

MANHATTAN PHARMACEUTICALS INC  
Form POS AM  
May 05, 2009

As filed with the Securities and Exchange Commission on May \_\_, 2009

Registration No. 333-150580

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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POST-EFFECTIVE AMENDMENT NO. 1  
TO  
FORM S-1  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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MANHATTAN PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number)	36-3898269 (I.R.S. Employer Identification Number)
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Manhattan Pharmaceuticals, Inc.  
48 Wall Street  
New York, NY 10005  
Telephone: (212) 582-3950

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mr. Michael G. McGuinness  
Chief Financial Officer  
Manhattan Pharmaceuticals, Inc.  
48 Wall Street  
New York, NY 10005  
Telephone: (212) 582-3950

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:  
Anthony O. Pergola, Esq.  
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65 Livingston Avenue  
Roseland, New Jersey 07068  
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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus

Subject to completion, dated May [\_\_\_], 2009

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 of common stock (the "Original Put 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 of common stock (the "Original Warrant 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 April 30, 2009, the last reported sales price for our common stock on the Over the Counter Bulletin Board was \$0.04 per share.

These securities involve a high degree of risk. See "Risk Factors" beginning on page 5 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 \_\_\_\_\_, 2009.

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

## 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 5 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 specialty healthcare product company focused on developing and commercializing innovative treatments 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. In the short term, we are focusing our efforts on the commercialization of the two product candidates we currently have in development: Hedrin™, a novel, non-insecticide treatment for pediculosis (head lice), which we are developing through a joint venture, and a topical product for the treatment of psoriasis. Longer term, we intend to acquire and commercialize low risk, quick to market products, specifically products that could be marketed over-the-counter, or OTC, treat everyday maladies, are simple to manufacture, and/or could be classified as medical devices by the FDA.

During 2007, we discontinued development of Oleoyl-estrone and Propofol Lingual Spray. In March 2009, we discontinued development of Altoderm and Altolyn. We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

### Recent Developments

#### 2008/2009 Private Placement

On February 3, 2009, we completed a private placement of 345 units, with each unit consisting of a 12% senior secured note promissory note in the principal amount of \$5,000 and a warrant to purchase up to 166,667 shares of our common stock at an exercise price of \$.09 per share which expires on December 31, 2013, for aggregate gross proceeds of \$1,725,000. The private placement was completed in three closings which occurred on November 19, 2008 with respect to 207 units, December 23, 2008 with respect to 56 units and February 3, 2009 with respect to 82 units.

To secure our obligations under the notes, we entered into a security agreement and a default agreement with the investors. The security agreement provides that the notes will be secured by a pledge of our assets other than (i) our interest in the Hedrin joint venture, including, without limitation, our interest in H Pharmaceuticals K/S (formerly H Pharmaceuticals K/S) and H Pharmaceuticals General Partner ApS (formerly Hedrin Pharmaceuticals General Partner ApS), (ii) our rent deposit for our former office space, (iii) our refund of a prepayment and (iv) our tax refund for the 2007 fiscal year from the State of New York and City of New York. In addition, to provide additional security for our obligations under the notes, we entered into a default agreement, which provides that upon an event of default under the notes, we shall, at the request of the holders of the notes, use our reasonable commercial efforts to either (i) sell a part or all of our interests in the Hedrin joint venture or (ii) transfer all or part of our interest in the Hedrin JV to the holders of the notes, as necessary, in order to fulfill our obligations under the notes, to the extent required and to the extent permitted by the applicable Hedrin joint venture agreements.

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On November 19, 2008, we completed the sale of 207 units in our first closing of our private placement. In connection with the first closing, we issued a warrant to purchase 5,175,010 shares of common stock at an exercise price of \$.09 per share to the placement agent as partial compensation for its services. Further, we granted the placement agent the right to nominate a member of our Board of Directors and such director shall receive all compensation and benefits provided to our other directors. Additionally, upon such director's appointment to the Board of Directors, he or she shall be issued a warrant to purchase 1,000,000 shares of our common stock at a per share exercise price equal to the greater of (i) the fair market value on the date of issuance or (ii) \$.09.

On December 23, 2008, we completed a second closing of our private placement. At the second closing, we sold an additional 56 units. In connection with the second closing, we issued to the placement agent a warrant to purchase 1,400,003 shares of our common stock at an exercise price of \$.09 per share as additional compensation for its services.

On February 3, 2009, we completed a third closing of our private placement. At the third closing, we sold an additional 82 units. In connection with the third closing, we issued to the placement agent a warrant to purchase 2,050,004 shares of our common stock at an exercise price of \$.09 per share as additional compensation for its services.

In connection with the private placement, we, the placement agent and the purchasers entered into a registration rights agreement. Pursuant to the registration rights agreement, we agreed to file a registration statement to register the resale of the shares of our common stock issuable upon exercise of the warrants issued to the investors in the private placement, within 20 days of the final closing date and to cause the registration statement to be declared effective within 90 days (or 120 days upon full review by the SEC). On April 2, 2009, the registration rights agreement was amended to, among other things, require us to register the shares of common stock issuable upon exercise of the warrants issued to the placement agent as partial compensation for its services. The registration statement relating to the registration of the shares underlying the warrants issued to the investors and the placement agent was initially filed with the SEC on February 23, 2009 and declared effective by the SEC on April 17, 2009.

#### Amendments to Employment Agreements

At the first closing of our private placement, we entered into (i) an amendment to our employment agreement with Douglas Abel, our Chief Executive Officer and (ii) an amendment to our employment agreement with Michael McGuinness, our Chief Financial Officer. These amendments provide for a reduction of up to 1/3 of the salary payable to Messrs. Abel and McGuinness, respectively, until we shall have received at least \$2,500,000 of gross proceeds from the sale of the units or other sales of securities or from other revenue received by us in the operation of our business or any combination of the foregoing.

#### 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. This transaction was accounted for as a purchase of Tarpan by us.

#### Principal Executive Offices

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





The Offering

Common Stock Offered by Selling Securityholder (1):	33,928,571 shares
Common Stock Issued and Outstanding as of April 1, 2009(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 H Pharmaceuticals K/S (formerly 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

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- (1) Includes (i) 26,785,714 shares of common stock (the "Original Put 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 H Pharmaceuticals K/S and (ii) 7,142,857 shares of common stock (the "Original Warrant Shares") are issuable upon exercise of an outstanding warrant held by the selling securityholder..
- (2) Excludes (i) up to 55,555,555 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 H Pharmaceuticals K/S; (ii) up to 11,111,111 shares of our common stock issuable upon the exercise of the warrant held by the selling securityholder and (iii) 84,673,731 shares of our common stock issuable upon exercise of outstanding warrants (excluding the warrant held by the selling securityholder) and options to purchase shares of our common stock.
- (3) Based on the number of shares of our common stock outstanding as of April 30, 2009. Excludes (i) the additional 3,968,254 shares of common stock underlying the warrant, as adjusted pursuant to the anti-dilution provisions of the warrant (the "Additional Warrant Shares") held by the selling securityholder; (ii) approximately 84,673,731 shares of our common stock issuable upon exercise of outstanding warrants and options to purchase shares of our common stock held by other securityholders; (iii) the additional 14,880,953 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 H Pharmaceuticals K/S, as adjusted pursuant to the anti-dilution provisions of the selling securityholder's put right (the "Additional Put Shares") and (iv) 13,888,889 additional shares which became 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 H Pharmaceuticals K/S upon the February 2009 classification of Hedrin by the FDA Class III medical device and selling securityholder's investment of an additional \$1.25 million in H

Pharmaceuticals K/S. Florian Schonharting and Christian Hansen have voting and investment control over such securities (the "Milestone Put Shares") held by the selling securityholder.

## Summary Financial Information

The summary financial information for the fiscal years ended December 31, 2008 and 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 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, 2008 and 2007.

	Year Ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2008
	2008	2007	
<b>Statements of Operations Data:</b>			
Revenue	\$ 0	\$ 0	\$ 0
Research and development expense	\$ 1,802,792	\$ 8,535,687	\$ 28,291,835
General and administrative expense	\$ 2,609,910	\$ 3,608,270	\$ 16,462,273
Net loss attributable to common shares	\$ (4,268,858)	\$ (12,032,252)	\$ (59,267,928)
Net loss per common share	\$ (0.06)	\$ (0.18)	N/A
<b>Statements of Cash Flows Data:</b>			
Net cash used in operating activities	\$ (4,444,009)	\$ (10,229,711)	\$ (38,619,565)
Net cash provided by (used in) financing activities	\$ 3,909,319	\$ 7,859,413	\$ 38,355,288
Cash dividends declared	\$ 0	\$ 0	\$ 0
<b>Balance Sheets Data:</b>			
	At December 31,		
	2008	2007	
Total assets	\$ 1,248,963	\$ 980,577	
Total liabilities	\$ 5,624,888	\$ 1,871,662	
Total stockholders' deficiency	\$ (4,375,925)	\$ (891,085)	

## 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 both of our remaining drug development programs and may not continue as a going concern.

We have generated no product revenues to date and will not until, and if, we receive approval from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities for our two 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, 2008, we had \$106,023 of cash and cash equivalents. We received additional funding of approximately \$0.5 million from a joint venture agreement in February 2009 and \$0.4 million from the sale of Secured 12% Notes in February 2009. 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.

Swiss Pharma Contract LTD, or Swiss Pharma, a clinical site that we used in one of our obesity trials, has received an arbitration award against us, in the Swiss Chamber of Commerce, and has initiated proceedings in New York State courts to confirm the arbitration award and enter a judgment on Swiss Pharma's behalf against us. We do not have sufficient cash or other current available assets to satisfy the arbitrators award. If Swiss Pharma is successful in entering a judgment against us, it could take actions against us that would significantly impair our ability to continue as a going concern. See "Item 3 - Legal Proceedings."

It is difficult for companies like ours to raise funds in the current economic conditions and 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 drug 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. Our auditors have concluded that our net losses, negative cash flow, accumulated deficit and negative working capital as of December 31, 2008, raise substantial doubt about our ability to continue as a going concern.



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 year ended December 31, 2008 and for the period from August 6, 2001 (inception) through December 31, 2008, we incurred net losses applicable to common shares of \$4,268,858, and \$59,267,928 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 auditors have concluded that our net losses, negative cash flow, accumulated deficit and negative working capital as of December 31, 2008, raise substantial doubt about our ability to continue as a going concern.

Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

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 depend greatly on the intellectual capabilities and experience of our key executives, and the loss of any of them could affect our ability to develop our remaining products.

We had only three full-time and one part-time employee as of March 30, 2009. The loss of Douglas Abel, our President and Chief Executive Officer, or Michael G. McGuinness, our Chief Operating and Financial Officer, could harm us. The current terms of our employment agreements with Messrs. Abel and McGuinness expire in April 2009 and July 2009, respectively. We cannot predict our success in hiring or retaining the personnel we require for continued operations.

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 product candidates, we must first submit to the FDA an IND, which will set forth our plans for clinical testing of our product candidates. In September 2007, the FDA accepted our IND for Topical PTH(1-34). Our remaining two products, Hedrin and the Topical GEL for psoriasis are currently considered pre-clinical. We are unable to estimate the size and timing of the clinical and non clinical trials required to bring our two 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 product candidates is complete, we will submit to the FDA a 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 any or all of our future NDAs. 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 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 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 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 product 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 product candidates. Accordingly, the successful development of our 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 product 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 product candidates.

We have no experience in drug and device 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 product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store and distribute supplies for our clinical trials. If any of our 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.
- Drug and device manufacturers 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. 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, forced to pay damages, and defend against litigation.

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 89,208,182 shares, or approximately 62%, of our outstanding voting stock as of April 1, 2009, including 6,051,936 shares underlying outstanding options, 12,534,830 shares underlying outstanding warrants and 55,555,555 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 66,666,666 shares, or approximately 49%, of our outstanding voting stock as of April 1, 2009, including 11,111,111 shares underlying its warrant and 55,555,555 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. 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 \$0.007 in the fourth quarter of 2008 to a high of \$0.96 in the first quarter of 2007. 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:

- the continuing global economic crisis, which has affected stock prices of many companies, and particularly many small pharmaceutical companies like ours;
- 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 H 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
<b>2007</b>		
First Quarter	\$ 0.960	\$ 0.700
Second Quarter	\$ 1.100	\$ 0.690
Third Quarter	\$ 0.780	\$ 0.220
Fourth Quarter	\$ 0.230	\$ 0.090
<b>2008</b>		
First Quarter	\$ 0.230	\$ 0.110
Second Quarter	\$ 0.180	\$ 0.100
Third Quarter	\$ 0.200	\$ 0.100
Fourth Quarter	\$ 0.090	\$ 0.007
<b>2009</b>		
First Quarter	\$ 0.060	\$ 0.007

The number of holders of record of our common stock as of March 20, 2009 was 437.

## 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, 2008 and 2007 and for the cumulative period from August 6, 2001 to December 31, 2008 was derived from our financial statements that have been audited by J.H. Cohn LLP for the fiscal years then ended. 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, 2008 and 2007.

	Year Ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2008
	2008	2007	
<b>Statements of Operations Data:</b>			
Revenue	\$ 0	\$ 0	\$ 0
Research and development expense	\$ 1,802,792	\$ 8,535,687	\$ 28,291,835
General and administrative expense	\$ 2,609,910	\$ 3,608,270	\$ 16,462,273
Net loss attributable to common shares	\$ (4,268,858)	\$ (12,032,252)	\$ (59,267,928)
Net loss per common share	\$ (0.06)	\$ (0.18)	N/A
<b>Statements of Cash Flows Data:</b>			
Net cash used in operating activities	\$ (4,444,009)	\$ (10,229,711)	\$ (38,619,565)
Net cash provided by (used in) financing activities	\$ 3,909,319	\$ 7,859,413	\$ 38,355,288
Cash dividends declared	\$ 0	\$ 0	\$ 0
	At December 31,		
	2008	2007	
<b>Balance Sheets Data:</b>			
Total assets	\$ 1,248,963	\$ 980,577	
Total liabilities	\$ 5,624,888	\$ 1,871,662	
Total stockholders' deficiency	\$ (4,375,925)	\$ (891,085)	

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." 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.

We are a specialty healthcare product company focused on developing and commercializing pharmaceutical treatments 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. In the short term we are focusing our efforts on the commercialization of the two product candidates we currently have in development: Hedrin™, through the Hedrin JV, a novel, non-insecticide treatment of pediculitis (head lice) and a topical product for the treatment of psoriasis. Longer term we intend to acquire and commercialize low risk, quick to market products, specifically products that could be marketed OTC, treat everyday maladies, are simple to manufacture, and/or could be classified as medical devices by the FDA.

You should read the following discussion of our results of operations and financial condition in conjunction with the 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. All share and per share information in this discussion has been adjusted for the 1-for-5 combination of our common stock effected on September 25, 2003.

## Results of Operations

Fiscal Year Ended December 31, 2008 versus Fiscal Year Ended December 31, 2007

During each of the years ended December 31, 2008 and 2007, 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, 2009.

	Years ended December 31,		Increase (decrease)	% Increase (decrease)
	2008	2007		
<b>Costs and expenses:</b>				
<b>Research and development:</b>				
Share-based compensation	\$ 122,000	\$ 539,000	\$ (417,000)	-77.37%
In-license, milestone and related fees	-	2,245,000	(2,245,000)	-100.00%
Other research and development expenses	1,681,000	5,752,000	(4,071,000)	-70.78%
Total research and development expenses	1,803,000	8,536,000	(6,733,000)	-78.88%
<b>General and administrative:</b>				
Share-based compensation	342,000	902,000	(560,000)	-62.08%
Other general and administrative expenses	2,268,000	2,706,000	(438,000)	-16.19%
Total general and administrative expenses	2,610,000	3,608,000	(998,000)	-27.66%
Other income	144,000	112,000	32,000	28.57%
Net loss	\$ 4,269,000	\$ 12,032,000	\$ (7,763,000)	-64.52%

For the year ended December 31, 2008 research and development expense was \$1,803,000 as compared to \$8,536,000 for the year ended December 31, 2007. This decrease of \$6,733,000, or 78.9%, is primarily comprised of a decrease in in-license, milestone and related fees of \$2,245,000, a decrease in other research and development expenses of \$4,071,000 and a decrease in stock based compensation of \$417,000.

For the year ended December 31, 2008 general and administrative expense was \$2,610,000 as compared to \$3,608,000 for the year ended December 31, 2007. This decrease of \$998,000, or 27.7%, is primarily comprised of a decrease in share-based compensation of \$560,000 and a decrease in other general and administrative expenses of \$438,000.

For the year ended December 31, 2008 other income was \$144,000 as compared to \$112,000 for the year ended December 31, 2007. This increase of \$32,000, or 28.6%, is primarily due to increases in management fee revenue from the Hedrin JV of \$447,000 and in other income of \$7,000 offset by equity in losses of the Hedrin JV of \$250,000, a decrease in interest income of \$108,000 and an increase in interest expense of \$64,000.

Net loss for the year ended December 31, 2008 was \$4,269,000 as compared to \$12,032,000 for the year ended December 31, 2007. This decrease of \$7,763,000, or 64.5%, is primarily due to a decrease in research and development expenses of \$6,733,000, a decrease in general and administrative expense of \$998,000 and an increase in other income of \$32,000.

## Liquidity and Capital Resources

From inception to December 31, 2008, we incurred a deficit during the development stage of \$59,268,000 primarily as a result of our net losses, and we expect to continue to incur additional losses through at least December 31, 2009 and for the foreseeable future. These losses have been incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity and debt financings and a joint venture transaction. During the year ended December 31, 2008, we had a net decrease in cash and cash equivalents of \$544,000. This decrease resulted largely from net cash used in operating activities of \$4,444,000 partially offset by net cash provided by financing activities of \$3,909,000. Total liquid resources as of December 31, 2008 were \$106,000 compared to \$650,000 at December 31, 2007.

Our current liabilities as of December 31, 2008 were \$1,486,000 compared to \$1,872,000 at December 31, 2007, a decrease of \$386,000. As of December 31, 2008, we had working capital deficit of \$612,000 compared to working capital deficit of \$1,006,000 at December 31, 2007.

We received approximately \$1.8 million in February 2008 and approximately \$0.9 million in June 2008 from a joint venture agreement. We also received \$70,000 in Secured 10% Notes in September 2008 and net proceeds of \$1.0 million from the sale of Secured 12% Notes in November and December 2008.

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 nonclinical 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, in-licensing activities, competing technological and market developments, changes in our existing collaborative and licensing relationships, the resources that we devote to developing manufacturing and 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 December 31, 2008, a significant portion of our financing has been through private placements of common stock and warrants. Unless our operations generate significant revenues and cash flows from operating activities, we will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. We believe 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 December 31, 2008, the net proceeds of \$500,000 received in February 2009 from a joint venture agreement and net proceeds of \$360,000 received from the sale of additional Secured 12% Notes in February 2009, management believes that we have sufficient capital to fund our operations through 2009. Management believes that we will need additional equity or debt financing or will need to generate positive cash flow from the Hedrin joint venture, or generate revenues through licensing of our products or entering into strategic alliances to be able to sustain our operations into 2010. 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 our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have reported net losses of \$4,269,000 and \$12,032,000 for the years ended December 31, 2008 and 2007, respectively. The net loss attributable to common shares from date of inception, including preferred stock dividends, August 6, 2001 to December 31, 2008, amounts to \$59,268,000. Management believes that we will continue to incur net losses through at least December 31, 2009.

#### 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 to the joint venture agreement, in February 2008, (i) Nordic contributed cash in the amount of \$2.5 million to H Pharmaceuticals K/S (formerly H 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 was required to contribute to the Hedrin JV an additional \$1.25 million in cash, \$0.5 million of which was to be distributed to us and equity in the Hedrin JV was to be distributed to each of us and Nordic sufficient to maintain our respective ownership interests at 50%. The FDA notified the Hedrin JV that Hedrin has been classified as a Class III medical device and in February 2009, Nordic made the \$1.25 million investment in the Hedrin JV, the Hedrin JV made the \$0.5 million milestone payment to us and equity in the Hedrin JV was distributed to us and Nordic sufficient to maintain our respective ownership interests at 50%. In accordance with the terms of the joint venture agreement, as of December 31, 2008, the Hedrin JV had received a total of \$1.75 million cash to be applied toward the development and commercialization of Hedrin in North America.

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 Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV has engaged us to provide management services to the Hedrin JV in exchange for an annualized management fee, which for 2008, on an annualized basis, is approximately \$527,000. As of December 31, 2008, we had recognized approximately \$447,000 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) 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.

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 \$0.09, as adjusted for the sale of the Secured 12% Notes in the fourth quarter of 2008, and as further 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 \$0.09, as adjusted for the sale of the Secured 12% Notes in the fourth quarter of 2008, and as further 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 \$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 11,111,111 shares of our common stock at \$0.09 per share, as adjusted for the sale of the Secured 12% Notes in the fourth quarter of 2008, and as further 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, 2008. 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 filed an initial registration statement on May 1, 2008, which was declared effective on October 15, 2008 and this prospectus forms a part of the post-effective amendment to such registration statement.

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 if we fail to maintain the effectiveness of a registration statement 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.

#### Secured 10% Notes Payable

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. The secured 10% notes were repaid in February 2009 along with interest thereon.

### Secured 12% Notes Payable

On February 3, 2009, we completed a private placement of 345 units, with each unit consisting of secured 12% notes in the principal amount of \$5,000 and a warrant to purchase up to 166,667 shares of our common stock at an exercise price of \$.09 per share which expires on December 31, 2013, for aggregate gross proceeds of \$1,725,000. The private placement was completed in three closings which occurred on November 19, 2008 with respect to 207 units, December 23, 2008 with respect to 56 units and February 3, 2009 with respect to 82 units.

To secure our obligations under the notes, we entered into a security agreement and a default agreement with the investors. The security agreement provides that the notes will be secured by a pledge of our assets other than (i) our interest in the Hedrin joint venture, including, without limitation, our interest in H Pharmaceuticals K/S and H Pharmaceuticals General Partner ApS, (ii) our rent deposit for our former office space, (iii) our refund of a prepayment and (iv) our tax refund for the 2007 fiscal year from the State of New York and City of New York. In addition, to provide additional security for our obligations under the notes, we entered into a default agreement, which provides that upon an event of default under the notes, we shall, at the request of the holders of the notes, use our reasonable commercial efforts to either (i) sell a part or all of our interests in the Hedrin joint venture or (ii) transfer all or part of our interest in the Hedrin JV to the holders of the notes, as necessary, in order to fulfill our obligations under the notes, to the extent required and to the extent permitted by the applicable Hedrin joint venture agreements.

On November 19, 2008, we completed the sale of 207 units in our first closing of our private placement. In connection with the first closing, we issued a warrant to purchase 5,175,010 shares of common stock at an exercise price of \$.09 per share to the placement agent as partial compensation for its services. Further, we granted the placement agent the right to nominate a member of our Board of Directors and such director shall receive all compensation and benefits provided to our other directors. Additionally, upon such director's appointment to the Board of Directors, he or she shall be issued a warrant to purchase 1,000,000 shares of our common stock at a per share exercise price equal to the greater of (i) the fair market value on the date of issuance or (ii) \$.09.

On December 23, 2008, we completed a second closing of our private placement. At the second closing, we sold an additional 56 units. In connection with the second closing, we issued to the placement agent a warrant to purchase 1,400,003 shares of our common stock at an exercise price of \$.09 per share as additional compensation for its services.

On February 3, 2009, we completed a third closing of our private placement. At the third closing, we sold an additional 82 units. In connection with the third closing, we issued to the placement agent a warrant to purchase 2,050,004 shares of our common stock at an exercise price of \$.09 per share as additional compensation for its services.

In connection with the private placement, we, the placement agent and the investors entered into a registration rights agreement. Pursuant to the registration rights agreement, we agreed to file a registration statement to register the resale of the shares of our common stock issuable upon exercise of the warrants issued to the investors in the private placement, within 20 days of the final closing date and to cause the registration statement to be declared effective within 90 days (or 120 days upon full review by the SEC). On April 2, 2009, the registration rights agreement was amended to, among other things, require us to register the shares of common stock issuable upon exercise of the warrants issued to the placement agent as partial compensation for its services. We filed an initial registration statement relating to the registration of the shares underlying the warrants issued to the investors and the placement agent on February 23, 2009, which was declared effective by the SEC on April 17, 2009.



## 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 American Stock Exchange Company guide. Specifically, the American Stock Exchange 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 did not make progress consistent with the plan during the period, AMEX staff could initiate 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 of the agreement, 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.

Expenses associated with the clinical trials conducted during 2007 and 2008 were recognized on this activity based basis. At December 31, 2007 we recognized accrued expenses of \$74,000 related to these clinical trials. At December 31, 2008 all clinical trials had been concluded and there was no remaining financial commitments.

Swiss Pharma Contract LTD, or Swiss Pharma, a clinical site that we used in one of our obesity trials, gave notice to us that Swiss Pharma believed it was entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. The contract between us and Swiss Pharma provided 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 did not believe that Swiss Pharma was entitled to additional payments, we defended 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 approximately \$646,000 which amount includes a contract penalty of approximately \$323,000, a final services invoice of approximately \$48,000, reimbursement of certain of Swiss Pharma's legal and other expenses incurred in the arbitration process of approximately \$245,000, reimbursement of arbitration costs of approximately \$13,000 and interest through September 5, 2008 of approximately \$17,000. Further, the arbitrator ruled that we must pay interest at the rate of 5% per annum on approximately \$371,000, the sum of the contract penalty of approximately \$323,000 and the final services invoice of approximately \$48,000, from October 12, 2007 until paid. We had previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice. The remainder of the award was expensed in 2008. We have recognized research and development expense of approximately \$267,000, general and administrative expense of approximately \$257,000 and interest expense of approximately \$23,000 during the year ended December 31, 2008. On January 22, 2009, we received notice that Swiss Pharma submitted a petition to the Supreme Court of the State of New York, County of New York seeking to confirm and to enter a judgment on the Arbitration Award. On February 17, 2009, we filed an answer to Swiss Pharma's petition. A hearing has not yet been scheduled. We will continue to accrue interest at the rate of 5% per annum on the approximate \$371,000 amount until such amount has been settled. We do not have sufficient cash or other current available 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 ourselves should the former employee file claims against us. There have been no further developments with respect to these contentions.

## Development Commitments

At present the Company has no development commitments.

## Hedrin

During 2008, we and Nordic Biotech Venture Fund II K/S entered into a joint venture agreement, or the Hedrin JV agreement. 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 Thornton & Ross Ltd., or T&R, the licensor of Hedrin.

## Topical PTH (1-34)

In July 2008, we announced the results of a phase 2a trial conducted with PTH 1-34 to evaluate the safety and preliminary efficacy of PTH 1-34 in the treatment of mild to moderate chronic plaque psoriasis. In the clinical trial, PTH 1-34 failed to show statistically or clinically meaningful improvements in the disease. We have conducted no further clinical activities with the product and are considering the next steps in the program, including returning the project to IGI under the terms of our license agreement.

Through our April 2005 acquisition of Tarpan Therapeutics, Inc., 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 December 31, 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.

#### Altoderm

On April 3, 2007, we entered into a license agreement for “Altoderm” (the “Altoderm Agreement”) with T&R. Pursuant to the Altoderm 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 using sodium cromoglicate for the treatment of atopic dermatitis. In accordance with the terms of the Altoderm 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 common stock upon the achievement of various clinical and regulatory milestones. We 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. We agreed to pay T&R 30% of the royalties received by us under such sublicense agreements.

Subsequent to December 31, 2008, we terminated the Altoderm Agreement for convenience. We have no further financial liability or commitment to T&R under the Altoderm Agreement.

#### Altolyn

On April 3, 2007, we and T&R also entered into a license agreement for “Altolyn” (the “Altolyn Agreement”). Pursuant to the Altolyn 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 sodium cromoglicate for the treatment of mastocytosis, food allergies, and inflammatory bowel disorder. In accordance with the terms of the Altolyn 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 cash milestone payments to T&R in an aggregate amount of \$5,675,000 upon the achievement of various clinical and regulatory milestones. We 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. We may sublicense the patent rights. We agreed to pay T&R 30% of the royalties received by us under such sublicense agreements.

Subsequent to December 31, 2008, we terminated the Altolyn Agreement for convenience. We have no further financial liability or commitment to T&R under the Altolyn Agreement.

#### 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 our Oleoyl-estrone programs in both common obesity and morbid obesity during 2007.

#### Propofol Lingual Spray

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





## 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 (U.K.).

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 U.K. 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 U.K. 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.

Two new, unpublished Hedrin studies were completed by T&R in 2008. In the first, Hedrin achieved a 100% kill rate in vitro, including in malathion resistant head lice. In the other, a clinical field study conducted in Manisa province, a rural area of Western Turkey, Hedrin was administered to 36 adult and child subjects with confirmed head lice infestations. Using per protocol analysis, Hedrin achieved a 97% cure rate. Using intent-to-treat analysis, Hedrin achieved a 92% cure rate since 2 subjects were eliminated due to protocol violations. No subjects reported any adverse events.

In the U.S., Manhattan Pharmaceuticals, through the Hedrin JV, is pursuing the development of Hedrin as a medical device. In January 2009, the FDA Center for Devices and Radiological Health, or CDRH, notified H Pharmaceuticals that Hedrin had been classified as a Class III medical device. A Class III designation means that a Premarket Approval, or PMA, Application will need to be obtained before Hedrin can be marketed in the U.S. We expect to be required to complete at least one clinical trial as part of that PMA Application.

To date, we have incurred \$1,084,000 of project costs for the development of Hedrin. During 2008, \$14,000 of these costs were incurred. We do not expect to incur any future costs as the Hedrin JV is now responsible for all costs associated with 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 (“IGI”).

In April 2006, we encountered a stability issue with the original topical PTH (1-34) product which utilized IGI’s Novosome ® formulation technology. In order to resolve that stability issue we created a new topical gel version of PTH (1-34) and filed new patent applications in the U.S. for this new proprietary formulation.

In September 2007, the U.S. FDA accepted our 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 was designed to evaluate safety and preliminary efficacy of Topical PTH (1-34) in patients with mild to moderate psoriasis. Approximately 54 subjects were enrolled and randomized to receive one of two dose levels of Topical PTH (1-34), or the gel vehicle (placebo), for an 8 week treatment period. In this study the vehicle was the topical gel (“GEL”) without the active ingredient, PTH (1-34). In July 2008, we announced the results of the Phase 2a study where Topical PTH (1-34) failed to demonstrate a statistically significant or clinically meaningful improvement in psoriasis.

In July 2008 we announced the results of a Phase 2a clinical study where PTH (1-34) failed to show statistically or clinically meaningful improvements in psoriasis as compared to the vehicle (placebo). We have conducted no further clinical activities with PTH (1-34) and intend to return the project to IGI under the terms of the license agreement.

The gel vehicle (placebo) used in the above-mentioned study is our proprietary topical GEL and it unexpectedly showed evidence of psoriasis improving properties. At the end of week 2, 15% of study subjects treated with the GEL achieved a clear or almost clear state. At the end of week 4, 20% of subjects treated with the GEL had achieved a clear or almost clear state, and at the end of week 8, 25% of subjects had achieved a clear or almost clear state. We own worldwide rights to this topical GEL and are exploring the possibility of developing it as an OTC product for mild psoriasis.

To date, we have incurred \$6,504,000 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 2008, \$1,382,000 of these costs were incurred.

#### Altoderm

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 known 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.



## Product 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.

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.

In a second, Phase 3, randomized, double-blind, vehicle-controlled clinical study (also conducted in Europe by T&R) 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.

Subsequent to December 31, 2008, we terminated the Altoderm Agreement for convenience. We have no further financial liability or commitment to T&R under the Altoderm Agreement.

To date we have incurred \$1,110,000 for the development of Altoderm. During 2008, \$98,000 of these costs were incurred.

## Altolyn

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.

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. 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 U.K. manufacturer of Altolyn to develop a Good Manufacturing Process (“cGMP”) compliant manufacturing process.

Subsequent to December 31, 2008, we terminated the Altolyn Agreement for convenience. We have no further financial liability or commitment to T&R under the Altolyn Agreement.

To date, we have incurred \$831,000 for the development of Altolyn. During 2008, \$98,000 of these costs were incurred.

#### 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 our Oleoyl-estrone programs in both common obesity and morbid obesity.

To date, we have incurred \$15,510,000 for the development of OE, none of which was incurred during 2008.

#### Propofol Lingual Spray

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

To date, we have incurred \$2,984,000 for the development of Propofol Lingual Spray, none of which was incurred during 2008.

#### Summary of Contractual Commitments

##### Employment Agreement

We have employment agreements with two employees for the payment of aggregate annual base salary of \$675,000 as well as performance based bonuses. These agreements have a remaining term of three months for one employee and six months for the second employee and have a remaining obligation of \$226,000 as of December 31, 2008. As per the terms of the Secured 12% Notes sold in the fourth quarter of 2008 and the first quarter of 2009 management, comprised of the two employees under contract, has agreed to reduce their salaries effective as of October 1, 2008. If we sell less than \$1.5 million of Secured 12% Notes then their salaries shall be reduced by one-third. If we sell at least \$1.5 million but less than \$2 million of Secured 12% Notes then their salaries shall be reduced by 20%. We sold \$1.725 million of Secured 12% Notes, and management, therefore, was paid 80% of their salaries during the fourth quarter of 2008. Also as per the terms of the Secured 12% Notes, the reduction in management's salaries shall be further reduced to 10% if we realize gross proceeds of \$500,000 or more from other sources and shall be reduced to 0% if we realize gross proceeds of \$1,000,000 or more from other sources. In February 2009, we received a \$500,000 milestone payment from the Hedrin JV; therefore management's salaries are currently reduced by 10%.

## Leases

Rent expense for the years ended December 31, 2008 and 2007 was \$139,636 and \$141,012, respectively. Future minimum rental payments subsequent to December 31, 2008 under an operating lease for the Company's office facility are as follows:

Years Ending December 31,	Commitment
2009	\$ 63,900
2010 and subsequent	\$ 0

## 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 our company 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 ensure that research and development costs are expensed as incurred, we record 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, 2008 and 2007 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 February 2008, the FASB issued two Staff Positions on SFAS 157: (1) FASB Staff Position No. FAS 157-1 (“FAS 157-1”), “Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement Under Statement 13,” and (2) FASB Staff Position No. FAS 157-2 (“FAS 157-2”), “Effective Date of FASB Statement No 157.” FAS 157-1 excludes FASB Statement No. 13, Accounting for Leases, as well as other accounting pronouncements that address fair value measurements on lease classification or measurement under Statement 13, from SFAS 157’s scope. FAS157-2 partially defers Statement 157’s effective date. The adoption of FAS 157-1 and FAS 157-2 did not have a material impact on our financial statements.

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

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 our financial statements.

In May 2008, the FASB issued SFAS No. 163, "Accounting for Financial Guarantee Insurance Contracts" ("SFAS 163"). SFAS 163 requires recognition of a claim liability prior to an event of default when there is evidence that credit deterioration has occurred in an insured financial obligation. SFAS 163 clarifies how FAS 60 applies to financial guarantee insurance contracts, including the recognition and measurement to be used to account for premium revenue and claim liabilities. SFAS 163 also requires expanded disclosures about financial guarantee insurance contracts. SFAS 163 is effective for years beginning after December 15, 2008, and interim periods within those years, except for certain disclosure requirements which are effective for the first period (including interim periods) beginning after May 23, 2008. We do not believe that SFAS 163 will have any impact on our financial statements.

The FASB and the Securities and Exchange Commission had issued certain other accounting pronouncements as of December 31, 2008 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected our financial accounting measures or disclosures had they been in effect during the years ended December 31, 2008 and 2007 and for the period from August 6, 2001 (inception) to December 31, 2008 or that will have a significant effect at the time they become effective.

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. We do not expect the adoption of SFAS 141(R) to have a significant impact on our results of operations or financial position.

In June 2008, the FASB ratified EITF Issue No. 07-5, "Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock" ("EITF 07-5"). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. We currently are assessing the impact of EITF 07-5 on our financial position and results of operations.



## BUSINESS

### Overview

We are a specialty healthcare product company focused on developing and commercializing innovative treatments 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. In the short term, we are focusing our efforts on the commercialization of the two product candidates we currently have in development: Hedrin™, a novel, non-insecticide treatment for pediculosis (head lice), which we are developing through a joint venture, and a topical product for the treatment of psoriasis. Longer term, we intend to acquire and commercialize low risk, quick to market products, specifically products that could be marketed over-the-counter, or OTC, treat everyday maladies, are simple to manufacture, and/or could be classified as medical devices by the FDA.

During 2007, we discontinued development of Oleoyl-estrone and Propofol Lingual Spray. In March 2009, we discontinued development of Altoderm and Altolyn. 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. Our telephone number is (212) 582-3950 and our internet website address is [www.manhattanpharma.com](http://www.manhattanpharma.com).

### 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. This transaction was accounted for as a purchase of Tarpan by us.

### Our Research and Development Programs

#### Hedrin™

In June 2007, Manhattan Pharmaceuticals entered into an exclusive license agreement, or the Hedrin 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, or the Hedrin Supply Agreement, with T&R pursuant to which T&R will be the Company’s exclusive supplier of Hedrin product.

In February 2008, we announced that it had entered into a joint venture agreement with Nordic Biotech Advisors ApS to develop and commercialize Hedrin. The 50/50 joint venture entity, H Pharmaceuticals, or the Hedrin JV, now owns, is developing, and is working to secure commercialization partners for Hedrin in North America. Manhattan Pharmaceuticals manages the day-to-day operations of the Hedrin JV under a management contract with the Hedrin

JV. H Pharmaceuticals is independently funded and is responsible for all costs associated with the Hedrin project, 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 ("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, rather than by acting on the central nervous system, the insects cannot 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.

## Product Development

To date, Hedrin has been clinically studied in 362 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 U.K. In addition, according to the same study, the Hedrin treated subjects experienced significantly less irritation (2%) than those treated with phenothrin (9%).

A 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 U.K. 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.

Two new, unpublished Hedrin studies were completed by T&R in 2008. In the first, Hedrin achieved a 100% kill rate in vitro, including in malathion resistant head lice. In the other, a clinical field study conducted in Manisa province, a rural area of Western Turkey, Hedrin was administered to 36 adult and child subjects with confirmed head lice infestations. Using per protocol analysis, Hedrin achieved a 97% cure rate. Using intent-to-treat analysis, Hedrin achieved a 92% cure rate since 2 subjects were eliminated due to protocol violations. No subjects reported any adverse events.

In the U.S., we, through the Hedrin JV, are pursuing the development of Hedrin as a medical device. In January 2009, the FDA Center for Devices and Radiological Health, or CDRH, notified H Pharmaceuticals that Hedrin had been classified as a Class III medical device. A Class III designation means that a Premarket Approval, or PMA, Application will need to be obtained before Hedrin can be marketed in the U.S. We expect to be required to complete at least one clinical trial as part of that PMA Application.

#### Market and Competition

In Europe, Hedrin has been launched in 27 countries and, according to T&R, has achieved 2008 annual sales through its licensees of approximately \$48 million (€35 million) at in-market public prices, garnering approximately 23% market share across Europe. It is the market leader in the U.K. with \$10 million in sales (25% market share) and France with a 25% market share.

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. We believe there is significant market potential for a convenient, non-insecticide treatment for head 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 experts 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 Psoriasis Product

Since 2005, we have been developing a topical formulation of parathyroid hormone (1-34), or Topical PTH (1-34), for the prescription treatment of mild to moderate psoriasis. In July 2008, we announced Phase 2a study results where PTH (1-34) failed to demonstrate a statistically significant or clinically meaningful improvement in psoriasis versus a vehicle (placebo). In this study, the vehicle (placebo) was a topical gel, or GEL, that had been developed by the Company and was identical to the Topical PTH (1-34) product minus the active ingredient, PTH (1-34). Both the active and vehicle (placebo) arms of the study showed similar improvements in study subjects’ psoriasis plaques. In summary, the study results indicated that PTH (1-34) was not effective for the treatment of psoriasis since it did not achieve superiority or a statistical separation in efficacy over the GEL. The GEL placebo may be effective enough to market as an OTC product. Due to these study results, we have decided to discontinue development of PTH (1-34) as a prescription topical pharmaceutical candidate, and instead, we are exploring the possibility of developing the GEL as an OTC product for mild psoriasis.

We currently hold an exclusive, worldwide license to develop and commercialize Topical PTH (1-34) for the treatment of psoriasis. This license was obtained as a result of our merger with Tarpan Therapeutics in 2005, and

Tarpan had acquired the exclusive, worldwide rights pursuant to a 2004 license agreement with IGI, Inc (“IGI”). We intend to return the rights to PTH (1-34) to IGI under the terms of the license agreement.

## 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.

### PTH (1-34) Product Development History

In April 2006, we encountered a stability issue with the original topical PTH (1-34) product which utilized IGI's Novosome® formulation technology. In order to resolve that stability issue we created a new topical gel delivery system to be used with peptides, including PTH (1-34), and other types of molecules. In 2007 we filed new patent applications in the U.S. for this new proprietary GEL formulation.

In September 2007, the U.S. FDA accepted our 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 was designed to evaluate safety and preliminary efficacy of Topical PTH (1-34) in patients with mild to moderate psoriasis. Approximately 54 subjects were enrolled and randomized to receive one of two dose levels of Topical PTH (1-34), or the GEL vehicle (placebo), for an 8 week treatment period. In this study the vehicle was the topical GEL without the active ingredient, PTH (1-34). In July 2008, we announced the results of the Phase 2a study where Topical PTH (1-34) failed to demonstrate a statistically significant or clinically meaningful improvement in psoriasis. We have conducted no further clinical activities with Topical PTH (1-34) and we intend to return the product to IGI under the terms of the license agreement.

### Topical GEL for Psoriasis

The GEL vehicle (placebo) used in the above-mentioned study is the Company's proprietary topical GEL showed evidence of psoriasis improving properties. In this Phase 2a study, when it was utilized as the vehicle (placebo), 15% of study subjects achieved a clear or almost clear state at the end of week 2. At the end of week 4, 20% of subjects treated with the GEL had achieved a clear or almost clear state, and at the end of week 8, 25% of subjects treated with the GEL had achieved a clear or almost clear state. The Company owns worldwide rights to this topical GEL and is exploring the possibility of developing it as an OTC product for mild psoriasis.

### Market and Competition

According to the National Psoriasis Foundation approximately 125 million people worldwide, including approximately 6 million Americans, suffers from psoriasis. Of these, approximately 65% (4.4 million) have mild psoriasis and maybe likely to be treated with an OTC product. According to Datamonitor, only an estimated 55% of psoriasis sufferers have been formally diagnosed by a physician, so the OTC market could potentially be much larger.

There are a number of treatments available today for psoriasis, including numerous OTC creams and ointments that help to reduce inflammation, stop itching, and soothe skin. Products such as Psoriasin, CortAid, Dermarest, and Cortizone 10 are the most common, but none are viewed as particularly effective for psoriasis. Steroids are also prescribed as an adjunct prescription therapy for pain and anti-inflammation.

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





## Discontinued Research and Development Programs

### Altoderm™

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 known 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.

### Product 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.

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.

In a second, Phase 3, randomized, double-blind, vehicle-controlled clinical study (also conducted in Europe by T&R) 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.

As a result of the inconclusive European study data and a lack of sufficient funds to develop Altoderm, in March 2009, we discontinued development and returned the project to T&R under the terms of the license agreement.

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

## Altolyn™

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.

## Product Development

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. 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 U.K. manufacturer of Altolyn to develop a Good Manufacturing Process (“cGMP”) compliant manufacturing process.

Due to small market opportunity and lack of sufficient funds to develop Altolyn, in March 2009 the Company discontinued development and returned the project to T&R under the terms of the license agreement.

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, the Company discontinued its OE programs in both common obesity and morbid obesity.

## Propofol Lingual Spray

On July 9, 2007 the Company 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.

#### Hedrin

On June 26, 2007, we entered into an exclusive license the Hedrin agreement with T&R and Kerris. Pursuant to the Hedrin License Agreement, we have 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 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 September 14, 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 (jointly, 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 December 31, 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 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 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 the Hedrin License Agreement and the 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. (the "IGI Agreement"). 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:

- 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.
- 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.
- 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, 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. 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, the Company entered into a license agreement for Altoderm (the "Altoderm Agreement") with T&R. Pursuant to the Altoderm 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 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; 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 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, 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 (the "Altolyn Agreement"). Pursuant to the Altolyn 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 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, 2008, 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 our 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), the topical GEL for psoriasis and, on behalf of the Hedrin JV, Hedrin that will be necessary to conduct human clinical trials, if needed.

#### 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 April 1, 2009, we had one part time and three full time employees, including: our Chief Executive Officer, our Chief Operating and Financial Officer and two individuals in business development, administration and finance. None of our employees is covered by a collective bargaining unit. We believe our relations with our employees are 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 our obesity trials, gave notice to us that Swiss Pharma believed it was entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. The contract between us and Swiss Pharma provided 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 did not believe that Swiss Pharma was entitled to additional payments, we defended 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 under the auspices of the Swiss Chamber of Commerce. 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 had previously recognized a liability to Swiss Pharma in the amount of \$104,000 for the final services invoice. The remainder of the award was expensed in 2008. We have recognized research and development expense of \$267,000, general and administrative expense of \$257,000 and interest expense of \$23,000 during the year ended December 31, 2008. On January 22, 2009, we received notice that Swiss Pharma submitted a petition to the Supreme Court of the State of New York, County of New York seeking to confirm and to enter a judgment on the Arbitration Award. On February 17, 2009, we filed an answer to Swiss Pharma's petition. A hearing has not yet been scheduled. We will continue to accrue interest at the rate of 5% per annum on the \$371,000 until such amount has been settled. We do not have sufficient cash or other current available 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 April 1, 2009, 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	Director Since
		President, Chief Executive Officer and	
Douglas Abel	47	Director	2005
Neil Herskowitz	52	Director	2004
Malcolm Hoenlein	65	Director	2004
Timothy McInerney	48	Director	2004
Richard I. Steinhart	51	Director	2004
Michael Weiser, M.D.	46	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)

55

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### 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; determines whether to retain or terminate the existing 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 [www.manhattanpharma.com](http://www.manhattanpharma.com) ..

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 [www.manhattanpharma.com](http://www.manhattanpharma.com).

### 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](http://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

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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 [www.manhattanpharma.com](http://www.manhattanpharma.com). 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 February 13, 2009. 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	55	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 Vysteris 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, 2008 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	Option Awards	Nonqualified Non-Equity Incentive Plan Compensation			All Other Compensation	Total
					Deferred Compensation	Sign-on Bonus	Termination Compensation		
Douglas Abel Chief Executive Officer and President	2008	\$ 338,750	\$ 0(2)	\$ 153,244(4)	\$ 0	\$ 0	\$ 34,000(3)	\$ 525,994	
	2007	\$ 345,000	\$ 90,000(2)	\$ 910,224(4)	\$ 0	\$ 0	\$ 42,333(3)	\$ 1,387,557	
Michael McGuinness Chief Operating and Financial Officer, Secretary	2008	\$ 263,750	\$ 0(2)	\$ 199,274(4)	\$ 0	\$ 0	\$ 9,000(5)	\$ 472,024	
	2007	\$ 238,333	\$ 50,000(2)	\$ 95,528(4)	\$ 0	\$ 0	\$ 9,000(5)	\$ 392,861	
Alan G. Harris (1) Chief Medical Officer	2008	\$ 49,167	\$ 0	\$ 0(4)	\$ 0	\$ 0	\$ 0	\$ 49,167	
	2007	\$ 288,333	\$ 0	\$ 292,530(4)	\$ 0	\$ 0	\$ 9,000(5)	\$ 589,863	

(1) Dr. Harris' employment with us ended effective December 31, 2007.

- (2) We accrued \$180,000 for Mr. Abel and \$100,00 for Mr. McGuinness as of December 31, 2007 for such bonuses but had not paid such bonuses as of that date. Payment of such bonuses were contingent upon our raising additional financing and were to be paid as follows: (i) 50% when we have consummated a financing transaction with gross proceeds to the Company of at least \$1,000,000 (net of commissions) and (ii) the remaining 50% 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). We reached the condition (i) with the initial closing of the Hedrin JV transaction and such 50% was paid. We reached the condition (ii) with the closing of Secured 12% Notes transactions, however we did not pay the second 50% as we needed to retain the cash to fund operations. Mr. Abel and Mr. McGuinness have agreed to forfeit the second 50% payment.
- (3) For 2008 represents a payment in the amount of \$25,000, which amount represents the approximate amount of additional expense incurred by Mr. Abel relating to his commuting between Boston and New York, without a tax “gross up”, and a matching contributions by us pursuant to our company’s 401(k) retirement plan of \$9,000. 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.
- (4) Represents the amount of share-based costs recognized by us during 2008 and 2007 under SFAS No. 123(R). See Note 3 to our Financial Statements included in our annual reports for 2008 and 2007 on Form 10-K

for the assumptions made in the valuation.

- (5) Represents matching contributions by us pursuant to our company's 401(k) retirement plan.

## 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, 2008.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Option Awards		
		Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Douglas Abel	2,923,900	0	\$ 1.50	04/01/2015
	83,333	166,667	\$ 0.95	04/25/2017
	433,333	866,667	\$ 0.17	03/25/2018
Michael McGuinness	146,666	73,334	\$ 0.70	07/10/2016
	40,000	20,000	\$ 1.35	07/10/2016
	106,667	213,333	\$ 0.95	04/25/2017
	366,667	733,333	\$ 0.17	03/25/2018

## 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. On November 19, 2008, at the first closing of our Secured 12% Notes private placement, we entered an amendment to the employment agreement, which provide for a reduction of up to one-third of the salary payable to Mr. Abel until we shall have received at least \$2,500,000 of gross proceeds from the sale of the units or other sales of securities or from other revenue received by us in the operation of our business or any combination of the foregoing.

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.

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. On November 19, 2008, at the first closing of our Secured 12% Notes private placement, we entered an amendment to the employment agreement, which provide for a reduction of up to one-third of the salary payable to

Mr. McGuinness until we shall have received at least \$2,500,000 of gross proceeds from the sale of the units or other sales of securities or from other revenue received by us in the operation of our business or any combination of the foregoing.

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 serving on a committee of the Board is entitled to a fee of \$1,000 for each meeting of such committee attended by such 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.

Due to our need to retain funds for the Company's operations payment of fees to our directors were suspended for all periods subsequent to March 31, 2008.

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2008:



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Name		Fees Earned or Paid in Cash	Option Awards (1)	All Other Compensation	Total
Neil Herskowitz	(2)	\$ 6,500	\$ 14,767	\$ -	\$ 21,267
Malcolm Hoenlein	(3)	\$ 6,000	\$ 14,767	\$ -	\$ 20,767
Timothy McInerney	(4)	\$ 5,500	\$ 14,767	\$ -	\$ 20,267
Richard Steinhart	(5)	\$ 6,500	\$ 14,767	\$ -	\$ 21,267
Michael Weiser	(6)				