

MANHATTAN PHARMACEUTICALS INC  
Form 10-K  
March 31, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2007

Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from \_\_\_ to \_\_\_

Commission File Number 1-32639

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

Delaware  
(State or other jurisdiction of incorporation or organization)

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

810 Seventh Avenue, 4<sup>th</sup> Floor, New York, New York  
(Address of Principal Executive Offices)

10019  
(Zip Code)

(212) 582-3950  
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.001 par value	OTC Bulletin Board

**Securities registered pursuant to Section 12(g) of the Exchange Act:** None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.  Yes  No

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant on March 17, 2008 based on the closing price of the common stock as reported on the American Stock Exchange on such date was \$7,206,064.

As of March 17, 2008 there were 70,624,232 outstanding shares of common stock, par value \$.001 per share.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant’s definitive Proxy Statement for its Annual Meeting of Stockholders to be held on June 25, 2008 (the “2008 Proxy Statement”) are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III. The 2008 Proxy Statement will be filed within 120 days after the fiscal year ended December 31, 2007.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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References to the “Company,” the “Registrant,” “we,” “us,” or “our” or in this Annual Report on Form 10-K refer to Manhattan Pharmaceuticals, Inc., a Delaware corporation, and our consolidated subsidiaries, together taken as a whole, unless the context indicates otherwise.

### **Forward-Looking Statements**

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

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

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

## **PART I**

### **ITEM 1. DESCRIPTION OF BUSINESS**

#### **Overview**

We are a clinical stage specialty pharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have four product candidates in development: Hedrin™, a novel, non-insecticide treatment for pediculosis (head lice); Topical PTH (1-34) for the treatment of psoriasis; Altoderm™ (topical cromolyn sodium) for the treatment of pruritus associated with dermatologic conditions including atopic dermatitis; and Altolyn™ (oral tablet cromolyn sodium) for the treatment of mastocytosis. We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

Our executive offices are located at 810 Seventh Avenue, 4<sup>th</sup> floor, New York, NY 10019 USA. 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. (“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 the Company.

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

##### ***Hedrin***™

In June 2007, Manhattan Pharmaceuticals entered into an exclusive license agreement with Thornton & Ross Ltd. (“T&R”) and Kerris, S.A. (“Kerris”) for a product candidate called Hedrin (the “Hedrin License Agreement”). We acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin, a non-insecticide product candidate for the treatment of head lice. In addition, and at the same time, we also entered into a Supply Agreement with T&R pursuant to which T&R will be the Company’s exclusive supplier of Hedrin product (the “Hedrin Supply Agreement”).

In February 2008, Manhattan Pharmaceuticals announced that it had entered into a joint venture agreement with Nordic Biotech Advisors ApS (“Nordic”) to develop and commercialize Hedrin. A 50/50 joint venture entity was formed that now owns, will develop and will secure a commercialization partner for the Hedrin product in North America (the “Hedrin JV”). Manhattan Pharmaceuticals will manage the day-to-day operations of the Hedrin JV. The joint venture entity has been independently funded and will be responsible for all costs associated with the Hedrin project, including any necessary United States (“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 and by asphyxiation (smothering), rather than by acting on the central nervous system, the insects have not build up resistance to the treatment. Recent studies have indicated that resistance to chemical insecticides may be increasing and therefore contributing to insecticide treatment failure. Manhattan Pharmaceuticals believes there is significant market potential for convenient, non-insecticide treatment alternatives. Both silicones in this proprietary formulation of Hedrin are used extensively in cosmetics and toiletries.

#### *Clinical Development*

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

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%).

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 has become resistant to malathion, and we believe this resistance may have influenced the study results. To date, there have been no reports of malathion resistance in the U.S. Additionally, Hedrin treated subjects experienced no irritant reactions, and Hedrin showed clinical equivalence to malathion in its ability to inhibit egg hatching. Overall, investigators and study subjects rated Hedrin as less odorous, easier to apply, and easier to wash out, and 97% of Hedrin treated subjects stated they were significantly more inclined to use the product again versus 31% of those using malathion.

In the U.S., Manhattan Pharmaceuticals, through the Hedrin JV, is pursuing the development of Hedrin as a medical device and has submitted an initial regulatory package to the U.S. Food and Drug Administration (“FDA”) Center for Devices and Radiological Health. The Company expects to be required to complete at least one clinical trial with this product candidate.

#### *Market and Competition*

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

According to the American Academy of Pediatrics an estimated 6-12 million Americans are infested with head lice each year, with pre-school and elementary children and their families affected most often. The total U.S. head lice market is estimated to be over \$200 million with prescription and over-the-counter (OTC) therapies comprising approximately 50% of that market. The remaining 50% of the market is comprised of alternative therapies such as tea tree oils, mineral oils, and “nit picking”, or physical combing to remove lice. 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 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”). Topical PTH (1-34) has been tested in a Phase 1/2 clinical study conducted under a physician investigational new drug application (“P-IND”).



### *Psoriasis*

Psoriasis is a common, chronic, immune-mediated disease that results in the over-production of skin cells. In healthy skin, immature skin cells migrate from the lowest layer of the epidermis to the skin's surface over a period of 28-30 days. In psoriasis, these cells reproduce at an extremely accelerated rate and advance to the surface in only 7 days. This results in a build up of excess, poorly differentiated skin cells that accumulate in dry, thick patches known as plaques. These plaques can appear anywhere on the body resulting in skin irritation and disability.

### *Mechanism of Action*

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

### *Clinical Development*

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

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

In September 2007, the U.S. FDA accepted our corporate Investigational New Drug ("IND") application for this new gel formulation of Topical PTH (1-34), and in October 2007, we initiated and began dosing subjects in a Phase 2a clinical study of Topical PTH (1-34) for the treatment of psoriasis. This U.S., multi-center, randomized, double-blind, vehicle-controlled, parallel group study is designed to evaluate safety and preliminary efficacy of Topical PTH (1-34) for the treatment of psoriasis. Approximately 54 subjects will be enrolled and randomized to receive one of two dose levels of Topical PTH (1-34), or vehicle, for an 8 week treatment period. In this study the vehicle is the topical formulation without the active ingredient, PTH (1-34). We expect to announce the results of this study in Summer 2008.

### *Market and Competition*

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

The efficacy and safety profile of Topical PTH (1-34) potentially make it an attractive alternative to existing topical treatments, photo therapies and systemic treatments such as methotrexate and biologics for the treatment of psoriasis. We are developing Topical PTH (1-34) as a monotherapy and for use in combination with currently available therapies. Some of Topical PTH (1-34)'s competitors would include, but are not limited to over-the-counter, or "OTC," prescription topical treatments, and laser treatment. Treatments such as phototherapy, methotrexate, cyclosporine, Remicade® (Johnson & Johnson), Enbrel® (Amgen), Amiveve® (Astellas), and Raptiva® (Genentech) are generally used for more severe patients due to their harsh side effect profiles.

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

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

### *Altoderm™*

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.

### *Mechanism of Action*

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



### *Clinical Development*

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

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

On March 6, 2008, Manhattan Pharmaceuticals announced it 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.

### *Market and Competition*

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

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

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

### *Altolyn™*

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

### *Mastocytosis*

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

### *Mechanism of Action*

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

### *Nonclinical Development*

On March 6, 2008, Manhattan Pharmaceuticals announced it 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. The Company is working with T&R and the current U.K. manufacturer of Altolyn to develop a Good Manufacturing Process (“cGMP”) compliant manufacturing process.

Early clinical experience with Altolyn in the U.K. suggests promising activity in patients with various allergic disorders, including food allergy and inflammatory bowel conditions. The Company may pursue these as additional indications.

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

### *Oleoyl-estrone*

On July 9, 2007 the Company announced the results of its 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. none 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, the Company entered into an exclusive license the Hedrin agreement with T&R and Kerris. Pursuant to the Hedrin License Agreement, the Company has acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin<sup>TM</sup>, a non-insecticide product candidate for the treatment of pediculosis (“head lice”):

1. 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, the Company entered into the Hedrin Supply Agreement with T&R pursuant to which T&R will be the Company's exclusive supplier of the Hedrin product.

In consideration for the license, the Company issued to T&R and Kerris (jointly, the "Licensor") a combined total of 150,000 shares of its common stock valued at \$120,000. In addition, the Company also made a cash payment of \$600,000 to the Licensor. Further, the Company 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, 2007, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

The Company also agreed to pay royalties to the Licensor of 8% (or, under certain circumstances, 4%) on net sales of licensed products. The Company's 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. The Company may sublicense its 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, the Company has agreed that it and its sublicensees will purchase their respective requirements of the Hedrin product from T&R at agreed upon prices. Under certain circumstances where T&R is unable to supply Hedrin products in accordance with the terms and conditions of the Supply Agreement, the Company 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 the Company assigned and transferred its rights in Hedrin to the Hedrin JV. The Hedrin JV is now responsible for all of the Company's 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:

- 1.U.S. Patent No. 5,527,772, entitled "Regulation of cell proliferation and differentiation using peptides." M.F. Holick, Inventor. Application filed July, 28, 1994. Patent issued June 18, 1996. This patent expires June 18, 2013.



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

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

The IGI sublicense agreement requires us to make certain milestone payments as follows: \$300,000 payable upon the commencement of a Phase 2 clinical trial; \$500,000 upon the commencement of a Phase 3 clinical trial; \$1,500,000 upon the acceptance of an Investigational New Drug Application ("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. At December 31, 2008 this \$300,000 liability is reflected in accounts payable.

In addition, we are obligated to pay IGI, Inc. an annual royalty of 6% on annual net sales up to \$200,000,000. In any calendar year in which net sales exceed \$200,000,000, we are obligated to pay IGI, Inc. an annual royalty of 9% annual net sales. Through December 31, 2007 sales have not commenced, therefore we have not paid any such royalties.

IGI, Inc. may terminate the agreement (i) upon 60 days' notice if we fail to make any required milestone or royalty payments, or (ii) if we become bankrupt or if a petition in bankruptcy is filed, or if we are placed in the hands of a receiver or trustee for the benefit of creditors. IGI, Inc. may terminate the agreement upon 60 days' written notice and an opportunity to cure in the event we commit a material breach or default. We may terminate the agreement in whole or as to any portion of the PTH patent rights upon 90 days' notice to IGI, Inc.

### **Altoderm**

On April 3, 2007, the Company entered into a license agreement for Altoderm (the "Altoderm Agreement") with T&R. Pursuant to the Altoderm Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate 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 the Altoderm Agreement, the Company issued 125,000 shares of its common stock, valued at \$112,500, and made a cash payment of \$475,000 to T&R upon the execution of the agreement. Further, the Company agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 and 875,000 shares of 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, 2007, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

### **Altolyn**

On April 3, 2007, the Company and T&R also entered into a license agreement for Altolyn (the "Altolyn Agreement"). Pursuant to the Altolyn Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altolyn, an oral 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, the Company made a cash payment of \$475,000 to T&R upon the execution of the agreement. Further, the Company agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 upon the achievement of various clinical and regulatory milestones. as follows: \$450,000 upon acceptance filing by the FDA of an IND; \$625,000 upon the first dosing of a patient in the first Phase 3 clinical trial; \$1,000,000 upon the achievement of a successful outcome of a Phase 3 clinical trial; \$1,100,000 upon the acceptance for filing of a NDA application by the FDA; \$2,000,000 upon the final approval of an NDA by the FDA; and \$500,000 upon receipt of marketing authorization in Canada.



In addition, we are obligated to pay T&R an annual royalty of 10% on annual net sales of up to \$100,000,000; 15% of the amount of annual net sales in excess of \$100,000,000 and 20% of annual net sales in excess of \$200,000,000. There is a minimum royalty of \$1,000,000 per year. There is a one-time success fee of \$10,000,000 upon the achievement of cumulative net sales of \$100,000,000. Through December 31, 2007, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

### **Oleoyl-estrone**

On July 9, 2007 the Company announced the results of its 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, 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.

### **Manufacturing**

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

### **Government Regulation**

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

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

· nonclinical laboratory tests, animal studies, and formulation studies,

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

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

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

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

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

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

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

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

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

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

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



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

**Non-United States Regulation.** Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

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

## **Employees**

We currently have 1 part time and 6 full time employees, including 1 person devoted to research and development and 6 persons in business development, administration and finance, including our senior management. None of our employees is covered by a collective bargaining unit. We believe our relations with our employees is satisfactory.



## **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 Annual Report before making an investment in our securities.*

### **Risks Related to Our Business**

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

We have generated no product revenues to date and will not until, and if, we receive approval from the FDA and other regulatory authorities for our product candidates. We have already spent substantial funds developing our potential products and business, however, and we expect to continue to have negative cash flow from our operations for at least the next several years. As of December 31, 2007, we had \$649,686 of cash and cash equivalents. We received additional funding of approximately \$2 million net from a joint venture agreement in February 2008. We will still have to raise substantial additional funds to complete the development of our drug candidates and to bring them to market. Beyond the capital requirements mentioned above, our future capital requirements will depend on numerous factors, including:

- the results of any clinical trials;
- the scope and results of our research and development programs;
- the time required to obtain regulatory approvals;
- our ability to establish and maintain marketing alliances and collaborative agreements; and
- the cost of our internal marketing activities.

Additional financing may not be available on acceptable terms, if at all. If adequate funds are not available, we will be required to delay, scale back or eliminate one or more of our 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.

### **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, 2007 and for the period from August 6, 2001 (inception) through December 31, 2007, we incurred net losses applicable to common shares of \$12,032,252, and \$54,999,070 respectively. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake nonclinical development and clinical trials for our product candidates;
- seek regulatory approvals for our product candidates;
- implement additional internal systems and infrastructure;
- lease additional or alternative office facilities; and
- hire additional personnel.

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

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

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

- continuing to undertake nonclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

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

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

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our 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 three products, Hedrin, Altoderm, and Altolyn, 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 four 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 FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our 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 drugs. 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 drugs.**

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 drugs;
- cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

**Our drug-development program depends 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 drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, 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 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 drug 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 drugs. 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 drugs 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 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 drug 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 drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

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

- developing drugs;
- undertaking nonclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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

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

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

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

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

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

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

- if and when patents will issue;

- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or

- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

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

**If we infringe the rights of third parties we could be prevented from selling products, 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 drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.**

Our ability to commercialize our drugs, 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.



**We are controlled by current officers, directors and principal stockholders.**

Our directors, executive officers and principal stockholders beneficially own approximately 27 percent of our outstanding voting stock and, including shares underlying outstanding options and warrants. 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.

**Risks Related to Our Securities**

**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 \$0.09 in the fourth quarter of 2007 to a high of \$1.64 in the first quarter of 2006. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
  - achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
  - developments concerning proprietary rights, including patents;
  - developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; and
  - sales of our common stock.

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

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



**We have delisted from the American Stock Exchange.**

As a result of our delisting, 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.

**We have never paid dividends.**

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.

**ITEM 2. LEGAL PROCEEDINGS**

Swiss Pharma Contract LTD (“Swiss Pharma”), a clinical site that the Company used in one of its obesity trials, gave notice to the Company that Swiss Pharma believes it is entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. While the contract between the Company and Swiss Pharma provides for additional payments if certain conditions are met, Swiss Pharma has not specified which conditions they believe have been achieved and the Company does not believe that Swiss Pharma is entitled to additional payments and has not accrued any of these costs as of December 31, 2007. The contract between the Company and Swiss Pharma provides for arbitration in the event of a dispute, such as this claim for an additional payment. Swiss Pharma has filed for arbitration. As the Company does not believe that Swiss Pharma is entitled to additional payments, it intends to defend its position in arbitration. The arbitration process is currently in its initial stage.

**ITEM 3. DESCRIPTION OF PROPERTY**

Our executive offices are located at 810 Seventh Avenue, 4th Floor, New York, New York 10019. We currently occupy this space pursuant to a written lease that expires on September 30, 2008 under which we pay rent of approximately \$11,800 per month.

We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

We held our Annual Meeting of Stockholders at the American Stock Exchange, 86 Trinity Place, New York, New York on May 24, 2007. The stockholders took the following actions:

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

<b>Nominee</b>	<b>Votes For</b>	<b>Votes Withheld</b>
Douglas Abel	35,536,892	65,132
Neil Herskowitz	35,376,093	225,931
Malcolm Hoenlein	35,518,495	83,529
Timothy McInerney	35,538,692	63,332
Joan Pons Gimbert	35,154,378	447,646
Richard I. Steinhart	35,529,736	72,288
Michael Weiser	34,493,245	1,108,779

(ii) The stockholders ratified the amendment to our 2003 Stock Option Plan increasing the number of shares available for issuance thereunder from 7,400,000 to 10,400,000. 34,440,971 votes were cast for the proposal; 1,107,853 votes were cast against the proposal, shares representing 53,200 votes abstained; and there were no broker non-votes.

(iii) The stockholders ratified the appointment of J.H. Cohn LLP as our independent registered public accounting firm for fiscal 2007. 35,519,099 votes were cast for the proposal; 8,205 votes were cast against the proposal, shares representing 74,720 votes abstained; and there were no broker non-votes.

**PART II****ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market for 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. The following table lists the high and low price for our common stock as quoted, in U.S. dollars, on the American Stock Exchange during each quarter within the last two fiscal years:

Quarter Ended	Price Range			
	2007		2006	
	High	Low	High	Low
March 31	\$ 0.96	\$ 0.70	\$ 1.640	\$ 1.160
June 30	1.10	0.69	1.360	0.075
September 30	0.78	0.22	0.880	0.620
December 31	0.23	0.09	0.920	0.620

On March 26, 2008 our common stock was voluntarily delisted from the AMEX and began trading on the Over the Counter Bulletin Board (“OCTBB”) under the symbol “MHAN”.

**Record Holders**

The number of holders of record of our common stock as of March 17, 2008 was 460.

**Dividends**

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock in the foreseeable future.

**Stock Repurchases**

We did not make any repurchases of our common stock during 2007.

**Securities authorized for issuance under equity compensation plans.**

See Note 6 to Consolidated Financial Statements.

## **ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

### **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. ("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 the Company.

We are a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have four product candidates in development: Hedrin, a novel, non-insecticide treatment of pediculitis (head lice); topical PTH (1-34) for the treatment of psoriasis; Altoderm for the treatment of pruritis (itch) associated with dermatologic conditions including atopin dermatitis; and Altolyn for the treatment of mastocytosis. We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

You should read the following discussion of our results of operations and financial condition in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K. This discussion includes "forward-looking" statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. Investors should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties inherent in future events, particularly those risks identified under the heading "Risk Factors" following Item 1 in this Annual Report, and should not unduly rely on these forward looking statements. All share and per share information in this discussion has been adjusted for the 1-for-5 combination of our common stock effected on September 25, 2003.

### **Results Of Operations**

#### ***2007 versus 2006***

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

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

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

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

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

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

### Liquidity and Capital Resources

From inception to December 31, 2007, we incurred a deficit during the development stage of \$54,999,000 primarily as a result of our net losses, and we expect to continue to incur additional losses through at least December 31, 2008 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 financing. During the year ended December 31, 2007, we had a net decrease in cash and cash equivalents of \$2,379,000. This decrease resulted largely from net cash used in operating activities of \$10,230,000 partially offset by net cash provided by financing activities of

\$7,859,000. Total liquid resources as of December 31, 2007 were \$650,000 compared to \$3,029,000.



Our current liabilities as of December 31, 2007 were \$1,872,000 compared to \$1,943,000 at December 31, 2006, a decrease of \$71,000. As of December 31, 2007, we had working capital deficit of \$1,006,000 compared to working capital of \$1,350,000 at December 31, 2006.

In February 2008, we completed a joint venture transaction. We received net proceeds of approximately \$2.0 million from this joint venture transaction.

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, 2007, 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, 2007 and the net proceeds from the February 2008 joint venture transaction, management believes we do not have sufficient capital to fund our operations through the end of 2008. Management believes that we will need additional equity or debt financing or will need to generate revenues through licensing our products or entering into strategic alliances during 2008 to be able to sustain our operations during 2008 and we will need additional financing thereafter until we can achieve profitability, if ever.

We have reported net losses of \$12,032,000 and \$9,695,000 for the years ended December 31, 2007 and 2006, respectively. The net loss attributable to common shares from date of inception, including preferred stock dividends, August 6, 2001 to December 31, 2007, amounts to \$54,999,000. Management believes that we will continue to incur net losses through at least December 31, 2008.

### **Joint Venture Agreement**

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

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

Should the Hedrin JV be successful in achieving a payment milestone, namely that by September 30, 2008, the FDA determines to treat Hedrin as a medical device, Nordic will purchase an additional \$2.5 million of equity in the Hedrin JV, whereupon the Hedrin JV will pay the Company an additional \$1.5 million in cash and issue to the Company an additional \$2.5 million in equity in the Hedrin JV, thereby maintaining the Company's 50% ownership interest in the Hedrin JV.

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

The Hedrin JV will engage the Company to provide management services to the Limited Partnership in exchange for an annualized management fee, which for 2008, on an annualized basis, is \$527,000.

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

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

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

The Hedrin JV 's Board will consist of 4 members, 2 appointed by the Company and 2 appointed by Nordic. Nordic has the right to appoint one of the directors as chairman of the Board. The chairman has certain tie breaking powers. In the event that the payment milestone described above is not achieved by June 30, 2008, then the Hedrin JV 's Board will increase to 5 members, 2 appointed by the Company and 3 appointed by Nordic.

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

The Company will grant Nordic registration rights for the shares to be issued upon exercise of the warrant, the put or the call. The Company is required to file an initial registration statement within 10 calendar days of filing its Form 10-K for the year ended December 31, 2007. The Company is required to file additional registration statements, if required, within 45 days of the date the Company first knows that such additional registration statement was required. The Company is required to use commercially reasonable efforts to cause the registration statement to be declared effective by the Securities and Exchange Commission ("SEC") within 105 calendar days from the filing date. If the Company fails to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of filing the Company will be required to pay to Nordic, or its assigns, an amount in cash, as partial liquidated damages, equal to 0.5% per month of the amount invested in the Hedrin JV by Nordic until the registration statement is declared effective by the SEC. In no event shall the aggregate amount payable by the Company exceed 9% of the amount invested in the Hedrin JV by Nordic.

The profits of the Hedrin JV will be shared by the Company and Nordic in accordance with their respective equity interests in Limited Partnership, which are currently 50% to each, except that Nordic will get a minimum guaranteed return from the Hedrin JV equal to 5% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Limited Partnership. If the Hedrin JV realizes a profit equal to or greater than a 10% royalty on Hedrin sales, then profits will be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership. However, in the event of a liquidation of the Limited Partnership, Nordic's distribution in liquidation will be at least equal to the amount Nordic invested in the Hedrin JV (\$5 million if the payment milestone described above is met, \$2.5 million if it is not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

### **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 are not in compliance with the continued listing standards at the end of the plan period, or if we do not make progress consistent with the plan during the period, AMEX staff may initiate delisting proceedings.

Under the terms of the Joint Venture Agreement, the number of potentially issuable shares represented by the put and call features of the Hedrin 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 the Company's financial viability depended on its completion of the transaction without further delay.

Accordingly, to maintain the Company's financial viability, on February 28, 2008 we announced that we had formally notified AMEX that we intend 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 ("OCTBB") 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 in common obesity and morbid obesity, which were concluded during 2007, were recognized on this activity based basis. At December 31, 2007 we recognized accrued expenses of \$74,000 related to these clinical trials. There are no remaining financial commitments for these clinical trials.

The Company is developing Topical PTH (1-34) as a topical treatment for psoriasis. Expenses associated with the manufacture of clinical and non-clinical supplies of Topical PTH (1-34) are recognized on this activity based method. At December 31, 2007 we recognized prepaid expense of \$30,000 related to the manufacture of Topical PTH (1-34). The remaining financial commitment related to the manufacture of Topical PTH (1-34) is negligible.

During 2007 we entered into an agreement with Therapeutics, Inc. for the conduct of a Phase 2a clinical trial of Topical PTH (1-34). The amount of the agreement is approximately \$845,000. At December 31, 2007 we recognized research and development expense of \$483,000 related to the conduct of this clinical trial. At December 31, 2007 we recognized prepaid expense of \$19,000 related to this clinical trial. The remaining financial commitment related to the conduct of the clinical trial is approximately \$340,000. This clinical trial is expected to conclude in the second quarter of 2008.

Swiss Pharma Contract LTD (“Swiss Pharma”), a clinical site that the Company used in one of its obesity trials, gave notice to the Company that Swiss Pharma believes it is entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. While the contract between the Company and Swiss Pharma provides for additional payments if certain conditions are met, Swiss Pharma has not specified which conditions they believe have been achieved and the Company does not believe that Swiss Pharma is entitled to additional payments and has not accrued any of these costs as of December 31, 2007. The contract between the Company and Swiss Pharma provides for arbitration in the event of a dispute, such as this claim for an additional payment. Swiss Pharma has filed for arbitration. As the Company does not believe that Swiss Pharma is entitled to additional payments, it intends to defend its position in arbitration. The arbitration process is currently in its initial stage.

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

### ***Development Commitments***

#### **Hedrin**

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

In consideration for the license, the Company issued to T&R and Kerris (jointly, the “Licensor”) a combined total of 150,000 shares of its common stock valued at \$120,000. In addition, the Company also made a cash payment of \$600,000 to the Licensor. These amounts are included in research and development expense.

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

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

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

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

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

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. At December 31, 2007 this \$300,000 liability is reflected in accounts payable.

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, 2007, sales have not commenced, therefore, we have not paid any such royalties.

IGI, Inc. may terminate the agreement (i) upon 60 days' notice if we fail to make any required milestone or royalty payments, or (ii) if we become bankrupt or if a petition in bankruptcy is filed, or if we are placed in the hands of a receiver or trustee for the benefit of creditors. IGI, Inc. may terminate the agreement upon 60 days' written notice and an opportunity to cure in the event we commit a material breach or default. 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, the Company entered into a license agreement for “Altoderm” (the “Altoderm Agreement”) with T&R. Pursuant to the Altoderm Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate with the active ingredient cromolyn sodium (also known as sodium cromoglicate) for the treatment of atopic dermatitis. In accordance with the terms of the Altoderm Agreement, the Company issued 125,000 shares of its common stock, valued at \$112,500, and made a cash payment of \$475,000 to T&R upon the execution of the agreement. These amounts have been included in research and development expense.

Further, the Company agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 and 875,000 shares of our common stock upon the achievement of various clinical and regulatory milestones, as follows: \$450,000 upon acceptance by the U. S. Food and Drug Administration (“FDA”) of an Investigational New Drug application (“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 New Drug Application (“NDA”) application by the FDA; 500,000 shares of our common stock and \$2,000,000 upon the final approval of an NDA by the FDA; and \$500,000 upon receipt of marketing authorization in Canada.

In addition, we are obligated to pay T&R an annual royalty of 10% on annual net sales of up to \$100,000,000; 15% of the amount of annual net sales in excess of \$100,000,000 and 20% of annual net sales in excess of \$200,000,000. There is a minimum royalty of \$1,000,000 per year. There is a one-time success fee of \$10,000,000 upon the achievement of cumulative net sales of \$100,000,000. Through December 31, 2007, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or royalties.

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

### **Altolyn**

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

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

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

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

### **Oleoyl-estrone**

On July 9, 2007, the Company announced the results of its 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, the Company discontinued its Oleoyl-estrone programs in both common obesity and morbid obesity.

### **Propofol Lingual Spray**

On July 9, 2007, the Company announced that it is 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.





In the United States, Manhattan Pharmaceuticals is pursuing the development of Hedrin as a medical device and has submitted a regulatory package to the FDA's Center for Devices and Radiological Health. The Company expects to be required to complete at least one clinical trial with this product candidate.

To date, we have incurred \$1,070,000 of project costs for the development of Hedrin. All of such costs were incurred during 2007.

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

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

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

In September 2007, the U.S. FDA accepted our corporate Investigational New Drug (IND) application for this new gel formulation of Topical PTH (1-34), and in October 2007, we initiated and began dosing subjects in a phase 2a clinical study of Topical PTH (1-34) for the treatment of psoriasis. This U.S. multi-center, randomized, double-blind, vehicle-controlled, parallel group study is designed to evaluate safety and preliminary efficacy of Topical PTH (1-34) for the treatment of psoriasis. Approximately 54 subjects will be enrolled and randomized to receive one of two dose levels of Topical PTH (1-34), or vehicle, for an 8 week treatment period. In this study the vehicle is the topical formulation without the active ingredient, PTH (1-34).

To date, we have incurred \$5,122,000 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 2007, \$2,426,000 of these costs were incurred.

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

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

### *Altoderm*

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

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

On March 6, 2008, Manhattan Pharmaceuticals announced it 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.

To date we have incurred \$1,012,000 for the development of Altoderm. All of such costs were incurred in 2007.

### ***Altolyn***

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

Early clinical experience with Altolyn in the U.K. suggests promising activity in patients with various allergic disorders, including food allergy and inflammatory bowel conditions. The Company may pursue these as additional indications.

To date we have incurred \$790,000 for the development of Altolyn. All of such costs were incurred in 2007.

### ***Oleoyl-estrone***

On July 9, 2007, the Company announced the results of its 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, the Company discontinued its Oleoyl-estrone programs in both common obesity and morbid obesity.

To date, we have incurred \$15,510,000 for the development of OE, \$3,209,000 of which was incurred during 2007.

### ***Propofol Lingual Spray***

On July 9, 2007, the Company announced that it 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, \$27,000 of which was incurred during 2007.

## **Summary of Contractual Commitments**

### ***Employment Agreements***

We have employment agreements with two employees for the payment of aggregate annual base salaries of \$530,000 as well as performance based bonuses. All of these agreements have terms of three years and have a remaining obligation of \$394,000 as of December 31, 2007.

**Leases**

Rent expense for the years ended December 31, 2007 and 2006 was \$141,012 and \$141,012, respectively. Future minimum rental payments subsequent to December 31, 2007 under an operating lease for the Company's office facility are as follows:

Years Ending December 31,	Commitment
2008	\$100,000
2009 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 the Company and its 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.

The Company often contracts 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, the Company records monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contracts.

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



### ***Share-Based Compensation***

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

Effective January 1, 2006, we adopted SFAS No. 123(R), “Share-Based Payment,” (“Statement 123(R)”) for employee options using the modified prospective transition method. Statement 123(R) revised Statement 123 to eliminate the option to use the intrinsic value method and required us to expense the fair value of all employee options over the vesting period. Under the modified prospective transition method, we recognized compensation cost for the years ended December 31,2007 and 2006 which includes a) period compensation cost related to share-based payments granted prior to, but not yet vested, as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement 123; and b) period compensation cost related to share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with Statement 123(R). In accordance with the modified prospective method, we have not restated prior period results.

### ***New Accounting Pronouncements***

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements” (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles (“GAAP”) in the United States of America, and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements under GAAP and is effective for fiscal years beginning after November 15, 2007. The Company will adopt SFAS 157 as of January 1, 2008. The effects of adoption will be determined by the types of instruments carried at fair value in our financial statements at the time of adoption, as well as the method utilized to determine their fair values prior to adoption. Based on the Company’s current use of fair value measurements, SFAS 157 is not expected to have a material effect on its results of operations or financial position.

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

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

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

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

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



## **ITEM 7. CONSOLIDATED FINANCIAL STATEMENTS**

For a list of the consolidated financial statements filed as part of this report, see the Index to Consolidated Financial Statements beginning at Page F-1 of this Annual Report.

## **ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 8A(T). CONTROLS AND PROCEDURES**

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

As of December 31, 2007, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of that date in alerting them on a timely basis to material information required to be disclosed our reports to the Securities and Exchange Commission. There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2007 that have materially affected, or are likely to materially affect, our internal controls over financial reporting.

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

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

### *Management's Report on Internal Control*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the SEC, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with U.S. generally accepted accounting principles.



Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting is effective as of December 31, 2007.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report on internal control in this report.

#### **ITEM 8B. OTHER INFORMATION**

On March 28, 2008 the employment agreement between the Company and Douglas Abel, the Company's president and chief executive officer, was extended by mutual agreement for a period of one year, through April 1, 2009.

#### **ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

Information in response to this Item is incorporated herein by reference to our 2008 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

**PART III**

**ITEM 10. EXECUTIVE COMPENSATION**

Information in response to this Item is incorporated herein by reference to our 2008 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

**ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS**

Information in response to this Item is incorporated herein by reference to our 2008 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

**ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

Information in response to this Item is incorporated herein by reference to our 2008 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

**ITEM 13. EXHIBITS LIST– REVIEW WITH ANTHONY**

The following documents are included or referenced in this report.

Exhibit No.	Description
2.1	Agreement and Plan of Merger among the Company, Manhattan Pharmaceuticals Acquisition Corp. and Manhattan Research Development, Inc. (formerly Manhattan Pharmaceuticals, Inc.) dated December 17, 2002 (incorporated by reference to Exhibit 2.1 from Form 8-K filed March 5, 2003).
2.2	Agreement and Plan of Merger among the Registrant, Tarpan Therapeutics, Inc. and Tarpan Acquisition Corp., dated April 1, 2005 (incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K/A filed June 15, 2005).
3.1	Certificate of incorporation, as amended through September 25, 2003 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-QSB for the quarter ended September 30, 2003).
3.2	Bylaws, as amended to date (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No.33-98478)).
4.1	Specimen common stock certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No.33-98478)).
4.2	Form of warrant issued by Manhattan Research Development, Inc., which automatically converted into warrants to purchase shares of the Registrant's common stock upon the merger transaction with such company (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
4.3	Form of warrant issued to placement agents in connection with the Registrant's November 2003 private placement of Series A Convertible Preferred Stock and the Registrant's January 2004 private placement (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (File No. 333-111897)).
4.4	Form of warrant issued to investors in the Registrant's August 2005 private placement (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed September 1, 2005).
4.5	Form of warrant issued to placement agents in the Registrant's August 2005 private placement (incorporated by reference to Exhibit 4.2 of the Registrant's Form 8-K filed September 1, 2005).
10.1	1995 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-QSB for the quarter ended September 30, 1996).
10.2	Form of Notice of Stock Option Grant issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.2 of the Registrant's Registration Statement non Form S-8 filed March 24, 1998 (File 333-48531)).

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- 10.3 Schedule of Notices of Stock Option Grants, the form of which is attached hereto as Exhibit 4.2.
- 10.4 Form of Stock Option Agreement issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.5 License Agreement dated on or about February 28, 2002 between Manhattan Research Development, Inc. (f/k/a Manhattan Pharmaceuticals, Inc.) and Oleoyl-Estrone Developments SL (incorporated by reference to Exhibit 10.6 to the Registrant's Amendment No. 2 to Form 10-QSB/A for the quarter ended March 31, 2003 filed on March 12, 2004).
- 10.6 License Agreement dated April 4, 2003 between the Registrant and NovaDel Pharma, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to Form 10-QSB/A for the quarter ended June 30, 2003 filed on March 12, 2004).++
- 10.7 2003 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed February 17, 2004).
- 10.8 Employment Agreement dated April 1, 2005, between the Registrant and Douglas Abel (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K/A filed June 15, 2005).
- 10.9 Sublicense Agreement dated April 14, 2004 between Tarpan Therapeutics, Inc., the Registrant's wholly-owned subsidiary, and IGI, Inc. (incorporated by reference to Exhibit 10.109 to IGI Inc.'s Form 10-Q for the quarter ended March 31, 2004 (File No. 001-08568)).
- 10.10 Form of subscription agreement between the Registrant and the investors in the Registrant's August 2005 private placement (incorporated by reference as Exhibit 10.1 to the Registrant's Form 8-K filed September 1, 2005).
- 10.11 Separation Agreement between the Registrant and Alan G. Harris December 21, 2007
- 10.12 Employment Agreement dated July 7, 2006 between the Registrant and Michael G. McGuinness (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed July 12, 2006).
- 10.13 Summary terms of compensation plan for Registrant's non-employee directors (incorporated by reference to Exhibit 10.1 of Registrant's Form 8-K filed February 5, 2007).
- 10.14 Form of Stock Option Agreement issued under the Registrant's 2003 Stock Option Plan.
- 10.15 Exclusive License Agreement for "Altoderm" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dates April 3, 2007. Incorporated by reference to Exhibit 10.3 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.

- 10.16 Exclusive License Agreement for “Altolyn” between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007. Incorporated by reference to Exhibit 10.4 of the registrant’s form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.
- 10.17 Exclusive License Agreement for “Hedrin” between Thornton & Ross Ltd. , Kerris, S.A. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007. Incorporated by reference to Exhibit 10.5 of the registrant’s form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.
- 10.18 Supply Agreement for “Hedrin” between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007. Incorporated by reference to Exhibit 10.6 of the registrant’s form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.
- 10.19 Joint Venture Agreement between Nordic Biotech fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008.
- 10.20 Amendment No. 1, dated February 25, 2008, to the Joint Venture Agreement between Nordic Biotech fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008.
- 10.21 Assignment and Contribution Agreement between Hedrin Pharmaceuticals K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008.
- 10.22 Registration Rights Agreement between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008.
- 10.23 Amendment to Employment Agreement by and between Manhattan Pharmaceuticals, Inc. and Douglas Abel
- 23.1 Consent of J.H. Cohn LLP.
- 31.1 Certification of Principal Executive Officer.
- 31.2 Certification of Principal Financial Officer.
- 32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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++Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.****Fees Billed to the Company by Its Independent Auditors – MIKE TO UPDATE**

The following is a summary of the fees billed to us by J.H. Cohn LLP, our independent registered public accounting firm for professional services rendered for fiscal years ended December 31, 2007 and 2006:

<b>Fee Category</b>	<b>J.H. Cohn LLP</b>	
	<b>Fiscal 2007 Fees</b>	<b>Fiscal 2006 Fees</b>
Audit Fees	\$ 103,940	\$ 100,111
Audit-Related Fees		
(1)	11,520	22,943
Tax Fees (2)	18,708	21,165
All Other Fees (3)	-	-
Total Fees	\$ 134,168	\$ 144,219

(1) Audit-Related Fees consist principally of assurance and related services that are reasonably related to the performance of the audit or review of the Company's financial statements but not reported under the caption "Audit Fees." These fees include review of registration statements.

(2) Tax Fees consist of fees for tax compliance, tax advice and tax planning.

(3) All Other Fees consist of aggregate fees billed for products and services provided by the independent registered public accounting firm, other than those disclosed above.

**Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm**

At present, our audit committee approves each engagement for audit or non-audit services before we engage our independent registered public accounting firm to provide those services. Our audit committee has not established any pre-approval policies or procedures that would allow our management to engage our independent registered public accounting firm to provide any specified services with only an obligation to notify the audit committee of the engagement for those services. None of the services provided by our independent registered public accounting firm for fiscal 2007 was obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act, of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2008.

Manhattan Pharmaceuticals, Inc.

By: /s/ Douglas Abel  
 Douglas Abel  
 Chief Executive Officer  
 and President

In accordance with the Securities Exchange Act, this report has been signed below by the following persons on behalf of Manhattan Pharmaceuticals, Inc. and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Douglas Abel Douglas Abel	Chief Executive Officer, President and Director (principal executive officer)	March 31, 2008
/s/ Michael G. McGuinness Michael G. McGuinness	Secretary and Chief Financial Officer (principal accounting and financial officer)	March 31, 2008
/s/ Neil Herskowitz Neil Herskowitz	Director	March 31, 2008
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 31, 2008
/s/ Timothy McInerney Timothy McInerney	Director	March 31, 2008
/s/ Richard Steinhart Richard Steinhart	Director	March 31, 2008
/s/ Michael Weiser Michael Weiser	Director	March 31, 2008

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
Manhattan Pharmaceuticals, Inc.

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

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

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

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

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

/s/ J.H. Cohn LLP

Roseland, New Jersey  
March 28, 2008

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

Consolidated Balance Sheets

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

See accompanying notes to consolidated financial statements.

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

Consolidated Statements of Operations

	Years ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2007
	2007	2006	
Revenue	\$ —	\$ —	—\$ —
Costs and expenses:			
Research and development	8,535,687	6,172,845	26,489,043
General and administrative	3,608,270	3,827,482	13,852,363
In-process research and development charge	—	—	11,887,807
Impairment of intangible assets	—	—	1,248,230
Loss on disposition of intangible assets	—	—	1,213,878
Total operating expenses	12,143,957	10,000,327	54,691,321
Operating loss	(12,143,957)	(10,000,327)	(54,691,321)
Other (income) expense:			
Interest and other income	(112,181)	(307,871)	(821,897)
Interest expense	476	1,665	26,034
Realized (gain)/loss on sale of marketable equity securities	—	1,002	(76,032)
Total other income	(111,705)	(305,204)	(871,895)
Net loss	(12,032,252)	(9,695,123)	(53,819,426)
Preferred stock dividends (including imputed amounts)	—	—	(1,179,644)
Net loss applicable to common shares	\$ (12,032,252)	\$ (9,695,123)	\$ (54,999,070)
Net loss per common share:			
Basic and diluted	\$ (0.18)	\$ (0.16)	
Weighted average shares of common stock outstanding:			
Basic and diluted	68,015,075	60,112,333	

See accompanying notes to consolidated financial statements.

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

Consolidated Statement of Stockholders' Equity (Deficiency)

	Series A convertible preferred stock Shares	Series A convertible preferred stock Amount	Common stock Shares	Common stock Amount	Additional paid-in capital Amount	Subscription receivable Amount	Deficit accumulated during development stage Amount	Dividends payable Series A preferred stock Amount	Accumulated other comprehensive income (loss) Amount	Unearned consulting services Amount
Stock issued at \$0.0004 per share for subscription receivable		\$ —	10,167,741	\$ 10,168	\$ (6,168)	\$ (4,000)	\$ —	\$ —	\$ —	
Net loss		—	—	—	—	—	(56,796)	—	—	
Balance at December 31, 2001		—	10,167,741	10,168	(6,168)	(4,000)	(56,796)	—	—	
Proceeds from subscription receivable		—	—	—	—	4,000	—	—	—	
Stock issued at \$0.0004 per share for license rights		—	2,541,935	2,542	(1,542)	—	—	—	—	
Stock options issued for consulting services		—	—	—	60,589	—	—	—	—	(60,589)
Amortization of unearned consulting services		—	—	—	—	—	—	—	—	22,721
Common stock issued at \$0.63 per share, net of expenses		—	3,043,332	3,043	1,701,275	—	—	—	—	
Net loss		—	—	—	—	—	(1,037,320)	—	—	
Balance at December 31, 2002		—	15,753,008	15,753	1,754,154	—	(1,094,116)	—	—	(37,868)
Common stock issued		—	1,321,806	1,322	742,369	—	—	—	—	

at \$0.63 per share, net of expenses										
Effect of reverse acquisition	—	—	6,287,582	6,287	2,329,954	—	—	—	—	
Amortization of unearned consulting costs	—	—	—	—	—	—	—	—	—	37,868
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	—	(7,760)
Payment for fractional shares for stock combination	—	—	—	—	(300)	—	—	—	—	—
Preferred stock issued at \$10 per share, net of expenses	1,000,000	1,000	—	—	9,045,176	—	—	—	—	—
Imputed preferred stock dividend					418,182	—	(418,182)	—	—	—
Net loss	—	—	—	—	—	—	(5,960,907)	—	—	—
Balance at December 31, 2003	1,000,000	1,000	23,362,396	23,362	14,289,535	—	(7,473,205)	—	—	(7,760)
Exercise of stock options	—	—	27,600	27	30,073	—	—	—	—	—
Common stock issued at \$1.10, net of expenses	—	—	3,368,952	3,369	3,358,349	—	—	—	—	—
Preferred stock dividend accrued	—	—	—	—	—	—	(585,799)	585,799	—	—
Preferred stock dividends paid by issuance of shares	24,901	25	—	—	281,073	—	—	(282,388)	—	—
Conversion of preferred	(170,528)	(171)	1,550,239	1,551	(1,380)	—	—	—	—	—

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

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

Consolidated Statement of Stockholders' Equity (Deficiency)

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

Stock issued in connection with acquisition of Tarpan Therapeutics, Inc.	—	—	10,731,052	10,731	11,042,253	—	—	—	—	—	11,042,253
Net loss	—	—	—	—	—	(19,140,997)	—	—	—	—	(19,140,997)
Balance at December 31, 2005	—	—	60,092,697	60,093	42,751,111	(33,271,695)	—	987	—	—	9,529,995
Cashless exercise of warrants	—	—	27,341	27	(27)	—	—	—	—	—	—
Share-based compensation	—	—	—	—	1,675,499	—	—	—	—	—	1,675,499
Unrealized loss on short-term investments	—	—	—	—	—	—	—	(987)	—	—	—
Costs associated with private placement	—	—	—	—	(15,257)	—	—	—	—	—	—
Net loss	—	—	—	—	—	(9,695,123)	—	—	—	—	(9,695,123)
Balance at December 31, 2006	—	—	60,120,038	60,120	44,411,326	(42,966,818)	—	—	—	—	1,444,520
Common stock issued at \$0.84 and \$0.90 per shares, net of expenses	—	—	10,185,502	10,186	7,841,999	—	—	—	—	—	7,841,999
Common stock issued to directors at \$0.72 per share in satisfaction of accounts payable	—	—	27,776	28	19,972	—	—	—	—	—	—
Common stock issued to in connection with in-licensing agreement at \$0.90 per	—	—	125,000	125	112,375	—	—	—	—	—	—

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

See accompanying notes to consolidated financial statements.

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

Consolidated Statements of Cash Flows

	Years ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2007
	2007	2006	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (12,032,252)	\$ (9,695,123)	\$ (53,819,426)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Share-based compensation	1,440,956	1,675,499	3,364,983
Shares issued in connection with in-licensing agreement	232,500	—	232,500
Warrants issued to consultant	83,670	—	83,670
Amortization of intangible assets	—	—	145,162
(Gain)/loss on sale of marketable equity securities	—	1,002	(76,032)
Depreciation	48,345	60,186	195,825
Non cash portion of in-process research and development charge	—	—	11,721,623
Loss on impairment and disposition of intangible assets	—	—	2,462,108
Other	—	—	5,590
<b>Changes in operating assets and liabilities, net of acquisitions:</b>			
Decrease (increase) in prepaid expenses and other current assets	48,734	(69,810)	(157,607)
Increase in other assets	—	—	(70,506)
Increase (decrease) in accounts payable	(93,812)	(224,193)	1,699,698
Increase in accrued expenses	42,148	501,701	51,856
Net cash used in operating activities	(10,229,711)	(7,750,738)	(34,160,556)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(9,134)	(37,052)	(230,635)
Cash paid in connection with acquisitions	—	—	(26,031)
Net cash provided from the purchase and sale of short-term investments	—	1,005,829	435,938
Proceeds from sale of license	—	—	200,001
Net cash (used in) provided by investing activities	(9,134)	968,777	379,273
<b>Cash flows from financing activities:</b>			
Repayments of notes payable to stockholders	—	—	(884,902)
Proceeds (costs) related to sale of common stock, net	7,852,185	(15,257)	25,896,262
Proceeds from sale of preferred stock, net	—	—	9,046,176
Proceeds from exercise of warrants and stock options	7,228	—	138,219
Other, net	—	—	235,214
Net cash provided by (used in) financing activities	7,859,413	(15,257)	34,430,969
Net (decrease) increase in cash and cash equivalents	(2,379,432)	6,797,218	649,686

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Cash and cash equivalents at beginning of period	3,029,118	9,826,336	—
Cash and cash equivalents at end of period	\$ 649,686	\$ 3,029,118	\$ 649,686
Supplemental disclosure of cash flow information:			
Interest paid	\$ 475	\$ 1,665	\$ 26,033
Supplemental disclosure of noncash investing and financing activities:			
Common stock issued in satisfaction of accounts payable	\$ 20,000	\$ —	\$ 770,000
Imputed preferred stock dividend	—	—	418,182
Preferred stock dividends accrued	—	—	761,462
Conversion of preferred stock to common stock	—	—	1,067
Preferred stock dividends paid by issuance of shares	—	—	759,134
Issuance of common stock for acquisitions	—	—	13,389,226
Issuance of common stock in connection with in-licensing agreement	232,500		232,500
Marketable equity securities received in connection with sale of license	—	—	359,907
Warrants issued to consultant	83,670	—	83,670
Net liabilities assumed over assets acquired in business combination	—	—	(675,416)
Cashless exercise of warrants	6	27	33

See accompanying notes to consolidated financial statements.

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MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**(1) Merger and Nature of Operations**

***2003 Reverse Merger***

On February 21, 2003, the Company (formerly known as “Atlantic Technology Ventures, Inc.”) completed a reverse acquisition of privately held Manhattan Research Development, Inc. (“Manhattan Research”) (formerly Manhattan Pharmaceuticals, Inc.), a Delaware corporation. At the effective time of the merger, the outstanding shares of common stock of Manhattan Research automatically converted into shares of the Company’s common stock representing 80 percent of the Company’s outstanding voting stock after giving effect to the merger. Since the stockholders of Manhattan Research received the majority of the voting shares of the Company, the merger was accounted for as a reverse acquisition whereby Manhattan Research was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer) under the purchase method of accounting. In connection with the merger, the Company changed its name from “Atlantic Technology Ventures, Inc.” to “Manhattan Pharmaceuticals, Inc.” The results of the combined operations have been included in the Company’s financial statements since February 2003.

As described above, the Company resulted from the February 21, 2003 reverse merger between Atlantic Technology Ventures, Inc. (“Atlantic”), which was incorporated on May 18, 1993, and privately-held Manhattan Research Development, Inc., incorporated on August 6, 2001. The Company was incorporated in the State of Delaware. In connection with the merger, the former stockholders of Manhattan Research received a number of shares of Atlantic’s common stock so that following the merger they collectively owned 80 percent of the outstanding shares. Upon completion of the merger, Atlantic changed its name to Manhattan Pharmaceuticals, Inc. and thereafter adopted the business of Manhattan Research.

The Company is a clinical stage biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. The Company acquires rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have four product candidates in development: Hedrin™, a novel, non-insecticide treatment of pediculitis (head lice); Topical PTH (1-34) for the treatment of psoriasis; Altoderm™ (topical cromolyn sodium) for the treatment of pruritus associated with dermatologic conditions including atopic dermatitis; and Altolyn™ (oral tablet cromolyn sodium) for the treatment of mastocytosis. During 2007, the Company discontinued development of Oleoyl-estrone and Propofol Lingual Spray.

***Acquisition of Tarpan Therapeutics, Inc.***

On April 1, 2005, the Company entered into an Agreement and Plan of Merger (the “Agreement”) with Tarpan Therapeutics, Inc., a Delaware corporation (“Tarpan”), and Tarpan Acquisition Corp., a Delaware corporation and wholly-owned subsidiary of the Company (“TAC”). Under the Agreement TAC merged with and into Tarpan, with Tarpan remaining as the surviving corporation and a wholly-owned subsidiary of the Company (the “Merger”). The Merger was completed April 1, 2005. In consideration for their shares of Tarpan capital stock and in accordance with the Agreement, the stockholders of Tarpan received 10,731,052 shares of the Company’s common stock such that, upon the effective time of the Merger, the Tarpan stockholders collectively received approximately 20 percent of the Company’s then outstanding common stock on a fully-diluted basis. Based on the five day average price of the Company’s common stock of \$1.03 per share, the value of the shares issued totaled \$11,052,984. In addition, there were \$166,184 of acquisition costs. At the time of the Merger, Tarpan had outstanding indebtedness of \$651,000 (inclusive of 5% accrued interest) resulting from a series of promissory notes issued to Paramount BioCapital Investments, LLC and Horizon BioMedical Ventures, LLC, both of which are owned or controlled by Dr. Lindsay

Rosenwald. The notes were repaid in full by the Company in two installments on April 15, 2005 and September 6, 2005.

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MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
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The acquisition of Tarpan has been accounted for by the Company under the purchase method of accounting in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 141 “Business Combinations”. Under the purchase method, assets acquired and liabilities assumed by the Company are recorded at their estimated fair values and the results of operations of the acquired company are consolidated with those of the Company from the date of acquisition.

Several of Tarpan’s former stockholders were directors or significant stockholders of the Company at the time of the transaction. Dr. Rosenwald and various trusts established for the benefit of Dr. Rosenwald and members of his immediate family collectively beneficially owned approximately 46 percent of Tarpan’s common stock and beneficially owned approximately 26 percent of the Company’s common stock at the time of the transaction. In addition, Joshua Kazam, David Tanen, Dr. Michael Weiser and Timothy McInerney, all of whom were members of the Company’s board of directors at the time of the transaction, collectively owned approximately 13.4 percent of Tarpan’s outstanding common stock. At the time of the transaction, Dr. Weiser and Mr. McInerney were employed by Paramount BioCapital, Inc., an entity owned and controlled by Dr. Rosenwald. As a result of such relationships between the Company and Tarpan, the Company’s board of directors established a special committee to consider and approve the Agreement. The members of the special committee did not have any prior relationship with Tarpan.

The excess purchase price paid by the Company to acquire the net assets of Tarpan was allocated to acquired in-process research and development totaling \$11,887,807. As required by Financial Accounting Standards Board (“FASB”) Interpretation No. 4, “Applicability of FASB Statement No. 2 to Business combinations Accounted for by the Purchase Method” (“FIN 4”), the Company recorded a charge in its consolidated statement of operations for the year ended December 31, 2005 for the in-process research and development. Tarpan was a biopharmaceutical company engaged in the development of the Phase II pharmaceutical product candidate, PTH (1-34).

## **(2) Liquidity and Basis of Presentation**

### ***Liquidity***

The Company incurred a net loss of \$12,032,252 and negative cash flows from operating activities of \$10,229,711 for the year ended December 31, 2007 and a net loss of \$9,695,123 and negative cash flows from operating activities of \$7,750,738 for the year ended December 31, 2006. The net loss applicable to common shares from date of inception, August 6, 2001, to December 31, 2007 amounts to \$54,999,070.

The Company received approximately \$7.9 million net from a private placement of common stock and warrants in March 2007. This private placement is more fully described in Note 5.



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The Company received approximately \$2.0 million from a joint venture agreement in February 2008. This joint venture agreement is more fully described in Note 12.

Management believes that the Company will continue to incur net losses through at least December 31, 2008 and for the foreseeable future thereafter. Based on the resources of the Company available at December 31, 2007 and the net proceeds received from the February 2008 joint venture agreement management does not believe that the Company has sufficient capital to fund its operations through 2008. Management believes that the Company will need additional equity or debt financing or will need to generate revenues through licensing of its products or entering into strategic alliances to be able to sustain its operations through 2008. Furthermore, we will need additional financing thereafter to complete development and commercialization of our products. There can be no assurances that we can successfully complete development and commercialization of our products.

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

The Company's continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances and its ability to realize the full potential of its technology in development. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long-term.

### **(3) Summary of Significant Accounting Policies**

#### ***Basis of Presentation***

The Company has not generated any revenue from its operations and, accordingly, the consolidated financial statements have been prepared in accordance with the provisions of SFAS No.7, "Accounting and Reporting by Development Stage Enterprises."

#### ***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. All of the Company's subsidiaries were dissolved as of December 31, 2006.

#### ***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.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Research and Development**

All research and development costs are expensed as incurred and include costs of consultants who conduct research and development on behalf of the Company and its 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.

The Company often contracts 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, the Company records monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contracts.

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

***Acquired in-process research and development***

Costs to acquire in-process research and development projects and technologies which have no alternative future use at the date of acquisition are expensed.

***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

***Computation of Net Loss per Common Share***

Basic net loss per common share is calculated by dividing net loss applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect because the Company incurred a net loss during each period presented. The amounts of potentially dilutive securities excluded from the calculation were 16,903,292 and 13,383,229 shares at December 31, 2007 and 2006, respectively.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
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**Share-Based Compensation**

The Company has stockholder-approved stock incentive plans for employees, directors, officers and consultants. Prior to January 1, 2006, the Company 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, the Company 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 the Company to expense the fair value of all employee options over the vesting period. Under the modified prospective transition method, the Company recognized compensation cost for the years ended December 31, 2007 and 2006 which includes a) period compensation cost related to share-based payments granted prior to, but not yet vested, as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement 123; and b) period compensation cost related to share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with Statement 123(R). In accordance with the modified prospective method, the Company has not restated prior period results.

The Company recognizes compensation expense related to stock option grants on a straight-line basis over the vesting period. For the years ended December 31, 2007 and 2006, the Company recognized share-based employee compensation cost of \$1,447,560 and \$1,670,661, respectively, in accordance with Statement 123(R). \$890,124 of the \$1,447,560 of expense recognized in 2007 resulted from the grant of stock options to officers, directors, and employees of the Company on or prior to December 31, 2005. \$1,500,690 of the \$1,670,661 of the expense recognized in 2006 resulted from the grants of stock options to officers, directors and employees of the Company on or prior to December 31, 2005. The balances for the years ended December 31, 2007 and 2006 of \$557,436 and \$169,971, respectively, relate to the granting of stock options to employees and officers on or after January 1, 2006. The Company did not capitalize any share-based compensation cost.

Options granted to consultants and other non-employees are accounted for in accordance with EITF No. 96-18 "Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services". Accordingly, such options are recorded at fair value at the date of grant and subsequently adjusted to fair value at the end of each reporting period until such options vest, and the fair value of the options, as adjusted, is amortized to consulting expense over the related vesting period. As a result of adjusting consultant and other non-employee options to fair value as of December 31, 2007 and 2006 respectively, net of amortization, the Company recognized an increase to general and administrative and research and development expenses of \$6,604 for the year ended December 31, 2007 and a reduction to general and administrative and research and development expenses of \$4,838 for the year ended December 31, 2006.

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

	2007	2006
<b>General and administrative expense:</b>		
Share-based employee compensation cost	\$ 891,897	\$ 1,176,618
Share-based consultant and non-employee cost	10,550	(29,842)
	\$ 902,447	\$ 1,146,776
<b>Research and development expense</b>		
Share-based employee compensation cost	\$ 555,663	\$ 494,043
Share-based consultant and non-employee cost	(17,154)	34,680
	\$ 538,509	\$ 528,723
<b>Total share-based cost</b>	<b>\$ 1,440,956</b>	<b>\$ 1,675,499</b>

As a result of adopting Statement 123(R), net loss for the year ended December 31, 2006 was greater than if the Company had continued to account for share-based compensation under APB 25 by approximately \$1,671,000. The effect of adopting Statement 123(R) on basic and diluted earnings per share for the year ended December 31, 2006 was \$0.03 per share.

To compute compensation expense in 2007 and 2006 the Company estimated the fair value of each option award on the date of grant using the Black-Scholes model. The Company based the expected volatility assumption on a volatility index of peer companies as the Company did not have a sufficient number of years of historical volatility of its common stock for the application of Statement 123 (R). The expected term of options granted represents the period of time that options are expected to be outstanding. The Company estimated the expected term of stock options by the simplified method as prescribed in Staff Accounting Bulletin No. 107. The expected forfeiture rates are based on the historical employee forfeiture experiences. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company has not declared a dividend on its common stock since its inception and has no intentions of declaring a dividend in the foreseeable future and therefore used a dividend yield of zero.

The following table shows the weighted average assumptions the Company used to develop the fair value estimates for the determination of the compensation charges in 2007 and 2006:

	2007	2006
Expected volatility	93%	84% - 98%
Dividend yield	—	—
Expected term (in years)	5 - 10	5 - 10
Risk-free interest rate	3.6% - 4.9%	4.45% - 5.1%
Forfeiture rate	7%	4%



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***Financial Instruments***

At December 31, 2007 and 2006, the fair values of cash and cash equivalents and accounts payable approximate their carrying values due to the short-term nature of these instruments.

***Cash and Cash Equivalents***

Cash equivalents consist of cash or short term investments with original maturities at the time of purchase of three months or less.

***Property and Equipment***

Property and equipment are stated at cost. Depreciation is provided using the straight-line method over estimated useful lives. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in operations for the period. Amortization of leasehold improvements is calculated using the straight-line method over the remaining term of the lease or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged to operations as incurred; significant renewals and improvements are capitalized.

***Short-term Investments***

Short-term investments are carried at market value since they are marketable and considered available-for-sale. The Company did not have any short-term investments at December 31, 2007 or 2006.

***New Accounting Pronouncements***

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

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

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

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

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

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

#### (4) Property and Equipment

Property and equipment consists of the following at December 31:

	2007	2006
Property and equipment	\$ 226,010	\$ 244,040
Less accumulated depreciation	(181,477)	(160,297)
Net property and equipment	\$ 44,533	\$ 83,743





MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
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**(5) Stockholders' Equity**

As described in Note 1 the Company completed a reverse acquisition of privately held Manhattan Research Development, Inc. on February 21, 2003. In July 2003, the Board of Directors adopted a resolution authorizing an amendment to the certificate of incorporation providing for a 1-for-5 combination of the Company's common stock. The resolution approving the 1-for-5 combination was thereafter consented to in writing by holders of a majority of the Company's outstanding common stock and became effective in September 2003. Accordingly, all share and per share information in these consolidated financial statements has been restated to retroactively reflect the 1-for-5 combination and the effects of the Reverse Merger.

**2001**

During 2001, the Company issued 10,167,741 shares of its common stock to investors for subscriptions receivable of \$4,000 or \$0.0004 per share. During 2002, the Company received the \$4,000 subscription receivable.

**2002**

During 2002, the Company issued 2,541,935 shares of its common stock to Oleoyl-estrone Developments, S.L. ("OED") in conjunction with a license agreement (the OED License Agreement"), as more fully described in Note 8. We valued these shares at their then estimated fair value of \$1,000.

During 2002, the Company issued options to purchase 1,292,294 shares of its common stock in conjunction with several consulting agreements. The fair value of these options was \$60,589. The Company expensed \$22,721 in 2002 and \$37,868 in 2003.

During 2002 and 2003 the Company completed two private placements. During 2002, the Company issued 3,043,332 shares of its common stock at \$0.63 per share and warrants to purchase 304,333 of its common stock in a private placement. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$1,704,318.

**2003**

During 2003, the Company issued an additional 1,321,806 shares of its common stock at \$0.63 per share and warrants to purchase 132,181 shares of its common stock. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$743,691. In connection with these private placements, the Company issued to the placement agent warrants to purchase 1,658,753 shares of its common stock.

As described in Note 1, during 2003, the Company completed a reverse acquisition. The Company issued 6,287,582 shares of its common stock with a value of \$2,336,241 in the reverse acquisition.

In November 2003, the Company issued 1,000,000 shares of its newly-designated Series A Convertible Preferred Stock (the "Convertible Preferred") at a price of \$10 per share in a private placement. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$9,046,176. Each share of Convertible Preferred was convertible at the holder's election into shares of the Company's common stock at a conversion price of \$1.10 per share. The conversion price of the Convertible Preferred was less than the market value of the Company's common stock on the date of issuance. Accordingly for the year ended December 31, 2003 the Company recorded a separate charge to deficit accumulated during development stage for the beneficial conversion feature associated with the issuance of Convertible Preferred of \$418,182. The Convertible Preferred had a payment-in-kind annual dividend of five percent. Maxim Group, LLC of New York, together with Paramount Capital,

Inc., a related party, acted as the placement agents in connection with the private placement.

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**2004**

During 2004, the Company issued 3,368,952 shares of its common stock at a price of \$1.10 per share in a private placement. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$3,361,718. In connection with the common stock private placement and the Convertible Preferred private placement, the Company issued to the placement agents a warrant to purchase 1,235,589 shares of its common stock.

During 2004 the Company recorded a dividend on the Convertible Preferred of \$585,799. 24,901 shares of Convertible Preferred were issued in payment of \$282,388 of this in-kind dividend. Also during 2004, 170,528 shares of Convertible Preferred were converted into 1,550,239 shares of the Company's common stock at \$1.10 per share.

During 2004 the Company issued 27,600 shares of common stock upon the exercise of stock options.

During 2004, the Company issued warrant to purchase 110,000 shares of its common stock in conjunction with three consulting agreements. The fair value of these warrants was \$120,968. The Company expensed \$100,800 in 2004 and \$20,168 in 2005.

**2005**

In August 2005, the Company issued 11,917,680 shares of its common stock and warrants to purchase 2,383,508 shares of its common stock in a private placement at \$1.11 and \$1.15 per share. After deducting commissions and other expenses relating to the private placement the Company received net proceeds of \$12,250,209. Paramount BioCapital, Inc. ("Paramount"), an affiliate of a significant stockholder of the Company, acted as placement agent and was paid cash commissions and expenses of \$967,968 of which \$121,625 was paid to certain selected dealers engaged by Paramount in the private placement. The Company also issued warrants to purchase 595,449 shares of common stock to Paramount and certain select dealers, of which Paramount received warrants to purchase 517,184 common shares. Timothy McInerney and Dr. Michael Weiser, each a director of the Company, were employees of Paramount BioCapital, Inc. at the time of the transaction.

During 2005 the Company recorded a dividend on the Convertible Preferred of \$175,663. 41,781 shares of Convertible Preferred were issued in payment of this \$175,663 in-kind dividend and the unpaid portion of the 2004 in-kind dividend, \$303,411. Also during 2005, the remaining 896,154 shares of Convertible preferred were converted into 8,146,858 shares of the Company's common stock.

During 2005, the Company issued 675,675 shares of its common stock at \$1.11 per share and warrants to purchase 135,135 shares of its common stock to Cato BioVentures, an affiliate of Cato Research, Inc., in exchange for satisfaction of \$750,000 of accounts payable owed by the Company to Cato Research, Inc. Since the value of the shares and warrants issued was approximately \$750,000, there is no impact on the statement of operations for this transaction.

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During 2005 the Company issued 312,245 shares of common stock upon the exercise of stock options and warrants.

As described in Note 1, in April 2005, the Company completed the Merger with Tarpan. In accordance with the Agreement, the stockholders of Tarpan received 10,731,052 shares of the Company's common stock with a value of \$11,052,984.

**2006**

During 2006 the Company issued 27,341 shares of common stock upon the exercise of warrants.

**2007**

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

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

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

**(6) Stock Options**

***2003 Stock Option Plan***

In December 2003, the Company established the 2003 Stock Option Plan (the "2003 Plan"), which provided for the granting of up to 5,400,000 options to officers, directors, employees and consultants for the purchase of stock. In August 2005, the Company increased the number of shares of common stock reserved for issuance under the 2003 Plan by 2,000,000 shares. At December 31, 2006, 7,400,000 shares were authorized for issuance. In May 2007, the Company increased the number of shares of common stock reserves for issuance under the 2003 Plan by 3,000,000 shares. At December 31, 2007, 10,400,000 shares were authorized for issuance. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally 3 years) and are issued at an exercise price equal to or greater than the fair market value of the shares at the date of grant. The 2003 Plan expires on December 10, 2013 or when all options have been granted, whichever is sooner. Under the 2003 Plan, the Company granted employees options to purchase an aggregate of 870,000 shares of common stock at an exercise price of \$0.95, 75,000 shares of common stock at an exercise price of \$0.82 and 397,500 shares of common stock at an

exercise price of \$0.72 during the year ended December 31, 2007. In addition, 27,776 shares of common stock were issued during 2007 under the 2003 Plan.

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At December 31, 2007 there were 3,475,626 shares reserved for future grants under the 2003 Plan.

***1995 Stock Option Plan***

In July 1995, the Company established the 1995 Stock Option Plan (the "1995 Plan"), which provided for the granting of options to purchase up to 130,000 shares of the Company's common stock to officers, directors, employees and consultants. The 1995 Plan was amended several times to increase the number shares reserved for stock option grants. In June 2005 the 1995 Plan expired and no further options can be granted. At December 31, 2007 options to purchase 1,137,240 shares were outstanding and no shares were reserved for future stock option grants under the 1995 Plan.

A summary of the status of the Company's stock options as of December 31, 2007 and changes during the year then ended is presented below:

	2007			
	Shares	Weighted average exercise price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at beginning of year	7,000,504	\$ 1.310		
Granted	1,342,500	\$ 0.875		
Exercised	-			
Cancelled	(309,166)	\$ 0.336		
Outstanding at end of year	8,033,838	\$ 1.253	6.887	\$
Options exercisable at year-end	5,601,714	\$ 1.263	6.625	\$
Weighted-average fair value of options granted during the year	\$ 0.63			

As of December 31, 2007 and 2006, the total compensation cost related to non-vested option awards not yet recognized is \$539,046 and \$1,365,581, respectively. The weighted average period over which it is expected to be recognized is approximately 0.5 and 0.9 years, respectively.

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The following table summarizes the information about stock options outstanding at December 31, 2007:

Exercise Price	Number of Options Outstanding	Remaining Contractual Life (years)	Number of Options Exercisable
\$ 0.40	876,090	5.16	876,090
0.43	400	5.15	400
0.70	220,000	8.53	73,333
0.72	365,000	9.09	32,500
0.82	75,000	9.08	-
0.89	16,667	8.38	16,667
0.95	670,000	9.32	100,000
0.97	440,000	6.75	440,000
1.00	65,000	4.24	65,000
1.00	290,698	7.04	290,698
1.25	12,000	4.08	12,000
1.25	163,750	4.14	163,750
1.35	108,333	8.08	64,999
1.35	300,000	8.09	300,000
1.35	60,000	8.53	20,000
1.50	2,923,900	7.25	1,949,277
1.50	250,000	2.58	25,000
1.60	100,000	7.46	75,000
1.65	1,077,000	6.08	1,077,000
4.38	10,000	3.14	10,000
20.94	10,000	2.28	10,000
Total	8,033,838		5,601,714

### (7) Stock Warrants

The following table summarizes the information about warrants to purchase shares of our common stock outstanding at December 31, 2007:

Exercise price	Number of Warrants outstanding	Remaining contractual life (years)	Number of warrants exercisable
\$ 0.28	150,000	4.64	150,000
0.78	10,000	1.98	10,000
1.00	3,564,897	4.25	3,564,897
1.00	509,275	4.25	509,275
1.10	909,090	.85	909,090
1.10	326,499	1.04	326,499
1.44	2,161,767	2.65	2,161,767

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1.44	540,449	2.65	540,449
1.44	135,135	2.65	135,135
1.49	221,741	2.67	221,741
1.49	55,000	2.67	55,000
1.90	10,000	1.21	10,000
1.90	90,000	1.21	90,000
6.69	185,601	.10	185,601
Total	8,869,454		8,869,454

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**(8) Related-Party Transactions**

**Oleolestrotrone Developments, SL**

The Company entered into a consulting agreement with OED. The agreement became effective in February 2002, at a fee of \$6,250 per month. The agreement was terminated in November 2007. The fees associated with the consulting agreement are expensed as incurred. OED currently owns approximately 5.7 percent of the Company's outstanding common stock. Additionally, Mr. Pons, chief executive officer of OED, was a member of the Company's board of directors until his resignation in July 2007.

Total milestone payments under the license agreement of \$0, \$250,000 and \$675,000 and consulting fees of \$68,750, \$75,000 and \$431,250 are included in the accompanying consolidated statements of operations for the years ended December 31, 2007, 2006 and for the cumulative period from August 6, 2001 to December 31, 2007.

**Paramount BioCapital, Inc.**

One member of the Company's board of directors, Timothy McInerney, was an employee of Paramount or one of its affiliates until April 2007. Another member of the Company's board of directors, Michael Weiser, was an employee of Paramount until December 2006. In addition, two former members of the Company's board of directors, Joshua Kazam and David Tanen, were employed by Paramount through August 2004 and were directors of the Company until September 2005. The sole shareholder of Paramount is Lindsay A. Rosenwald, M.D. Dr. Rosenwald beneficially owns more than 5 percent of the Company's common stock as of December 31, 2007 and various trusts established for Dr. Rosenwald's or his family's benefit, held in excess of 12% of the Company's common stock as of December 31, 2007. In November 2003, the Company paid to Paramount approximately \$460,000 as commissions earned in consideration for placement agent services rendered in connection with the private placement of the Company's Series A Convertible Preferred Stock, which amount represented 7 percent of the value of the shares sold by Paramount in the offering. In addition, in January 2004, the Company paid approximately \$260,000 as commissions earned in consideration for placement agent services rendered by Paramount in connection with a private placement of the Company's common stock, which amount represented 7 percent of the value of the shares sold by Paramount in the private placement. In connection with both private placements and as a result of their employment with Paramount, Mr. Kazam, Mr. McInerney and Dr. Weiser were allocated 5-year placement agent warrants to purchase 60,174, 58,642 and 103,655 shares of the Company's common stock, respectively, at a price of \$1.10 per share.

Paramount also served as the Company's placement agent in connection with the August 2005 private placement. As placement agent, the Company paid to Paramount total cash commissions of \$839,816 relating to the August 26, 2005 closing, of which \$121,625 was paid to certain selected dealers engaged by Paramount in connection with the private placement and issued five-year warrants to purchase an aggregate of 540,449 shares of common stock exercisable at a price of \$1.44 per share, of which Paramount received warrants to purchase 462,184 common shares. In connection with the August 30 closing, the Company paid cash commissions to Paramount of \$88,550 and issued an additional five-year warrant to purchase 55,000 common shares exercisable at a price of \$1.49 per share.

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Paramount also served as the Company's placement agent in connection with the March 2007 private placement. As placement agent, the Company paid to Paramount aggregate cash commissions of approximately \$600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares of common stock at an exercise price of \$1.00 per share.

**(9) Income Taxes**

There was no current or deferred tax expense for the years ended December 31, 2007 or 2006 because of the Company's operating losses.

The components of deferred tax assets as of December 31, 2007 and 2006 are as follows:

	2007	2006
Deferred tax assets:		
Tax loss carryforwards	\$ 22,513,000	\$ 18,265,000
Research and development credit	1,769,000	1,374,000
In-process research and development charge	4,850,000	4,850,000
Stock based compensation	1,270,000	682,000
Other	85,000	29,000
Gross deferred tax assets	30,487,000	25,200,000
Less valuation allowance	(30,487,000)	(25,200,000)
Net deferred tax assets	\$ —	\$ —

The reasons for the difference between actual income tax benefit for the years ended December 31, 2007 and 2006 and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit are as follows:

	2007		2006	
	Amount	% of pretax loss	Amount	% of pretax loss
Federal income tax benefit at statutory rate	\$ (4,102,000)	(34.0)%	\$ (3,296,000)	(34.0)%
State income taxes, net of federal tax	(820,000)	(6.8)%	(659,000)	(6.8)%
Research and development credits	(366,000)	(3.0)%	(200,000)	(1.7)%
Other	1,000	0.0%	(166,000)	(2.1)%
Change in valuation allowance	5,287,000	43.8%	4,321,000	44.6%
	—	—%	—	—%

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A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2007 and 2006 was an increase of \$5,287,000 and \$4,321,000, respectively. The tax benefit assumed using the federal statutory tax rate of 34% has been reduced to an actual benefit of zero due principally to the aforementioned valuation allowance.

At December 31, 2007, the Company had unused federal and state net operating loss carryforwards of approximately \$56,963,000 and \$46,261,000, respectively. The net operating loss carryforwards expire in various amounts through 2027 for federal and state income tax purposes. The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss carryforwards in the case of certain events including significant changes in ownership interests. Accordingly, a substantial portion of the Company's net operating loss carryforwards above will be subject to annual limitations (currently approximately \$100,000) in reducing any future year's taxable income. At December 31, 2007, the Company also had research and development credit carryforwards of approximately \$1,769,000 for federal income tax purposes which expire in various amounts through 2027.

The Company files income tax returns in the U.S. Federal, State and Local jurisdictions. With certain exceptions, the Company is no longer subject to U.S. federal and state income tax examinations by tax authorities for years prior to 2004. The Company adopted the provisions of FIN 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" on January 1, 2007 with no material impact to the consolidated financial statements. The Company had no unrecognized tax benefits during 2007 that would affect the annual effective tax rate and no unrecognized tax benefits as of January 1, 2007 and December 31, 2007. Further, the Company is unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

#### **(10) License and Consulting Agreements**

##### **IGI Agreement for PTH (1-34)**

On April 1, 2005, as part of the acquisition of Tarpan Therapeutics, Inc., the Company acquired a Sublicense Agreement with IGI, Inc. (the "IGI Agreement") dated April 14, 2004. Under the IGI Agreement the Company received the exclusive, world-wide, royalty bearing sublicense to develop and commercialize the licensed technology (see Note 1). Under the terms of the IGI Agreement, the Company is responsible for the cost of the preclinical and clinical development of the project, including research and development, manufacturing, laboratory and clinical testing and trials and marketing of licensed products for which the company will be responsible.

In consideration for the Company's rights under the IGI Agreement, a payment of \$300,000 was made upon execution of the agreement, prior to the Company's acquisition of Tarpan. In addition the IGI Agreement requires the Company 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.

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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. At December 31, 2007 this \$300,000 liability is reflected in accounts payable.

In addition, the Company is obligated to pay IGI, Inc. an annual royalty of 6% annual net sales on annual net sales up to \$200,000,000. In any calendar year in which net sales exceed \$200,000,000, the Company is obligated to pay IGI, Inc. an annual royalty of 9% annual net sales. Through December 31, 2007, the Company has not paid any such royalties.

IGI, Inc. may terminate the agreement (i) upon 60 days' notice if the Company fails to make any required milestone or royalty payments, or (ii) if the Company becomes bankrupt or if a petition in bankruptcy is filed, or if the Company is 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 the Company commits a material breach or default. Eighteen months from the date of the IGI Agreement, the Company may terminate the agreement in whole or as to any portion of the PTH patent rights upon 90 days' notice to IGI, Inc.

#### **Hedrin License Agreement**

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

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

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

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In February 2008 the Company assigned and transferred its rights in Hedrin to joint venture, see note 12- Subsequent Events, Joint Venture with Nordic.

**Altoderm License Agreement**

On April 3, 2007, the Company entered into a license agreement for "Altoderm" (the "Altoderm Agreement") with T&R. Pursuant to the Altoderm Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate using sodium cromoglicate for the treatment of atopic dermatitis. In accordance with the terms of the Altoderm Agreement, the Company issued 125,000 shares of its common stock, valued at \$112,500, and made a cash payment of \$475,000 to T&R upon the execution of the agreement. These amounts have been included in research and development expense. Further, the Company agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 and 875,000 shares of common stock upon the achievement of various clinical and regulatory milestones. The Company also agreed to pay royalties on net sales of products using the licensed patent rights at rates ranging from 10% to 20%, depending on the level of annual net sales, and subject to an annual minimum royalty payment of \$1 million in each year following the first commercial sale of Altoderm. The Company may sublicense the patent rights. The Company agreed to pay T&R 30% of the royalties received by the Company under such sublicense agreements.

**Altolyn License Agreement**

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

**OED License Agreement for Oleoyl-estrone**

On February 15, 2002, the Company entered into a License Agreement (the "License Agreement") with OED. Under the terms of the License Agreement, OED granted to the Company a world-wide license to make, use, lease and sell the products incorporating the licensed technology (see Note 1). OED also granted to the Company the right to sublicense to third parties the licensed technology or aspects of the licensed technology with the prior written consent of OED. OED retains an irrevocable, nonexclusive, royalty-free right to use the licensed technology solely for its internal, noncommercial use. The License Agreement shall terminate automatically upon the date of the last to expire patent contained in the licensed technology or upon the Company's bankruptcy. OED may terminate the License Agreement in the event of a material breach by the Company that is not cured within the notice period. The Company may terminate the License Agreement for any reason upon 60 days notice. The Company terminated this agreement in November 2007.

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In addition to the License Agreement, the Company entered into a consulting agreement with OED. The agreement became effective in February 2002, at a fee of \$6,250 per month, and terminated when the License Agreement terminated. The fees associated with the consulting agreement are expensed as incurred.

Under the License Agreement, the Company agreed to pay to OED certain licensing fees which are being expensed as they are incurred. The Company paid \$175,000 in up front licensing fees which is included in 2002 research and development expense. In addition, pursuant to the License Agreement, the Company issued 1,000,000 shares of its common stock to OED. The Company valued these shares at their then estimated fair value of \$1,000.

In connection with the License Agreement, the Company has agreed to milestone payments to OED as follows:

(i) \$250,000 upon the treatment of the first patient in a Phase I clinical trial under a Company-sponsored investigational new drug application ("IND"), which was paid in 2005; (ii) \$250,000 upon the treatment of the first patient in a Phase II clinical trial under a Company-sponsored IND, which was paid in 2006; (iii) \$750,000 upon the first successful completion of a Company-sponsored Phase II clinical trial under a Company-sponsored IND; (iv) \$2,000,000 upon the first successful completion of a Company-sponsored Phase III clinical trial under a Company sponsored IND; and (v) \$6,000,000 upon the first final approval of the first new drug application for the first licensed product by the United States Food and Drug Administration ("FDA"). Through December 31, 2007, the Company paid a total of \$675,000 in licensing fees and milestone payments. The Company has no further financial liability or commitment to OED under the License Agreement.

**NovaDel Agreement for Propofol Lingual Spray**

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

In consideration for the Company's rights under the NovaDel license agreement, the Company paid NovaDel an initial license fee of \$500,000 in 2003. In addition, the license agreement requires the Company to make certain milestone payments as follows: \$1,000,000 payable following the date that the first NDA for lingual spray propofol is accepted for review by the FDA; \$1,000,000 following the date that the first European Marketing Application is accepted for review by any European Union country; \$2,000,000 following the date when the first filed NDA for lingual spray propofol is approved by the FDA; \$2,000,000 following the date when the first filed European Marketing Application for lingual spray propofol is accepted for review; \$1,000,000 following the date on which an application for commercial approval of lingual spray propofol is approved by the appropriate regulatory authority in each of Australia, Canada, Japan and South Africa; and \$50,000 following the date on which an application for commercial approval for lingual spray propofol is approved in any other country (other than the U.S., a member of the European Union, Australia, Canada, Japan or South Africa).

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In addition, the Company is obligated to pay to NovaDel an annual royalty based on a fixed rate of net sales of licensed products, or if greater, the annual royalty is based on the Company's net profits from the sale of licensed products at a rate that is twice the net sales rate. In the event the Company sublicenses the licensed product to a third party, the Company is obligated to pay royalties based on a fixed rate of fees or royalties received from the sublicensee until such time as the Company recovers its out-of-pocket costs, and thereafter the royalty rate doubles. Because of the continuing development efforts required of NovaDel under the agreement, the royalty rates are substantially higher than customary for the industry. Through December 31, 2007, the Company has incurred, and paid a total of \$500,000 under the NovaDel license agreement, the initial license fee paid in 2003. The Company terminated this agreement during 2007 and has no continuing obligations under this agreement.

**(11) Commitments and Contingencies**

***Swiss Pharma***

Swiss Pharma Contract LTD ("Swiss Pharma"), a clinical site that the Company used in one of its obesity trials, gave notice to the Company that Swiss Pharma believes it is entitled to receive an additional payment of \$322,776 for services in connection with that clinical trial. While the contract between the Company and Swiss Pharma provides for additional payments if certain conditions are met, Swiss Pharma has not specified which conditions they believe have been achieved and the Company does not believe that Swiss Pharma is entitled to additional payments and has not accrued any of these costs as of December 31, 2007. The contract between the Company and Swiss Pharma provides for arbitration in the event of a dispute, such as this claim for an additional payment. Swiss Pharma has filed a demand for arbitration. As the Company does not believe that Swiss Pharma is entitled to additional payments, it intends to defend its position in arbitration. The arbitration is currently in its initial stages.

***Therapeutics, Inc.***

During 2007, we entered into an agreement with Therapeutics, Inc. for the conduct of a Phase 2a clinical trial of PTH (1-34). The amount of the agreement is approximately \$845,000. At December 31, 2007, we recognized research and development expense of \$483,000 related to the conduct of this clinical trial. At December 31, 2007, we recognized prepaid expense of \$19,000 related to this clinical trial. The remaining financial commitment related to the conduct of the clinical trial is approximately \$340,000. This clinical trial is expected to conclude in the second quarter of 2008.

***Contentions of a Former Employee***

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

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**Employment Agreement**

The Company has employment agreements with two employees for the payment of aggregate annual base salary of \$530,000 as well as performance based bonuses. These agreements have three year terms and have a remaining obligation of \$394,000 as of December 31, 2007.

**Leases**

The Company leases office space under a non-cancellable lease terminating in September 2008. Rent expense was \$141,012 for each of the years ended December 31, 2007 and 2006.

Future minimum rental payments subsequent to December 31, 2007 under an operating lease for the Company's office facility are as follows:

Years Ending December 31,	Commitment
2008	\$ 100,000
2009 and subsequent	\$ 0

**12. Subsequent events****Joint Venture with Nordic**

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

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

Should the Hedrin JV be successful in achieving a payment milestone, namely that by September 30, 2008, the FDA determines to treat Hedrin as a medical device, Nordic will purchase an additional \$2.5 million of equity in the Hedrin JV, whereupon the Hedrin JV will pay the Company an additional \$1.5 million in cash and issue to the Company an additional \$2.5 million in equity in the Hedrin JV, thereby maintaining the Company's 50% ownership interest in the Hedrin JV.

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

The Hedrin JV will engage the Company to provide management services to the Limited Partnership in exchange for an annualized management fee, which for 2008, on an annualized basis, is \$527,000.





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

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

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

The Hedrin JV 's Board will consist of 4 members, 2 appointed by the Company and 2 appointed by Nordic. Nordic has the right to appoint one of the directors as chairman of the Board. The chairman has certain tie breaking powers. In the event that the payment milestone described above is not achieved by June 30, 2008, then the Hedrin JV 's Board will increase to 5 members, 2 appointed by the Company and 3 appointed by Nordic.

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

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The Company will grant Nordic registration rights for the shares to be issued upon exercise of the warrant, the put or the call. The Company is required to file an initial registration statement within 10 calendar days of filing its Form 10-K for the year ended December 31, 2007. The Company is required to file additional registration statements, if required, within 45 days of the date the Company first knows that such additional registration statement was required. The Company is required to use commercially reasonable efforts to cause the registration statement to be declared effective by the Securities and Exchange Commission (“SEC”) within 105 calendar days from the filing date. If the Company fails to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of filing the Company will be required to pay to Nordic, or its assigns, an amount in cash, as partial liquidated damages, equal to 0.5% per month of the amount invested in the Hedrin JV by Nordic until the registration statement is declared effective by the SEC. In no event shall the aggregate amount payable by the Company exceed 9% of the amount invested in the Hedrin JV by Nordic.

The profits of the Hedrin JV will be shared by the Company and Nordic in accordance with their respective equity interests in Limited Partnership, which are currently 50% to each, except that Nordic will get a minimum guaranteed return from the Hedrin JV equal to 5% on Hedrin sales, as adjusted for any change in Nordic’s equity interest in the Limited Partnership. If the Hedrin JV realizes a profit equal to or greater than a 10% royalty on Hedrin sales, then profits will be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership. However, in the event of a liquidation of the Limited Partnership, Nordic’s distribution in liquidation will be at least equal to the amount Nordic invested in the Hedrin JV (\$5 million if the payment milestone described above is met, \$2.5 million if it is not met) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV. Further, in no event shall Nordic’s distribution in liquidation be greater than assets available for distribution in liquidation.

***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 are not in compliance with the continued listing standards at the end of the plan period, or if we do not make progress consistent with the plan during the period, AMEX staff may initiate delisting proceedings.

Under the terms of the Joint Venture Agreement, the number of potentially issuable shares represented by the put and call features of the Hedrin 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 be 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 estimate that obtaining stockholder approval to comply with AMEX regulations would take a minimum of 45 days to complete. We have discussed the financial viability exception with AMEX for several weeks and have neither received the exception nor been denied the exception. We determined that our financial condition required us to complete the

transaction immediately, and that the Company's financial viability depends on its completion of the transaction without further delay.

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Accordingly, to maintain the Company's financial viability, on February 28, 2008 we announced that we had formally notified the AMEX that we intend 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 ("OCTBB") under the symbol "MHAN". We intend to maintain corporate governance, disclosure and reporting procedures consistent with applicable law.

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**Index to Exhibits Filed with this Report**

Exhibit No.	Description
10.11	Separation Agreement between the Registrant and Alan G. Harris dated December 21, 2007.
10.19	Joint Venture Agreement between Nordic Biotech fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008.
10.20	Amendment No. 1, dated February 25, 2008, to the Joint Venture Agreement between Nordic Biotech fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008.
10.21	Assignment and Contribution Agreement between Hedrin Pharmaceuticals K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008.
10.22	Registration Rights Agreement between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008.
10.23	Amendment to Employment Agreement by and between Manhattan Pharmaceuticals, Inc. and Douglas Abel
23.1	Consent of J.H. Cohn LLP.
31.1	Certification of Principal Executive Officer.
31.2	Certification of Principal Financial Officer.
32.1	Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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