

Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 promulgated under the Securities Act, which rules are summarized below. As of June 30, 2008, all of the outstanding 3,141,387 shares of common stock that are held by our officers and directors (excluding shares issuable upon exercise of outstanding options held by our officers and directors) are eligible for sale under Rule 144.

#### **Rule 144**

The SEC recently adopted amendments to Rule 144, which became effective on February 15, 2008 and apply to securities acquired both before and after that date. Under these amendments, a person who has beneficially owned restricted common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale.

Persons who have beneficially owned restricted common stock for at least six months but who are our affiliates at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

**4**.0% of the number of ordinary shares then outstanding, which will equal 706,242 shares immediately after this offering; or

the average weekly trading volume of the ordinary shares during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are also limited by manner of sale provisions, notice requirements and the availability of current public information about us.

#### SELLING SECURITYHOLDER

This prospectus relates to the possible resale or other disposition by the selling securityholder of 33,928,571 shares of our common stock. The shares of our common stock underlying securities held by the selling securityholder are being registered for resale by the selling securityholder from time to time. See "Plan of Distribution." The securities held by the selling securityholder were acquired by the selling securityholder, as discussed below.

We and Nordic entered into a joint venture agreement on January 31, 2008, which was amended on February 18, 2008 and on June 9, 2008. Pursuant the joint venture agreement, in February 2008, (i) Nordic contributed cash in the amount of \$2.5 million to Hedrin Pharmaceuticals K/S, a newly formed Danish limited partnership, or the Hedrin JV, in exchange for 50% of the equity interests in the Hedrin JV, and (ii) we contributed certain assets to North American rights (under license) to our Hedrin product to the Hedrin JV in exchange for \$2.0 million in cash and 50% of the equity interests in the Hedrin JV. On or around June 30, 2008, in accordance with the terms of the joint venture agreement, Nordic contributed an additional \$1.25 million in cash to the Hedrin JV, \$1.0 million of which was distributed to us and equity in the Hedrin JV was distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Pursuant to the joint venture agreement, upon the classification by the FDA of Hedrin as a Class II or Class III medical device, Nordic will be required to contribute to the Hedrin JV an additional \$1.25 million in cash, \$0.5 million of which will be distributed to us and equity in the Hedrin JV will be distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. Upon classification by the FDA of Hedrin as a Class II or Class III medical device, the Hedrin JV will have received a total of \$1.5 million cash to be applied toward the development and commercialization of Hedrin in North America. If classification of Hedrin by the FDA as a Class II or Class III medical device is not received by June 30, 2009, then Nordic will not be obligated to make the final payment of \$1.25 million and Nordic will receive an additional 20% ownership of the joint venture and enhanced control over the joint venture's operations and other important decision-making.

The Hedrin JV will be 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 Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV will engage us to provide management services to the Hedrin JV in exchange for an annualized management fee, which for 2008, on an annualized basis, is \$527,000. The profits of the Hedrin JV will be shared by us and Nordic in accordance with our respective equity interests in the Hedrin JV, of which we each currently hold 50%, except that Nordic is entitled to receive a minimum return each year from the Hedrin JV equal to 6% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Hedrin JV, before any distribution is made to us. If the Hedrin JV realizes a profit in excess of the Nordic minimum return in any year, then such excess shall first be distributed to us until our distribution and the Nordic minimum return are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. However, in the event of a liquidation of the Hedrin JV, Nordic's distribution in liquidation must equal to the amount Nordic invested in the Hedrin JV (\$5 million if all of the milestones described above are met and \$3.5 million if they are not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV before any distribution is made to us. If the Hedrin JV's assets in liquidation exceed the Nordic liquidation preference amount, then any excess shall first be distributed to us until our distribution and the Nordic liquidation preference amount are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

Pursuant to the terms of the joint venture agreement, Nordic has the right to nominate one person for election or appointment to our board of directors. The Hedrin JV's board of directors will consist of four members, two members appointed by us and two members 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. In the event that the final payment milestone described above is not achieved by March 30, 2009, then the Hedrin JV 's board of directors will increase to five

members, two appointed by us and three appointed by Nordic.

Pursuant to the joint venture agreement, Nordic has the right to put all or a portion of its interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the amount of Nordic's investment in the Hedrin JV divided by \$0.14, as adjusted from time to time for stock splits and other specified events, multiplied by a conversion factor, which is (i) 1.00 for so long as Nordic's distributions from the Hedrin JV are less than the amount of its investment, (ii) 1.25 for so long as Nordic's distributions from the Hedrin JV are less than two times the amount of its investment but greater than or equal to the amount of its investment amount, (iii) 1.50 for so long as Nordic's distributions from the Hedrin JV are less than three times the amount of its investment but greater than or equal to two times the amount of its investment amount, (iv) 2.00 for so long as Nordic's distributions from the Hedrin JV are less than four times the amount of its investment but greater than or equal to three times the amount of its investment amount and (v) 3.00 for so long as Nordic's distributions from Hedrin JV are greater than or equal to four times the amount of its investment. The put right expires upon the earlier to occur of (i) February 25, 2018 and (ii) 30 days after the date when Nordic's distributions from the Hedrin JV exceed five times the amount Nordic has invested in the Hedrin JV (or 10 days after such date if we have provided Nordic notice thereof).

Pursuant to the joint venture agreement, we have the right to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for such number of shares of our common stock equal to the portion of Nordic's investment in the Hedrin JV that we call by the dollar amount of Nordic's investment as of such date in the Hedrin JV, divided by \$0.14, as adjusted from time to time for stock splits and other specified events. The call right is only exercisable by us if the price of our common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 25% of the call right. During the second 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 50% of the call right on a cumulative basis. During the third consecutive 30 trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 75% of the call right on a cumulative basis. During the fourth consecutive 30 days in which our common stock closes at or above \$1.40 per share, we may exercise up to 100% of the call right on a cumulative basis. Nordic may refuse the call, either by paying \$1.5 million multiplied by the percentage of Nordic's investment being called or forfeiting an equivalent portion of the put right, calculated on a pro rata basis for the percentage of the Nordic equity interest called by us. The call right expires on February 25, 2013.

For purposes of Nordic's right to put, and our right to call, all or a portion of Nordic's equity interest in the Hedrin JV, the amount of Nordic's investment is currently \$3,750,000; provided, that if, by June 30, 2009, the FDA either does not formally classify Hedrin as a Class II or Class III medical device or formally designates Hedrin as a drug and refers regulation thereof to the FDA Center for Drug Evaluation and Research, the amount of Nordic's investment will be reduced to \$3,500,000 and if by June 30, 2009, the FDA formally classifies Hedrin as a Class II or Class III medical device then upon Nordic's payment of the final milestone payment, Nordic's investment will be increased to \$5,000,000.

In connection with our joint venture agreement, on February 25, 2008, Nordic paid us a non-refundable fee of \$150,000 in exchange for the right to receive a warrant to purchase up to 7,142,857 shares of our common stock at \$0.14 per share, as adjusted from time to time for stock splits and other specified events, if Nordic did not exercise all or part of its put right on or before April 30, 3008. As of April 30, 2008, Nordic had not exercised all or any portion of its put right and we issued the warrant to Nordic.

In connection with the joint venture agreement, we and Nordic entered into a registration rights agreement, on February 25, 2008, as modified pursuant to a letter agreement, dated September 17, 2008, pursuant to which we agreed to file with the Securities and Exchange Commission, or the SEC, by no later than 10 calendar days following the date on which our Annual Report on Form 10-K for the year ended December 31, 2007 is required to be filed with the SEC, which was subsequently waived by Nordic until May 1, 2008, an initial registration statement registering the resale by Nordic of any shares of our common stock issuable to Nordic through the exercise of the warrant or the put right. We also have agreed to file with the SEC any additional registration statements which may be required no later

than 45 days after the date we first know such additional registration statement is required; provided, however, that (i) in the case of the classification by the FDA of Hedrin as a Class II or Class III medical device described above and the payment in full by Nordic of the related final milestone payment of \$1.25 million, the registration statement with respect to the additional shares of our common stock relating to such additional investment must be filed within 45 days after achievement of such classification; and (ii) in the event we provide Nordic with notice of exercise of our right to call all or a portion of Nordic's equity interest in the Hedrin JV, a registration statement with respect to the shares of our common stock payable to Nordic in connection with such call right (after giving effect to any reduction in the number of such shares resulting from Nordic's refusal of all or a portion of such call in accordance with the terms of our joint venture agreement) must be filed within 16 days after delivery of such notice to Nordic. If we fail to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of the required filing date or in the case of the registration statement of which this prospectus forms a part, by October 17, 2008 or if we receive comments from the SEC with respect to such registration statement, November 17, 2008, or otherwise fail to diligently pursue registration with the SEC in accordance with the terms of the registration rights agreement, we will be required to pay as partial liquidated damages and not as a penalty, to Nordic or its assigns, an amount equal to 0.5% of the amount invested in the Hedrin JV by Nordic pursuant to the joint venture agreement per month until the registration rights agreement is declared effective by the SEC; provided, however, that in no event shall the aggregate amount payable by us exceed 9% of the amount invested in the Hedrin JV by Nordic under the joint venture agreement.

Except as described above, no material relationship exists between the selling securityholder and us nor has any such material relationships existed within the past three years.

The following table lists the selling securityholder and presents certain information regarding its beneficial ownership of our common stock as well as the number of shares of our common stock it may sell from time to time pursuant to this prospectus. This table is prepared based on information supplied to us by the selling securityholder and the Schedule 13D filed by the selling securityholder with the SEC on March 5, 2008, and reflects holdings as of August 28, 2008. As of August 28, 2008, 70,624,232 shares of our common stock were issued and outstanding. As used in this prospectus, the term "selling securityholder" includes the entity listed below and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from the selling securityholder as a gift, pledge or other transfer.

	Number of Shares	Common Stock	•	
	of Common			8
	Stock			
	Beneficially	Shares	Number of	Percent
	Owned Prior	Being	Shares	of Shares
Selling Securityholder	to the Offering	Offered	Outstanding	Outstanding
Nordic Biotech Venture Fund II K/S	33,928,571(1)	33,928,571(1)	0	0

<sup>(1)</sup> Includes (i) 26,785,714 shares issuable upon exercise of the selling securityholder's right to put all or a portion of the selling securityholder's equity interest in Hedrin Pharmaceuticals K/S, a Danish limited partnership, of which we and the selling securityholder are partners and (ii) 7,142,857 shares issuable upon exercise of an outstanding warrant held by the selling securityholder. Does not include (i) 26,785,714 shares issuable upon exercise of our right to call all or a portion of the selling securityholder's equity interest in Hedrin Pharmaceuticals K/S to the extent such shares are not issued upon exercise of the selling securityholder's put right, which call right is subject to the satisfaction of certain conditions with respect to the closing price of our common stock and the selling securityholder's right to refuse such call upon payment of cash or forfeiture of equity interests in Hedrin Pharmaceuticals K/S, or (ii) 8,928,572 additional shares which may become issuable upon exercise of the selling securityholder's right to put, or subject to the satisfaction of certain conditions and to certain exceptions discussed above, our right to call, all or a portion of selling securityholder's equity interest in Hedrin Pharmaceuticals K/S upon classification of Hedrin by the FDA, as a Class II or Class III medical device and selling securityholder's investment of an additional \$1.25 million in Hedrin Pharmaceuticals K/S. Florian Schonharting and Christian Hansen have voting and investment control over such securities.

#### PLAN OF DISTRIBUTION

The selling securityholder of our common stock and any of its pledgees, assignees, and successors-in-interest may, from time to time, sell any or all of its shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling securityholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- · privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling securityholder to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- · a combination of any such methods of sale; or
- · any other method permitted pursuant to applicable law.

The selling securityholder may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

Broker-dealers engaged by the selling securityholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling securityholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

The selling securityholder and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling securityholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any

person to distribute our common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

#### **LEGAL MATTERS**

The legality of the securities offered in this prospectus has been passed upon for us by Lowenstein Sandler PC, Roseland, New Jersey.

#### **EXPERTS**

The financial statements as of December 31, 2007 and 2006 and for the years then ended, included in this prospectus have been audited by J.H. Cohn LLP, independent registered public accounting firm, as stated in its report appearing in this prospectus and elsewhere in the registration statement of which this prospectus forms a part, and have been so included in reliance upon the reports of such firm given upon its authority as experts in accounting and auditing.

# DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by one of our directors, officers or controlling persons in the successful defense of any action, suit or proceeding) is asserted by that director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether that indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement of Form S-1 relating to the securities being offered through this prospectus. As permitted by the rules and regulations of the SEC, the prospectus does not contain all the information described in the registration statement. For further information about us and our securities, you should read our registration statement, including the exhibits and schedules. In addition, we will be subject to the requirements of the Securities Exchange Act of 1934, as amended, following the offering and thus will file annual, quarterly and special reports, proxy statements and other information with the SEC. These SEC filings and the registration statement are available to you over the Internet at the SEC's web site at http://www.sec.gov/. You may also read and copy any document we file with the SEC at the SEC's public reference room in at 100 F. Street, N.E., Room 1580, Washington, D.C. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. Statements contained in this prospectus as to the contents of any agreement or other document are not necessarily complete and, in each instance, you should review the agreement or document which has been filed as an exhibit to the registration statement.

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(A Development Stage Company)
Condensed Consolidated Balance Sheets

		June 30, 2008 (Unaudited)		<b>December 31, 2007</b> (See Note 1)
Assets				
Current assets:				
Cash and cash equivalents	\$	576,354	\$	649,686
Prepaid expenses and other current assets		135,540		215,852
Total current assets		711,894		865,538
Investment in Hedrin JV		142,408		-
Property and equipment, net		34,912		44,533
Other assets		84,126		70,506
Total assets	\$	973,340	\$	980,577
Liabilities and Stockholders' Deficiency				
Current liabilities:				
Accounts payable	\$	617,346	\$	1,279,485
Accrued expenses	Ψ	849,746	Ψ	592,177
Total current liabilities		1,467,092		1,871,662
Total Carrent Intelligen		1,107,072		1,071,002
Exchange obligation		2,953,230		-
Total liabilities		4,420,322		1,871,662
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		2,0,2,002
Commitments and contingencies				
Stockholders' deficiency:				
Preferred stock, \$.001 par value. Authorized 1,500,000 shares; no shares				
issued and outstanding at June 30, 2008 and December 31, 2007				
Common stock, \$.001 par value. Authorized 300,000,000 shares;				
70,624,232 shares issued and outstanding at June 30, 2008 and December				
31, 2007		70,624		70,624
Additional paid-in capital		54,483,025		54,037,361
Deficit accumulated during the development stage		(58,000,631)		(54,999,070)
Total stockholders' deficiency		(3,446,982)		(891,085)
Total stockholders delicioney		(5,440,702)		(0)1,000
Total liabilities and stockholders' deficiency	\$	973,340	\$	980,577
See accompanying notes to condensed consolidated financial statements				

See accompanying notes to condensed consolidated financial statements.

F-2

(A Development Stage Company) Condensed Consolidated Statements of Operations (Unaudited)

								period from ugust 6, 2001
								inception) to
	T	hree months en	nde	d June 30, 2007	Six months en	ıded		June 30 2008
Costs and expenses:								
Research and development	\$		\$	3,871,634 \$	1,365,799	\$	5,551,082 \$	27,854,842
General and administrative		901,538		1,052,374	1,715,598		1,967,098	15,567,961
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		1,467,266		4,924,008	3,081,397		7,518,180	57,772,718
Operating loss		(1,467,266)		(4,924,008)	(3,081,397)		(7,518,180)	(57,772,718)
Other (income) expense:								
Equity in loss of Hedrin JV		87,718			107,593		_	107,593
Interest and other income		(132,772)		(29,608)	(187,429)		(59,998)	(1,009,327)
Interest expense		_		_	_	_	475	26,034
Realized gain on sale of								
marketable equity securities		_		_	_	_	_	(76,032)
Total other income		(45,054)		(29,608)	(79,836)		(59,523)	(951,731)
Net loss		(1,422,212)		(4,894,400)	(3,001,561)		(7,458,657)	(56,820,987)
Preferred stock dividends								
(including imputed amounts)		_		_	_	_	_	(1,179,644)
N. 11 11 1								
Net loss applicable to common	ф	(1.400.010)	ф	(4.004.400) Ф	(2.001.561)	Ф	(7. 450 (57) h	(50,000,621)
shares	\$	(1,422,212)	\$	(4,894,400)\$	(3,001,561)	\$	(7,458,657)\$	(58,000,631)
Net loss per common share:								
Basic and diluted	\$	(0.02)	Ф	(0.07)\$	(0.04)	Ф	(0.11)	
Dasic and unded	Ф	(0.02)	φ	(0.07)\$	(0.04)	ψ	(0.11)	
Weighted average shares of								
common stock outstanding:								
Basic and diluted		70,624,232		70,463,543	70,624,232		65,377,865	
Dasic and unuted		10,024,232		10,403,343	10,024,232		05,577,805	

See accompanying notes to unaudited condensed consolidated financial statements.

Cumulative

(A Development Stage Company)
Condensed Consolidated Statement of Stockholders' Equity (Deficiency)
(Unaudited)

	Series A convertible preferred stock Shares	konvertibl dpreferred stock	d Common stock		_	ll Subscription receivable	Deficit accumulated during development	in Series Aor preferred stock	other omprehens income (loss)	si <b>We</b> nearned
Stock issued										
at \$0.0004										
per share for subscription										
receivable		<del>-\$</del> -	<b></b> 10,167,741	\$ 10 168 \$	(6.16	58)\$ (4,000)\$	¢ .	<u>\$</u>	<u>-\$</u> -	<del>-\$</del>
Net loss		<del>—</del> –		Ψ 10,100 ç	_	— — —	– (56,796)		—	Ψ
Balance at							(= =, ,			
December										
31, 2001			_10,167,741	1 10,168	(6,16	58) (4,000)	(56,796)	)	_	
Proceeds										
from										
subscription receivable						<b></b> 4,000				
Stock issued						<del>- 4,000</del>				
at \$0.0004										ļ
per share for										ļ
license rights			_ 2,541,935	5 2,542	(1,54	-2)				
Stock										
options										
issued for										
consulting					50. FC					(50.50)
services			_		- 60,589	9 —	-			— (60,589
Amortization of unearned										ļ
of unearned consulting										ļ
services			_		_					_ 22,721
Common										
stock issued										
at \$0.63 per										
share, net of										
expenses			_ 3,043,332	2 3,043	1,701,27	5 —	-		_	
Net loss							- (1,037,320)	)		
Balance at										
December			15.752.000	15.752	1 754 16		11 004 116			(27.06)
31, 2002			<b>—</b> 15,753,008		1,754,154		- (1,094,116)	)		— (37,868
Common stock issued			— 1,321,806	5 1,322	742,369	9 —		_	_	_

at \$0.63 per share, net of expenses									
Effect of									
reverse									
acquisition	_	-	2 6,287	2,329,954	_	_	_	_	
Amortization		5,257,25	,	_,,,					
of unearned									
consulting									
costs	_				. <u>—</u>			_ 3	7,86
Unrealized									,,,,,
loss on									
short-term									
investments	_			. <u> </u>	. <u>—</u>	_	— (7,7	760)	
Payment for							(7,7	00)	
fractional									
shares for									
stock									
combination	_			(300)	_	_	_		
Preferred				(000)					
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	_			. <u> </u>		960,907)	_	_	
Balance at					· ·	,			
December									
31, 2003	1,000,000	1,000 23,362,39	6 23,362	14,289,535	— (7,	473,205)	(7,7)	760)	
Exercise of									
stock options	_	27,60	0 27	30,073		_	_	_	
Common									
stock issued									
at \$1.10, net									
of expenses	_	- 3,368,95	2 3,369	3,358,349	_	_	_	_	
Preferred									
stock									
dividend									
accrued	_				<u> </u>	585,799) 585,	799	_	
Preferred									
stock									
dividends									
paid by									
issuance of									
shares	24,901	25		281,073		—(282,	.388)		
Conversion	(170,528)	(171) 1,550,23	9 1,551	(1,380)	_	_	_	_	
of preferred									
stock to									

common									
common									
stock at									
\$1.10 per									
share									
Warrants									, , , , , , , , , , , , , , , , , , ,
issued for									7
consulting									Ţ
services					125,558				—(120,968
Amortization									
of unearned									
consulting									
costs		- <u> </u>							— 100,800
Unrealized									
gain on									Ţ
short-term									Ţ
investments									, , , , , , , , , , , , , , , , , , ,
and reversal									,
of unrealized									,
loss on									<b>!</b>
short-term									1
investments	_	- —				_	_	-20,99	77
Net loss						<b>—</b> (5,89	96.031)		
Balance at							,		
December									
31, 2004	854,373	854 28,30	09,187 28,3	309 18	,083,208	<b>—</b> (13,95	055,035) 303,	,411 13,23	37 (20,168
<b>-</b> , -	,		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		,		,	,	
F-4									

(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficiency)
(Unaudited)

	stock	l <b>e</b> nvertible preferred stock	Common stock	stock	capitalrecei	acc crip <b>di</b> on ivable	stage	in Series &o preferred stock	other omprehens income (loss)	s <b>l</b> v <b>n</b> earne consulting services	g eq (defi
Common	Shares	Amount	Shares	Amount	AmountAm	ount A	Amount	Amount	Amount	Amount	t An
stock issued at \$1.11 and \$1.15, net of											
expenses			-11,917,680	11,918	12,238,291	—	-	<u>—</u>	_	_	— 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		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		1 42			– 477,73 <b>6</b>			—(479,074			
Conversion of preferred stock to	·	42			- 477,730	_	-	—(479,074	)		
common stock at \$1.10 per share		4) (896)	8,146,858	8,147	(7,251)	_	-	_			
Share-based					66.071					20.160	
compensation Reversal of unrealized gain on short-term					- 66,971					—20,168	
investments		— –	-				-	_	-(12,250)		_

G. 1.1. 1									
Stock issued									
in connection with									
acquisition of									
Tarpan									
Therapeutics,									
Inc.		10,731,052	10 731	11 042 253					— 11,
Net loss				11,042,233	- (1	9,140,997)			— 11, —(19,
Balance at					(2.	J,140, <i>JJ1</i>			(1),
December 31,									
2005		-60,092,697	60,093	42,751,111	(3	33,271,695)		987	<b>—</b> 9,:
Cashless		00,072,071	00,073	72,731,111	= (3.	5,211,075)		701	
exercise of									
warrants		<b>—</b> 27,341	27	(27)		_		_	
Share-based		- 21,511	41	(21)					
compensation				- 1,675,499					— 1,
Unrealized				1,075,177					
loss on									
short-term									
investments	_					_	_	(987)	
Costs								(707)	
associated									
with private									
placement				- (15,257)					
Net loss				(13,231)	(	(9,695,123)	_		— — (9,
Balance at						7,075,125)			(>,
December 31,									
2006		-60,120,038	60.120 \$	\$ 44,411,326	— (4	-2.966.818)		_	— 1,
2000		00,120,000	00,120 +	11,111,525		2,700,010,			-,
Common									
stock issued at									
\$0.84 and									
\$0.90 per									
shares, net of									
expenses		10,185,502	10,186	7,841,999	_	_			— 7,
Common		10,101,.	10,12	1,012,5.					
stock issued to									
directors at									
\$0.72 per									
share in									
satisfaction of									
accounts									
payable	_	<b>—</b> 27,776	28	19,972		_	_		_
Common		,		- /-					
stock issued to									
in connection									
with									
in-licensing									
agreement at									
\$0.90 per									
share		— 125,000	125	112,375				_	_
		•							

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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,
Warrants									
issued for									
consulting				83,670					
Net loss				_	- — (12	2,032,252)	_	_	—(12,
Balance at									
December 31,		70.624.222	70.624. 7	4 005 061	/ <b>-</b>				,
2007	_	70,624,232	70,624 54	4,037,361	(54)	1,999,070)	_	_	— (
Sale of				150,000					
warrant				150,000					
Share-based				205.664					
compensation	<del>-</del>			295,664			_	<del>-</del>	—
Net loss	<u>—</u>			-	— (3	3,001,561)	_	<u> </u>	— (3,
Balance at	ф	70 (24 222	ф <b>7</b> 0. <b>6</b> 24. ф <b>5</b>	4 402 0 <b>2</b> 5 Φ	φ ( <b>5</b> 0	000 (21)) \$	ф	Ф	ф (2
June 30, 2008	-\$	-70,624,232	\$ 70,624 \$ 54	4,483,025 \$	<del>-\$</del> (58,	,000,631))\$	-\$	-\$	\$ (3,

See accompanying notes to condensed consolidated financial statements.

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(A Development Stage Company)
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six months end	ded Ju	nne 30, 2007	Cumulative period from August 6, 2001 (inception) to June 30, 2008
Cash flows from operating activities:				
Net loss	\$ (3,001,561)	\$	(7,458,657)	(56,820,987)
Adjustments to reconcile net loss to net cash used in				
operating activities:				
Equity in loss of Hedrin JV	107,593			107,593
Share-based compensation	295,664		706,549	3,660,647
Shares issued in connection with in-licensing				
agreement	_		112,500	232,500
Warrants issued to consultant	_		_	83,670
Amortization of intangible assets	_		_	145,162
Gain on sale of marketable equity securities				(76,032)
Depreciation	15,631		29,974	211,456
Non cash portion of in-process research and				
development charge	_		_	11,721,623
Loss on impairment and disposition of intangible				
assets	_		_	2,462,108
Other	2,962		<del>-</del>	8,552
Changes in operating assets and liabilities, net of				
acquisitions:				
(Increase)/decrease in prepaid expenses and other			(00.0-1)	<b></b>
current assets	80,311		(88,071)	(77,296)
Increase in other assets			-	(70,506)
Increase /(decrease) in accounts payable	(662,139)		(371,447)	1,037,559
Increase in accrued expenses	257,569		978,377	309,425
Net cash used in operating activities	(2,903,970)		(6,090,775)	(37,064,526)
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	<u> </u>		_	200,001
Investment in Hedrin JV's general partner	(13,620)		_	(13,620)
Net cash (used in) provided by investing activities	(22,592)		(9,135)	356,681
Cash flows from financing activities:				
Repayments of notes payable to stockholders				(884,902)
Proceeds related to sale of common stock, net	_		7,854,153	25,896,262
Proceeds from sale of preferred stock, net	_		_	9,046,176
Proceeds from exercise of warrants and stock options	<u> </u>		7,228	138,219
Proceeds from the Hedrin JV Agreement, net	2,703,230		_	2,703,230
Sale of warrant	150,000		_	150,000

Other, net	_		235,214
Net cash provided by financing activities	2,853,230	7,861,381	37,284,199
Net (decrease) increase in cash and cash equivalents	(73,332)	1,761,471	576,354
Cash and cash equivalents at beginning of period	649,686	3,029,118	_
Cash and cash equivalents at end of period	\$ 576,354 \$	4,790,589 \$	576,354
Supplemental disclosure of cash flow information:			
Interest paid	\$ — \$	475 \$	26,033
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	_	112,500	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

See accompanying notes to condensed consolidated financial statements.

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# 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 six month periods ended June 30, 2008 and 2007.

As of June 30, 2008, the Company has not generated any revenues from the development of its products and is therefore 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.

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### **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.

### 2. LIQUIDITY

The Company incurred a net loss of \$3,001,561 and negative cash flows from operating activities of \$2,903,970 for the six month period ended June 30, 2008. The net loss applicable to common shares from date of inception, August 6, 2001, to June 30, 2008 amounts to \$58,000,631.

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.

Management believes that the Company will continue to incur net losses through at least June 30, 2009 and for the foreseeable future thereafter. Based on the resources of the Company available at June 30, 2008 and the net proceeds received from the February 2008 joint venture agreement, management does not believe that the Company has sufficient capital to fund its operations into the fourth quarter of 2008. Management believes that the Company has an immediate 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 2008. 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 19,450,189 and 18,634,521 as of June 30, 2008 and 2007, respectively. These amounts do not include the shares issuable in connection with the Hedrin JV (see Note 8); the 17,857,143 shares of common stock issuable upon exercise of the put or call rights; the up to 17,857,143 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.

#### 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 six month periods ending June 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 \$102,810 and \$371,339 for the three month periods ended June 30, 2008 and 2007 respectively, and \$295,664 and \$706,549 for the six month periods ended June 30, 2008 and 2007, respectively, in accordance with Statement 123(R), 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 \$(287) and \$259, respectively, for the three-and six months ended June 30, 2008 and \$185 and \$3,556, respectively for the three-and six months ended June 30, 2007.

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

	,	Three months 6 2008	ende	d June 30, 2007	Six months e 2008	nded	led June 30, 2007	
General and administrative expense:								
Share-based employee compensation cost Share-based consultant and non-employee (credit) cost	\$	75,362  75,362	\$	249,623 \$  249,623 \$	, 	\$ - \$	471,544 10,550 482,094	
Research and development expense:								
Share-based employee compensation cost Share-based consultant and	\$	27,735	\$	121,531 \$	80,000	\$	231,449	
non-employee (credit) cost	\$	(287) 27,448	\$	185 121,716 \$	259 80,259	\$	(6,994) 224,455	
Total share-based cost	\$	102,810	\$	371,339 \$	295,664	\$	706,549	

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 end	led June 30,	Six months ended June 30,			
	2008	2007	2008	2007		
Expected Volatility	92.3%	79.7 - 93.2%	92.3%	79.7 - 93.2%		
Dividend yield	-	-	-	-		
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%		

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 June 30, 2008, under the 2003 Plan, 10,400,000 shares of common stock were authorized for issuance. At June 30, 2008, under the 2003 Plan, options to purchase 9,629,096 shares of common stock were outstanding. At June 30, 2008, there were 770,904 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 six months ended June 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 June 2005, the 1995 Plan expired and no further options can be granted. As of June 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 June 30, 2008 and changes during the six months then ended is presented below:

	Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	ggregate 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	(224,972)		0.17		
Outstanding at June 30, 2008	10,766,336	\$	0.93	7.46	\$ -
Exercisable at June 30, 2008	8,004,692	\$	1.12	6.80	
Weighted average fair value of options granted during the six months ended June 30, 2008	\$ 0.13				

As of June 30, 2008, the total compensation cost related to non-vested option awards not yet recognized is \$628,515. The weighted average period over which it is expected to be recognized is approximately 1.7 years.

### 5. COMMITMENTS AND CONTINGENCIES

### **Swiss Pharma**

Swiss Pharma Contract LTD, or Swiss Pharma, a clinical site that the Company used in one of its obesity trials, gave notice to the Company that Swiss Pharma believes it is entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. While the contract between the Company and Swiss Pharma provides for additional payments if certain conditions are met, Swiss Parma has not specified which conditions they believe have been achieved and the Company does not believe that Swiss Pharma is entitled to additional payments and has not accrued any of these costs as of June 30, 2008 and December 31, 2007. The contract between the Company and Swiss Pharma provides for arbitration in the event of a dispute, such as this claim for an additional payment. On March 10, 2008, Swiss Pharma filed for arbitration with the Swiss Chamber of Commerce. As the Company does not believe that Swiss Pharma is entitled to additional payments, the Company intends to defend its position in arbitration. On April 2, 2008, the Company filed its statement of defense and counterclaim for recovery of costs incurred by the Company as a result of Swiss Pharma's failure to meet agreed upon deadlines under the contract. On June 3, 2008 a hearing was held before the arbitrator. The arbitrator's decision is expected in late August or early September.

### Therapeutics, Inc.

During 2007, we entered into an agreement with Therapeutics, Inc. for the conduct of a Phase 2a clinical trial of PTH (1-34). The amount of the agreement is approximately \$845,000. The remaining financial commitment at June 30, 2008 related to the conduct of the clinical trial is approximately \$100,000. This clinical trial concluded in the beginning of the third quarter of 2008.

### **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.

### **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 one year for the second employee, and have a total remaining obligation under these agreements of \$589,469 as of June 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.

### **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(TM), 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.

### 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 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 six months ended June 30, 2008 the Company recognized \$107,593 of equity in the loss of the Hedrin JV. At June 30, 2008, the Company's investment in the Hedrin JV is \$142,408 and the Company's exchange obligation is \$2,953,230.

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 June 30, 2008, the Company has recognized \$183,266 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 six months ended june 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.

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 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 registration statement 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. As of the date of the filing of this Quarterly Report on Form 10-Q, the Company is negotiating an extension to the Effective Date, which has already passed, to reflect the time it has taken Nordic and the Company to resolve certain SEC comments concerning the current registrability of the shares underlying the put and call rights held by Nordic (which rights have not yet been exercised).

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, \$2.5 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.

Due to the complexity of the accounting for the Hedrin JV transaction, the Company has requested and received guidance from the SEC on the appropriate accounting for this transaction. The accounting as disclosed in this Form 10Q for the quarterly period ended June 30, 2008 takes into consideration this guidance. As a result of this guidance the Company's Form 10Q for the quarter period ended March 31, 2008 will need to be amended. The net effect of applying this guidance and amending the March 31, 2008 financial statements is an increase in assets of \$230,000 (Investment in Hedrin JV), an increase liabilities of \$2,059,000 (Exchange obligation), a decrease in Additional paid-in capital of \$1,809,000 and an increase in net loss of \$20,000 (Equity in loss of Hedrin JV).

### 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.

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 estimate 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. SUBSEQUENT EVENT

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.

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### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders Manhattan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Manhattan Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended, and for the period from August 6, 2001 (date of inception) to December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Manhattan Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2007 and 2006, and their consolidated results of operations and cash flows for the years then ended and for the period from August 6, 2001 (date of inception) to December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred net losses and negative cash flows from operating activities from its inception through December 31, 2007 and has an accumulated deficit and negative working capital as of December 31, 2007. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plan regarding these matters are also described in Note 2. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 3 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in fiscal 2006.

/s/ J.H. Cohn LLP

Roseland, New Jersey March 28, 2008

## MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES

(A Development Stage Company)

## Consolidated Balance Sheets

		December 31, 2007	December 31, 2006		
Assets					
Current assets:					
Cash and cash equivalents	\$	649,686	\$	3,029,118	
Prepaid expenses		215,852		264,586	
Total current assets		865,538		3,293,704	
Property and equipment, net		44,533		83,743	
Other assets		70,506		70,506	
Total assets	\$	980,577	\$	3,447,953	
Liabilities and Stockholders' Equity (Deficiency)					
C					
Current liabilities:	ф	1.070.405	ф	1 202 206	
Accounts payable	\$	1,279,485	\$	1,393,296	
Accrued expenses		592,177		550,029	
Total liabilities		1,871,662		1,943,325	
Total liabilities		1,071,002		1,943,323	
Commitments and contingencies					
Communicates and contingencies					
Stockholders' equity (deficiency):					
Preferred stock, \$.001 par value. Authorized 1,500,000 shares; no shares					
issued and outstanding at December 31, 2007 and 2006					
Common stock, \$.001 par value. Authorized 150,000,000 shares;					
70,624,232 and 60,120,038 shares issued and outstanding at December 31,					
2007 and December 31, 2006, respectively		70,624		60,120	
Additional paid-in capital		54,037,361		44,411,326	
Deficit accumulated during the development stage		(54,999,070)		(42,966,818)	
Total stockholders' equity (deficiency)		(891,085)		1,504,628	
Total liabilities and stockholders' equity (deficiency)	\$	980,577	\$	3,447,953	
See accompanying notes to consolidated financial statements.					
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## MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES

(A Development Stage Company)

## Consolidated Statements of Operations

		Years ended I	Decem	•	period from August 6, 2001 (inception) to December 31,
D	ф	2007	φ	2006	2007
Revenue	\$	<u> </u>	\$		<del>-</del>
Costs and expenses:					
Research and development		8,535,687		6,172,845	26,489,043
General and administrative		3,608,270		3,827,482	13,852,363
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
, o					
Total operating expenses		12,143,957		10,000,327	54,691,321
Operating loss		(12,143,957)		(10,000,327)	(54,691,321)
Other (income) expense:					
Interest and other income		(112,181)		(307,871)	(821,897)
Interest expense		476		1,665	26,034
Realized (gain)/loss on sale of marketable equity					
securities		_		1,002	(76,032)
Total other income		(111,705)		(305,204)	(871,895)
** *		(10.000.050)		(0.607.400)	(50.010.106)
Net loss		(12,032,252)		(9,695,123)	(53,819,426)
Preferred stock dividends (including imputed					(1.170.644)
amounts)		_		_	(1,179,644)
Not loss and inchis to some on shows	ф	(12.022.252)	\$	(0.605.122) (	(54,000,070)
Net loss applicable to common shares	\$	(12,032,252)	Ф	(9,695,123)	(54,999,070)
Net loss per common share:					
Basic and diluted	\$	(0.18)	\$	(0.16)	
Dasic and unuted	Ψ	(0.16)	Ψ	(0.10)	
Weighted average shares of common stock					
outstanding:					
Basic and diluted		68,015,075		60,112,333	
230.0 3.10 3.1000		50,015,075		30,112,333	

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See accompanying notes to consolidated financial statements.

Cumulative

## MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES

(A Development Stage Company)

Consolidated Statement of Stockholders' Equity (Deficiency)

Series A Series A

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Defi	OI	•••		71	~	nn	~	0
17611	C.I		4 1	<i>y</i> 11	u	СП	u	

accumulapedya Akcimulated

**Total** 

	convertible			~			during Seri			
	-	-				_	evelopm <b>ente</b> fo	-	_	
	stock Shares	stock Amount	stock t Shares	-	nid-in capit Amount		stage sto AmountAm			(deficiency Amount
Stock issued	Shares	7 IIII Odiii	Sildies	7 Hinount	Timount	7 I III O CIII C	7 Killount / Kill	ountiloun	rimount	1 IIII OUII C
at \$0.0004										
per share for										
subscription										
receivable		\$ -	-10,167,741	\$ 10,168	\$ (6,168)	\$ (4,000)\$	S <u>-</u> \$	\$	-\$ -	\$
Net loss							- (56,796)	_		<b>—</b> (56,79
Balance at										
December										
31, 2001			<b>—</b> 10,167,741	10,168	(6,168)	(4,000)	(56,796)	_		<b>—</b> (56,79
,			,	,		, , , ,	, ,			,
Proceeds										
from										
subscription										
receivable						<b></b> 4,000	<u> </u>	- —		_ 4,00
Stock issued										·
at \$0.0004										
per share for										
license rights			2,541,935	2,542	(1,542)	) —		- —		
Stock										
options										
issued for										
consulting										
services			<u> </u>		- 60,589	_		- —	-(60,589)	)
Amortization	l									
of unearned										
consulting										
services					_		_		— 22,721	22,72
Common										
stock issued										
at \$0.63 per										
share, net of										
expenses			<b>-</b> 3,043,332	3,043	1,701,275	_		- —		<b>—</b> 1,704,31
Net loss			_		_	_	-(1,037,320)			-(1,037,32)
Balance at										
December										
31, 2002			-15,753,008	15,753	1,754,154	_	-(1,094,116)	_	-(37,868)	637,92
Common			<b>—</b> 1,321,806	1,322	742,369	_	_	- —		<b>—</b> 743,69
stock issued										

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at \$0.63 per												
share, net of												
expenses												
Effect of												
reverse												<b>I</b>
acquisition			— 6,287,582	2 6,7	287 2,	,329,954						- 2,336,24
Amortization												
of unearned												
consulting												
costs	_	a de la companya de					_				37,868	37,86
Unrealized												
loss on												1
short-term												
investments			_					_	— —(7,70	60)		- (7,76
Payment for												
fractional												
shares for												
stock												
combination	_				_	(300)	_					- (30
Preferred												
stock issued												Ţ
at \$10 per												Ţ
share, net of	000											
expenses	1,000,000	1,000			—9,	,045,176						- 9,046,17
Imputed												
preferred												
stock												
dividend						418,182	_	- (418,18				
Net loss	_					_	_	-(5,960,90)	)7			