

MANHATTAN PHARMACEUTICALS INC  
Form 10KSB  
April 02, 2007

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

FORM 10-KSB

Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2006

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 issuer as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

36-3898269  
(IRS 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  
(Issuer's telephone number)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

| Title of each class             | Name of each exchange on which registered |
|---------------------------------|---|
| Common Stock, \$0.001 par value | American Stock Exchange                   |

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

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

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

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

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

The issuer's revenues for the fiscal year ended December 31, 2006 were \$0.

The aggregate market value of the common stock of the issuer held by non-affiliates of the issuer on March 20, 2007 based on the closing price of the common stock as reported on the American Stock Exchange on such date was \$41,204,541.

As of March 16, 2007 there were 60,120,038 outstanding shares of common stock, par value \$.001 per share.

Traditional Small Business Disclosure Format: Yes o No x

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the issuer's definitive Proxy Statement for its Annual Meeting of Stockholders to be held on May 24, 2007 (the "2007 Proxy Statement") are incorporated by reference into Part III of this Form 10-KSB, to the extent described in Part III. The 2007 Proxy Statement will be filed within 120 days after the fiscal year ended December 31, 2006.

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References to the “Company,” the “Registrant,” “we,” “us,” or “our” or in this Annual Report on Form 10-KSB 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-KSB 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 biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have three product candidates in development: Oleoyl-estrone, an orally administered small molecule for the treatment of obesity; topical PTH (1-34) for the treatment of psoriasis; and Lingual Spray Propofol for sedation prior to diagnostic, therapeutic or endoscopic procedures. In addition to the development of our current products, we are actively working to expand our product candidate pipeline. 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 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**

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

We hold an exclusive, worldwide license to develop and commercialize oral Oleoyl-estrone pursuant to a 2002 license agreement with Oleoyl-estrone Developments, SL, (“OED”) a Spanish corporation. We are currently conducting clinical studies of Oleoyl-estrone in two distinct patient populations. One clinical study is a multi-center, international Phase IIa in common obesity clinical trial being conducted at one clinical site in Europe and two clinical sites in the United States and the other study is a multi-center Phase IIa in morbid obesity being lead by St. Luke’s-Roosevelt Hospital Center, University Hospital of Columbia University in New York City.

Oral Oleoyl-estrone is a novel small molecule that has been shown to cause significant weight loss in preclinical animal studies. Oleoyl-estrone is a naturally occurring hormone. It was discovered and initially developed by researchers at the University of Barcelona (“UB”) in Spain.

#### *Mechanism of Action*

We have seen evidence in pre-clinical studies that Oleoyl-estrone has both central and peripheral mechanisms of action. Centrally, it is believed to act on the hypothalamus, resetting the body’s ponderostat, the “food control center” in the brain that detects and integrates signals that control both appetite and metabolic behavior. Peripherally, it is believed to decrease the activity of Lipoprotein Lipase (LPL) in white adipose tissue (WAT) and increases its activity in the skeletal muscle. This causes reduced storage of fat in the WAT and allows skeletal muscle to use fat as a preferential energy source.

#### *Preclinical and Clinical Development*

Extensive preclinical studies of Oleoyl-estrone have shown evidence of weight loss, sustained weight loss after dosing stops, and reduced food intake. These studies have also shown evidence of beneficial changes in blood glucose and cholesterol levels. This work is supported by 38 peer-reviewed journal publications over the past ten years.

In January 2005, the FDA accepted our investigational new drug application, or “IND” for the human clinical testing of Oleoyl-estrone. We completed Phase Ia and Ib clinical trials in 2005 and released data on both studies in October 2005. The objective of both dose-escalation studies was to determine the safety and tolerability of defined doses of orally administered Oleoyl-estrone in obese adult subjects.

The Phase Ia study involved 36 obese volunteers. Twelve of the 36 patients received placebo and 24 received a single dose in one of six strengths ranging from 1 mg to 150 mg. Oleoyl-estrone was shown to be well tolerated with no serious adverse events noted in this study.

The Phase Ib study was a seven day repeat dose study involving 24 obese volunteers in four cohorts of 6 patients each who received either placebo or Oleoyl-estrone in doses ranging from 10 mg to 150 mg once daily for seven consecutive days. The results indicated that Oleoyl-estrone was generally well tolerated at all doses and no serious adverse events were reported. There were also no clinically significant changes in the physical exams, vital signs, ECGs, coagulation and liver function tests. The study demonstrated evidence of greater weight loss among some of the Oleoyl-estrone treated groups compared with the placebo group as well as evidence of reduction in desire to eat, hunger levels, fasting glucose and LDL cholesterol. Important clinical laboratories findings included reversible, dose-dependent elevations in estrone and estradiol levels, as well as reductions in testosterone levels.

In March 2006, we commenced a Phase IIa clinical study of oral Oleoyl-estrone for the treatment of obesity. This randomized, double-blind, placebo-controlled, parallel group study is designed to evaluate the safety and preliminary efficacy of oral Oleoyl-estrone in 100 common obese male and female subjects. Enrollment in this study was completed in February 2007. We expect the last patient to complete the study in mid-June 2007, and we plan to complete data analysis in mid-July 2007.

This ongoing Phase IIa study is evaluating common obese adult subjects with a body mass index (BMI) of 27-38.9. Each subject has been randomized into one of four treatment groups to evaluate safety, preliminary efficacy, and pharmacokinetics of two 14-day dosing cycles of 5mg, 10mg, or 20mg of oral OE compared to placebo given once daily during each dosing cycle. Each 14-day dosing cycle is followed by a 28-day treatment free evaluation period. In addition to safety and tolerability, this Phase IIa study is also designed to further evaluate weight loss, maintenance of weight loss, and other therapeutic outcomes.





In the fourth quarter of 2006, we also commenced a Phase IIa clinical study of oral Oleoyl-estrone in morbidly obese male subjects. This study is being led by St.Luke's-Roosevelt Hospital Center, University Hospital of Columbia University College of Physicians and Surgeons. F. Xavier Pi-Sunyer, MD, is serving as Principal Investigator. The study is expected to conclude mid-year 2007.

This Phase IIa randomized, double-blind, placebo-controlled, parallel group study is designed to evaluate oral Oleoyl-estrone in approximately 24 morbidly obese male subjects with a body mass index (BMI) of 40-55. These subjects will be randomized into three treatment groups to evaluate the safety and efficacy of 10mg or 30mg of oral OE compared to placebo given once daily for 30 days. Subjects will be evaluated at Days 1, 15, and 30. A final follow-up visit will also occur at Day 60, 30 days after the final dose.

We consider oral Oleoyl-estrone as a potential out-licensing candidate. We plan to complete enough development work to ensure that, should the product candidate be out licensed, it will continue to be successful and maintain urgency in a larger partner's hands.

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

### *Market and Competition*

#### *Obesity*

Being overweight is defined as having a Body Mass Index (BMI) that is equal to or greater than 25; obesity is defined as having a BMI equal to or greater than 30. Morbid obesity is defined as having a BMI equal to or greater than 40 (usually equaling 100+ lbs over ideal weight).

The US Centers for Disease Control and Prevention (CDC) estimate there are approximately 70 million obese Americans, and according to the World Health Organization (WHO), there are nearly 300 million obese adults worldwide. Obesity is a major health risk and a burden on the US healthcare system. It increases the risk of type 2 diabetes, heart disease, hypertension, gall bladder disease, stroke, sleep apnea, some forms of cancer, and many other conditions. The US Department of Health and Human Services (DHHS) estimated the economic cost of obesity in the US was estimated to be over \$117 billion in 2000, a significant portion of that cost was paid by Medicare and Medicaid.

Market research specialist, Decision Resources, estimates the worldwide anti-obesity drug market will be \$13 billion by 2013. The currently available therapies such as Xenical® (orlistat), Meridia® (sibutramine) and phentermine have experienced limited sales, most likely due to tolerability issues, side effects and limited efficacy. We believe that the disease currently lacks a treatment that is safe and effective for most patient groups. We are developing Oleoyl-estrone to potentially address these unmet needs.

Competition in the pharmaceutical industry, and the anti-obesity drug market in particular, is intense. In addition to Abbott Laboratories, Inc. and Roche Holdings AG, the makers of Meridia® and Xenical® respectively, some of the largest drug companies in the world have anti-obesity drugs currently in development, including Merck, Pfizer, Bayer, and Amgen, Inc. These companies are all substantially larger and more established than we are and have significantly greater financial and other resources than we do.

### *Morbid Obesity*

Morbid obesity (also referred to as clinically severe obesity or extreme obesity) is defined as having a BMI equal to or greater than 40 (usually equaling 100+ pounds over ideal body weight). According to The American Obesity Association and US Centers for Disease Control and Prevention the morbid obese population in the US is estimated to be 14 million people (or 4.7% of the US population). We believe that there are currently no pharmaceutical agents specifically approved to treat morbid obesity.

According to the American Obesity Association, the morbidity and mortality risk from being overweight is proportional to its degree. Individuals with morbid obesity, therefore, have the highest risk for developing numerous illnesses that often reduce mobility and quality of life due to their excess weight. In particular, cardiovascular disease, type 2 diabetes, gallbladder disease, osteoarthritis and sleep apnea have been found to increase concurrently with higher BMI. Premature death has also been found in individuals with morbid obesity.

Morbidly obese males are considered to be the most at risk segment of the obese population. Published studies have indicated that morbidly obese males have a mortality rate higher than the general, non-obese population and a higher mortality rate than morbidly obese women. Morbidly obese males are also at significantly higher risk for other life threatening conditions including cardiovascular disease, coronary heart disease, and unexplained cardiac arrest. In addition, the trend toward developing morbid obesity has dramatically risen in recent years. A 2003 study published in the Archives of Internal Medicine shows a 500-percent increase in the number of morbidly obese adults since 1986.

Bariatric surgery is one of the few options available to those who are morbidly obese. There are several different approaches to bariatric surgery including gastric bypass, vertical banded gastroplasty, and laparoscopic gastric banding (or LAP-BAND®). While these procedures have shown to be an effective way to decrease body weight they carry significant risk. According to the Journal of the American Medical Association (JAMA) nearly 40 percent of patients who undergo bariatric surgery for weight loss are re-hospitalized within 2 years following surgery. Further, the average cost for weight loss surgery is \$25,000 per patient, and the cost can increase substantially with complications or re-hospitalization. The American Society of Bariatric Surgeons (ASBS) estimates that, of the 14 million morbidly obese adults in the US, only 200,000 underwent bariatric surgery procedures in 2006.

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

As a result of our merger with Tarpan Therapeutics in 2005, we hold an exclusive, worldwide license to develop and commercialize topical PTH (1-34) for the treatment of psoriasis. Tarpan acquired the exclusive, worldwide rights pursuant to a 2004 license agreement with IGI, Inc. Topical PTH (1-34) has completed a physician IND conducted Phase 1 and II clinical study.

In 2003, researchers, led by Michael Holick, PhD, MD, Professor of Medicine, Physiology, and Biophysics at Boston University Medical Center, reported positive results from a US Phase I and II clinical trial evaluating the safety and efficacy of PTH (1-34) as a topical treatment for psoriasis. This double-blind, controlled trial in 15 patients compared PTH (1-34) formulated in the Novasome® Technology versus the Novasome® vehicle alone. Following 8 weeks of treatment, the topical application of 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 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 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 PTH (1-34), we believe that it may have an important clinical advantage over current topical psoriasis treatments. A follow on physician IND Phase IIa trial involving PTH (1-34) was initiated in December 2005 under the auspices of Boston University. In April 2006, we reported a delay in our planned Phase IIa clinical study of topical PTH (1-34) due to a formulation issue. We believe we have identified and resolved this issue. In conjunction with formulation experts, we have produced several alternative formulations of PTH (1-34) that have successfully completed preliminary testing and have shown high levels of activity in preclinical models. These formulations will now advance into the final stages of testing after which we intend to resume clinical testing of the product candidate. Based on discoveries made during this formulation effort, we are preparing several patent applications.

See also “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Research and Development Projects - PTH (1-34).”

#### *Market and Competition*

The efficacy and safety profile of 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 PTH (1-34) as a monotherapy and for use in combination with currently available therapies. Some of 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 2005 were \$136 million.

#### *Lingual Spray Propofol*

Pursuant to a 2003 license agreement with NovaDel Pharma, Inc., we hold exclusive, worldwide rights to deliver propofol using NovaDel’s proprietary lingual spray technology for pre-procedural sedation prior to diagnostic, therapeutic or endoscopic procedures.

Propofol is currently delivered intravenously as an oily emulsion for induction and maintenance of general anesthesia or “monitored anesthesia care” in operating rooms, or deep sedation in intensive care units. Propofol has not previously been available for dosing via a convenient route of administration for pre-procedural sedation prior to diagnostic, therapeutic or endoscopic procedures. A patent application for this new method of use has been filed. Other patent applications are being prepared related to our novel formulation.

We believe that delivering propofol via this proprietary delivery system provides many advantages over currently formulated sedatives. In addition to the convenience and ease of administration, we believe the lingual spray route will eliminate delayed onset and poor coordination of timing associated with administering oral sedatives, and allow for rapid clinical responses typical of intravenous delivery (i.e., less than 5 minutes). Lingual spray propofol is intended to allow patients to tolerate unpleasant procedures, by relieving anxiety and producing a pleasant, short-term amnesia. Particularly in children and adults unable to cooperate, mild sedation expedites the conduct of numerous ambulatory procedures that are not particularly painful, but which require the patient to remain still for the best technical result.

NovaDel’s delivery systems (both patented and patent-pending) are lingual sprays, enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. We are working with NovaDel to develop, manufacture and commercialize the licensed product, having jointly announced commencement of a development program for lingual spray propofol in 2003.

In 2004, we reported results of the first human trial for our proprietary lingual spray formulation of propofol. The study, which took place in the United Kingdom, was a single-center, randomized, double-blind, placebo-controlled dose-escalating clinical study of propofol lingual spray in twelve healthy adult volunteers. The primary objectives were to compare the safety and tolerability of three dose levels of lingual spray propofol to a single intravenous bolus low dose of propofol, as well as to determine the respective pharmacokinetic profiles and relative bioavailability of the three escalating doses.

No serious adverse events, nor dose-dependent changes in vital signs, occurred in any group. The mean time to maximum blood concentration of propofol following spray was approximately 30 minutes across all doses. Propofol was detectable in blood as early as 4 minutes following spray administration. The mean maximum blood concentrations plateaued at the highest of the three doses tested, and the mean bioavailability of the current spray formulation was up to 18% of that of the intravenous formulation.

In 2005, the FDA accepted our IND for the initiation of the human clinical trials in the United States of lingual spray propofol. We continue to pursue FDA approval of lingual spray propofol under the 505(b)(2) regulatory pathway. Section 505(b)(2) of the U.S. Food, Drug & Cosmetic Act allows the FDA to approve a drug on the basis of existing data in the scientific literature or data used by the FDA in the approval of other drugs. See “—Government Regulation - Drug Approval Process.” Accordingly, the FDA has indicated to us that we will be able to utilize Section 505(b)(2) to proceed directly to a pivotal Phase III trial for lingual spray propofol following completion of Phase I trials.

Spending during 2006 on lingual spray propofol was minimal as we were, and continue, planning the next steps of the development of this product candidate through meetings with our scientific advisors, NovaDel and others. See also “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Research and Development Projects - Lingual Spray Propofol.”

### *Market and Competition*

To date, midazolam (now a generic), which is delivered both intravenously and orally, has dominated the preprocedural sedation market posting sales of \$536 million in 1999. However, serious adverse events are reported in the midazolam package insert, including respiratory depression, airway obstruction, oxygen desaturation, apnea and even respiratory arrest. In contrast, at the doses being developed by us, we believe that lingual spray propofol may offer a safer, noninvasively administered alternative to midazolam. Propofol's rapid onset profile will allow clinicians to more accurately time its peak effects during procedures, as well as to determine the precise concentration needed for desired levels of 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 of which is patentable. 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.

#### *Oleoyl-estrone License Agreement*

We currently have worldwide, exclusive license rights to the U.S. and foreign patents and patent applications regarding Oleoyl-estrone and its use for the treatment of human disease:

1. US Patent No. 5,798,348 entitled "Fatty-acid monesters of estrogens for the treatment of obesity and/or overweight." M. Alemany, Inventor. Application filed, October 30, 1996. Patent issued August 25, 1998. This patent expires on October 30, 2016.
2. European Patent No. 771.817 entitled "Oleate monoesters of estrogens for the treatment of obesity and/or overweight." M. Alemany, Inventor. Application filed, October 28, 1996. Patent issued March 26, 2003. This patent expires on October 28, 2016.
3. Spanish Patent Application No. ES 200100785 entitled "Fatty-acid monoesters of estrogens acting as anti-diabetic and hypolipidemia agents." M. Alemany Lamana, Francisco Javier Remesar Betiloch, and Jose Antonio Fernandez Lopez, Inventors. Application filed March 28, 2001, European Patent Application No. EP1380300A1, filed March 25, 2002, and Canadian Patent Application No. 2441890, filed March 25, 2002.

The U.S. and European patents have numerous, detailed, and specific claims for both the composition of Oleoyl-estrone, and its method of use for weight loss. Our rights to these patents are subject to the terms of a February 2002 license agreement between us and OED. The license agreement provides us with an exclusive, worldwide right to the intellectual property covered by the license agreement, including the right to grant sublicenses. Our success in developing Oleoyl-estrone depends on our ability to maintain and enforce the patents relating to Oleoyl-estrone.



In consideration for the license, we paid an initial license fee of \$175,000. The license agreement provides for further cash payments of \$9,250,000 in the aggregate, payable as follows: \$250,000 payable upon treatment of the first patient in a Phase I clinical trial under an IND sponsored by us; \$250,000 upon treatment of the first patient in a Phase II clinical trial; \$750,000 upon the first successful completion of a Phase II clinical trial; \$2,000,000 upon the first successful completion of a Phase III clinical trial; and \$6,000,000 upon the first final approval of a New Drug Application (“NDA”) for oleoyl-estrone by the FDA. The license agreement does not require us to make any royalty payments. Through December 31, 2006, we have paid the initial license fee of \$175,000 and \$500,000 in milestone payments.

Subject to earlier termination as described below, the term of the license expires on the last to expire patent right licensed under the agreement, which is currently October 2016. Oleoyl-estrone Developments has the right to terminate the license agreement sooner, subject to certain requirements to provide us advance notice, in the event we become bankrupt or similar proceedings are initiated, fail to make the required milestone payments required under the agreement or otherwise materially breach the license agreement. We have the right to terminate the license agreement for any reason upon written notice.

*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 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. Patent No. 6,066,618, entitled “Regulation of cell proliferation and differentiation using peptides.” M.F. Holick, Inventor. Application filed November 13, 1998. Patent issued May 23, 2000. This patent expires October 20, 2007.
4. European Patent Specification PCT/US88/03639

These patents have numerous, detailed and specific claims relating to the topical use of PTH (1-34) In consideration for our rights under the IGI Agreement, a payment of \$300,000 was made upon execution of the agreement, prior to our acquisition of Tarpan. In addition the IGI Agreement requires us to make certain milestone payments as follows: \$300,000 payable upon the commencement of a Phase II clinical trial; \$500,000 upon the commencement of a Phase III 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 III 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.

In addition, we are 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, we are obligated to pay IGI, Inc. an annual royalty of 9% annual net sales. Through December 31, 2006 none of the milestones have been reached and sales have not commenced, we, therefore, have not paid any such milestone fees or 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 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.

#### *Propofol LS License Agreement*

Pursuant to the NovaDel license agreement, we have an exclusive, worldwide license to NovaDel's proprietary lingual spray technology to deliver propofol for preprocedural sedation prior to diagnostic, therapeutic or endoscopic procedures. Our rights under the NovaDel License include license rights to the following patents held by NovaDel:

1. U.S. Patent No. 5,955,098, entitled "Buccal Non Polar Spray or Capsule." H.A. Dugger, III, Inventor. Application filed April 12, 1996. Patent issued September 21, 1999. This patent expires April 12, 2016.
2. U.S. Patent No. 6,110,486, entitled "Buccal Polar Spray or Capsule." H.A. Dugger, III, Inventor. Application filed November 25, 1998. Patent issued August 29, 2000. This patent expires April 12, 2016.
3. U.S. Patent No. 6,969,508, entitled "Buccal, polar and non-polar spray or capsule containing drugs for treating pain." H.A. Dugger, III, Inventor. Application filed December 4, 2003. Patent issued November 29, 2005. This patent expires October 1, 2017.
4. European Patent No. 0904055 entitled "Buccal, Non-Polar Spray or Capsule." H.A. Dugger, III, Inventor. Application filed, February 21, 1997. Patent issued April 16, 2003. This patent expires February 21, 2017.
5. U.S. Patent Application No. 10/834815 entitled "Buccal, Polar and Non-Polar Sprays Containing Propofol." H.A. Dugger and M.A. El-Shafy, Inventors. Application filed April 27, 2004.

These issued patents have numerous, detailed, and specific claims relating to the formulation for lingual spray applications and their method of use. We have the right to use the technology in connection with one application - delivering propofol. Our success in developing lingual spray propofol depends substantially on the maintenance and enforcement of NovaDel's patents covering its proprietary spray technology. In consideration for our rights under the NovaDel license agreement, we paid NovaDel an initial license fee of \$500,000 in 2003. In addition, the license agreement requires us 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 approved by a European Union country; \$1,000,000 following the date on which an application for commercial approval of lingual spray propofol is approved by the appropriate regulatory authority in each of Australia, Canada, Japan and South Africa; and \$50,000 following the date on which an application for commercial approval for lingual spray propofol is approved in any other country (other than the U.S., a member of the European Union, Australia, Canada, Japan or South Africa). Through December 31, 2006, none of these milestones have been reached we, therefore, have not paid any such milestone fees. In addition, we are obligated to pay NovaDel an annual royalty based on a fixed rate of net sales of licensed products, or



if greater, the annual royalty is based on our net profits from the sale of licensed products at a rate that is twice the net sales rate.

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Subject to certain requirements to provide us with notice and an opportunity to cure, NovaDel may terminate the license agreement in the event we (1) become subject to a bankruptcy or similar proceeding that is not dismissed within 60 days, (2) default in our obligation to make a required payment under the license agreement, or (3) otherwise materially breach the license agreement. We may terminate the license agreement for any reason upon 90 days' notice to NovaDel.

### **Manufacturing**

We do not have any manufacturing capabilities. We are in contact with several contract "current Good Manufacturing Process", or cGMP manufacturers for the supply of Oleoyl-estrone, lingual spray propofol, and PTH(1-34) that will be necessary to conduct Phase I and Phase II human clinical trials. A method has been identified for synthesizing Oleoyl-estrone, and can be done through simple reactions that produce the substance at above 99 percent purity. We believe that the production of Oleoyl-estrone will involve one contract manufacturer for clinical trials. In addition, we will be outsourcing the manufacture of lingual spray propofol and PTH(1-34) as well.

### **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:

- preclinical 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.

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical 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 I 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 II 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 III 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 I, phase II, or phase III 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 preclinical 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 lingual spray propofol.

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 which 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 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 8 full time employees, including 3 persons 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, 2006, we had \$3,029,118 of cash and cash equivalents. We received additional funding of approximately \$8 million net from the sale of common stock and warrants in a private placement in March 2007. Even though we were successful in raising funds in March 2007 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, 2006 and for the period from August 6, 2001 (inception) through December 31, 2006, we incurred net losses of \$9,695,123, and \$41,787,174, 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 pre-clinical 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 pre-clinical 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 pre-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 Investigational New Drug Application, or an IND, which will set forth our plans for clinical testing of our product candidates. In January 2005, the FDA accepted INDs for both our Oleoyl-estrone and Propofol LS product candidates. We have not yet filed a corporate IND for PTH(1-34). In May and July 2005, we completed Phase Ia and Phase Ib trials in Basel, Switzerland to evaluate the safety and tolerability as well as preliminary signs of efficacy of defined doses of orally administered Oleoyl-estrone in obese adults, in accordance with relevant regulatory guidelines. Because propofol has already been approved by the FDA for intravenous use, the FDA has informed us that we may utilize a rapid development strategy that will enable us to go directly to a Pivotal Phase III trial following completion of Phase I trials. We are unable to estimate the size and timing of all the Phase II and Phase III programs for Oleoyl-estrone at this time and, accordingly, cannot estimate the time when development of that product candidate will be completed.

When the clinical testing for our product candidates is complete, we will submit to the FDA a New Drug Application, or NDA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical 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 pre-clinical 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 pre-clinical 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 pre-clinical 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. We expect that our clinical trials will only involve a small sample size. 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 NovaDel Pharma, from which we license our rights to lingual spray propofol, in the development of that product candidate in the pre-clinical and early clinical trial stages. Under our agreement with NovaDel, it has agreed to perform certain development on our behalf and at our expense, including formulation stability testing, formulation analytic method development and testing and manufacture of clinical trial material for the pre-clinical and early clinical development of propofol lingual spray. Beyond those limited activities, we need to engage independent investigators and other third party collaborators to conduct pre-clinical and clinical trials for lingual spray propofol. We are not currently collaborating with any third party with respect to the development of oleoyl-estrone, but we intend to engage third party independent investigators and collaborators, which may include universities and medical institutions, to conduct our pre-clinical and clinical trials for that product candidate, as well. 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 currently have no contract for the manufacture of our product candidate. 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 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.

Each of these risks could delay our clinical trials, the approvals, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

**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 its 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 oleoyl-estrone and perhaps our other 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 its 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 pre-clinical 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.**

Companies that currently sell both generic and proprietary anti-obesity compounds formulations include among others Abbot Laboratories, Inc., Amgen, Inc., and Regeneron Pharmaceuticals, Inc. Alternative technologies are being developed to treat obesity and overweight disease, several of which are in advanced clinical trials. In addition, companies pursuing different but related fields represent substantial competition. Many of these 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 patents. We license the exclusive rights to two issued patents relating to Oleoyl-estrone, which expire in 2016. We also license the exclusive rights to four issued patents relating to lingual spray propofol, which expire from 2016 to 2017. In addition we license the exclusive rights to three patents relating to topical PTH (1-34), which expire from 2007 to 2013. 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. For example, despite covenants in our license agreements with Oleoylestrone Developments and NovaDel Pharma, from which we license Oleoyl-estrone and lingual spray propofol, respectively, that generally prohibit those companies from disclosing information relating to our licensed technology, the respective license agreements allow for each company to publish data and other information relating to our licensed technology. 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 pre-clinical 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 32 percent of our outstanding voting stock and, including shares underlying outstanding options and warrants, this group beneficially owns approximately 35 percent of our common stock. 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 \$0.62 (in the third and fourth quarters of 2006) to a high of \$2.10 (in the first quarter of 2005). 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 pre-clinical 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 received notice from the American Stock Exchange that we fail to comply with certain of its continued listing standards, which may result in the delisting of our common stock from the exchange.**

Our common stock is currently listed for trading on the American Stock Exchange, or AMEX, and the continued listing of our common stock on the AMEX is subject to our compliance with a number of listing standards. On January 8, 2007, we received notice from the AMEX informing us that, as of September 30, 2006, we are not in compliance with an AMEX listing standard that requires us to have stockholders' equity of at least \$4,000,000, if we have had net losses in three of our four most recent fiscal years, as well as a similar listing standard that requires that we have stockholders' equity of at least \$6,000,000 if we have net losses in our 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 February 2007. AMEX accepted our plan in March 2007, allowing us to continue our listing during the period ending April 16, 2008, during which time we will be subject to periodic review to determine if we are making progress consistent with the plan. 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 plan period, AMEX staff may initiate delisting proceedings. There can be no assurance that we will be able to make progress consistent with such plan.

If we fail to make sufficient progress under our plan, AMEX may initiate delisting proceedings. If our common stock is delisted from AMEX, trading in our common stock would likely be conducted on the OTC Bulletin Board, a regulated quotation service. If our common stock is delisted from the AMEX, 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**

We are not a party to any legal proceedings.

**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 December 15, 2006. 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<br/>Withheld</b> |
|----------------------|------------------|---------------------------|
| Douglas Abel         | 37,627,263       | 809,645                   |
| Neil Herskowitz      | 38,104,850       | 332,058                   |
| Malcolm Hoenlein     | 37,906,150       | 530,758                   |
| Timothy McInerney    | 37,820,746       | 616,162                   |
| Joan Pons Gimbert    | 37,817,746       | 619,162                   |
| Richard I. Steinhart | 37,904,150       | 532,758                   |
| Michael Weiser       | 37,549,808       | 887,100                   |

(ii) The stockholders ratified the appointment of J.H. Cohn LLP as our independent registered public accounting firm for fiscal 2006. 38,345,996 votes were cast for the proposal; 88,072 votes were cast against the proposal, shares representing 2,840 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 currently trades on the American Stock Exchange under the symbol "MHA." Prior to October 7, 2005, our common stock was quoted on the OTC Bulletin Board under the symbol "MHTT." The following table lists the high and low price for our common stock as quoted, in U.S. dollars, on the American Stock Exchange and OTC Bulletin Board during each quarter within the last two fiscal years:. The quotations from the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

| Quarter Ended | Price Range |          |          |          |
|---------------|-------------|----------|----------|----------|
|               | 2006        |          | 2005     |          |
|               | High        | Low      | High     | Low      |
| March 31      | \$ 1.640    | \$ 1.160 | \$ 2.100 | \$ 0.850 |
| June 30       | 1.360       | 0.075    | 1.640    | 1.200    |
| September 30  | 0.880       | 0.620    | 1.600    | 1.110    |
| December 31   | 0.920       | 0.620    | 1.520    | 1.040    |

The quotations from the OTC Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

**Record Holders**

The number of holders of record of our common stock as of March 16, 2007 was 480.

**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 2006.

## **ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OR PLAN 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 biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have three product candidates in development: Oleoyl-estrone, an orally administered small molecule for the treatment of obesity; topical PTH (1-34) for the treatment of psoriasis; and Lingual Spray Propofol for sedation prior to diagnostic, therapeutic or endoscopic procedures. In addition to the development of our current products, we are focused on expanding our product candidate pipeline. 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-KSB. 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**

#### ***2006 Versus 2005***

During each of the years ended December 31, 2006 and 2005, we had no revenues, and are considered a development stage company. We do not expect to have revenues relating to our technologies prior to December 31, 2007.

For the year ended December 31, 2006 research and development expense was \$6,173,000 as compared to \$5,178,000 for the year ended December 31, 2005. The increase of \$995,000 is due to shared-based compensation of \$529,000, increases in spending on the development of Oleoyl-estrone of \$66,000 and on the development of PTH (1-34) of \$517,000, partially offset by a decrease in spending on the development of Propofol Lingual Spray of \$117,000. As we continue with Phase IIa clinical trials in Oleoyl-estrone and begin Phase II clinical trials in PTH (1-34), we expect research and development to continue to increase in 2007.

For the year ended December 31, 2006, general and administrative expense was \$3,827,000 as compared to \$2,291,000 for the year ended December 31, 2005. The increase of \$1,536,000 is due primarily to shared-based compensation of \$1,147,000 and increases in compensation expense of \$342,000, in professional fees of \$143,000 and in insurance costs of \$43,000, partially offset by a decrease in investor services costs of \$133,000. As a result of our continued expansion of our infrastructure required to support the planned growth, we expect general and administrative expenses to continue to increase in 2007.

For the year ended December 31, 2006, other income, including realized gain on the sale of marketable equity securities, was \$305,000 as compared to \$216,000 for the year ended December 31, 2005. The increase of \$89,000 is a result of higher balances of cash and short-term investments earning investment income.

Net loss for the year ended December 31, 2006, was as \$9,695,000 compared to \$19,141,000 for the year ended December 31, 2005. This decrease of \$9,446,000 is attributable primarily to the in-process research and development charge of \$11,888,000 related to the acquisition of Tarpan recognized in the year ended December 31, 2005 offset by share-based compensation of \$1,675,000 recognized in the year ended December 31, 2006. Additionally, there were increases in other research and development expenses of \$466,000 and in other general and administrative expenses of \$389,000. There was also an increase in interest and other income of \$89,000.

Preferred stock dividends of \$176,000 had no effect on earnings per share for the year ended December 31, 2005. There were no shares of preferred stock outstanding during 2006.

#### ***2005 Versus 2004***

During each of the years ended December 31, 2005 and 2004, we had no revenues, and are considered a development stage company

For the year ended December 31, 2005 research and development expense was \$5,178,000 as compared to \$4,153,000 for the year ended December 31, 2004. The increase of \$1,025,000 is due primarily to an acceleration of pre-clinical and clinical development of our Oleoyl-estrone drug and, commencing after the April 2005 acquisition of Tarpan, the pre-clinical and clinical development of our PTH (1-34) which amounted to approximately \$970,000.

For the year ended December 31, 2005, general and administrative expense was \$2,291,000 as compared to \$1,990,000 for the year ended December 31, 2004. The increase of \$301,000 is due primarily to increases in payroll, outside services and investor relations expenses of approximately \$139,000, \$146,000 and \$106,000, respectively. In addition, we had increases in expenses related to franchise taxes, depreciation and accounting fees of approximately \$50,000, \$34,000, and \$31,000, respectively. These increases are partially offset by reductions in consulting, legal fees and all other expenses of approximately \$168,000, \$19,000 and \$18,000, respectively.

The in-process research and development charge in 2005 relates to the allocation of the purchase price of the Tarpan acquisition. See Note 1 to the consolidated financial statements for further details.

For the year ended December 31, 2005, interest and other income including realized gain on the sale of marketable equity securities was \$216,000 as compared to \$247,000 for the year ended December 31, 2004. The decrease of \$31,000 is a result of a non-recurring realized gain on sale of marketable equity securities in 2004, partially offset by higher balances of cash and short-term investments earning investment income.

Net loss for the year ended December 31, 2005, was \$19,141,000 as compared to \$5,896,000 for the year ended December 31, 2004. This increase in net loss is attributable primarily to the in-process research and development charge of \$11,888,000 related to the acquisition of Tarpan. Additionally, there were increases in research and development expenses of \$1,025,000 and general and administrative expenses of \$301,000. Additionally, there was a decrease in interest and other income of \$31,000.

Preferred stock dividends of \$176,000 and \$586,000 reduced earnings per share for the years ended December 31, 2005 and 2004 by \$0.00 and \$0.02, respectively.

### **Liquidity and Capital Resources**

From inception to December 31, 2006, we incurred a deficit during the development stage of \$42,967,000 primarily as a result of our net losses, and we expect to continue to incur additional losses through at least December 31, 2007 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, 2006, we had a net decrease in cash, cash equivalents and short-term investments of \$7,805,000. This decrease resulted largely from net cash used in operating activities of \$7,751,000. Total liquid resources as of December 31, 2006 were \$3,029,000 compared to \$10,834,000, including short term investments, at December 31, 2005.

Our current liabilities as of December 31, 2006 were \$1,943,000 compared to \$1,666,000 at December 31, 2005, an increase of \$277,000,. The increase was primarily due to increases in expenditures associated with our Oleoyl-estrone product candidate and our PTH (1-34) product candidate. As of December 31, 2006, we had working capital of \$1,350,000 compared to \$9,363,000 at December 31, 2005.

In March 2007 we completed a private placement of common stock and warrants. We received net proceeds of approximately \$8 million from this private placement.

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned pre-clinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, 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, 2006, 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, 2006 and the net proceeds from the March 2007 private placement management believes we have sufficient capital to fund our operations through the end of 2007. 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 2007 to be able to sustain our operations beyond 2007 and we will need additional financing thereafter until we can achieve profitability, if ever.

We have reported net losses of \$9,695,000 and \$19,141,000 for the years ended December 31, 2006 and 2005, respectively. The net loss from date of inception, excluding preferred stock dividends, August 6, 2001 to December 31, 2006, amounts to \$41,787,000. Management believes that we will continue to incur net losses through at least December 31, 2007. Based on the current resources available to us, we will need additional equity or debt or financing or we will need to generate revenues through licensing our products or entering into strategic alliances to be able to sustain our operations until we can achieve profitability, if ever.

In January 2007 we received notice from the staff of the American Stock Exchange, or AMEX, indicating that we were not in compliance with certain continued listing standards set forth in the American Stock Exchange Company Guide. Specifically, the American Stock Exchange notice cited our failure to comply, as of September 30, 2006, with section 1003(a)(ii) of the AMEX Company Guide as we had less than the \$4,000,000 of stockholders' equity and had losses from continuing operations and/or net losses in three of its four most recent fiscal years, and with section 1003(a) (iii) which requires the Company 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 February 2007. AMEX accepted our plan in March 2007, so we are now able to continue our listing during the period ending April 16, 2008, during which time we will be subject to periodic review to determine if we are making progress consistent with the plan. 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 plan period, AMEX staff may initiate delisting proceedings. There can be no assurance that we will be able to make progress consistent with such plan.

If we fail to make sufficient progress under our plan, AMEX may initiate delisting proceedings. If our common stock is delisted from AMEX, trading in our common stock would likely be conducted on the OTC Bulletin Board, a regulated quotation service. If our common stock is delisted from the AMEX, 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. Further, if we are delisted from AMEX, we may find it more difficult to raise additional capital through sales of our common stock or other equity securities.



## ***Development Commitments***

### **Oleoyl-estrone**

On February 15, 2002, we entered into a License Agreement (the "License Agreement") with Oleoylestrone Developments, S.L. ("OED"). Under the terms of the License Agreement, OED granted to us a world-wide license to make, use, lease and sell the products incorporating the licensed technology. OED also granted to us 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 our bankruptcy. OED may terminate the License Agreement in the event of a material breach by us that is not cured within the notice period. We may terminate the License Agreement for any reason upon 60 days notice.

Under the License Agreement, we agreed to pay to OED certain licensing fees which are being expensed as they are incurred. We paid \$175,000 in up front licensing fees in 2002. In addition, pursuant to the License Agreement, we issued 1,000,000 shares of our common stock to OED. We valued these shares at their then estimated fair value of \$1,000.

In connection with the License Agreement, we have 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, which we expect to pay during 2007; (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 FDA. Through December 31, 2006, we have paid \$675,000 in licensing fees and milestone payments.

In addition to the License Agreement, we entered into a consulting agreement with OED. The agreement became effective in February 2002, at a fee of \$6,250 per month, and will terminate when the License Agreement terminates. The fees associated with the consulting agreement are expensed as incurred. OED agreed to designate a member of our Scientific Advisory Board and to render consultative and advisory services to us. Such services include research, development and clinical testing of our technology as well as the reporting of the findings of such tests, assistance in the filing of patent applications and oversight and direction of efforts in regards to personnel for clinical development.

### **Propofol Lingual Spray**

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



In consideration of the license, we are required to make certain license and milestone payments. Specifically, we were required to pay a \$500,000 license fee at such time as we had completed a financing transaction resulting in aggregate gross proceeds of at least \$10,000,000. We paid and expensed the \$500,000 license fee in 2003.

We are also required to make various milestone payments to NovaDel under the license agreement as follows: \$1,000,000 payable following the date that the first 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 approved by a European Union country; \$1,000,000 following the date on which an application for commercial approval of lingual spray propofol is approved by the appropriate regulatory authority in each of Australia, Canada, Japan and South Africa; and \$50,000 following the date on which an application for commercial approval for lingual spray propofol is approved in any other country (other than the U.S., a member of the European Union, Australia, Canada, Japan or South Africa). Through December 31, 2006, none of the milestones have been reached, therefore, we have not paid any such milestone fees.

In addition, we are obligated to pay to NovaDel an annual royalty based on a fixed rate of net sales of licensed products, or if greater, the annual royalty is based on our net profits from the sale of licensed products at a rate that is twice the net sales rate. In the event we sublicense the licensed product to a third party, we are obligated to pay royalties based on a fixed rate of fees or royalties received from the sublicensee until such time as we recover our out-of-pocket costs, and thereafter the royalty rate doubles. Because of the continuing development efforts required of NovaDel under the agreement, the royalty rates are substantially higher than customary for the industry.

NovaDel may terminate the agreement (i) upon 10 days' notice if we fail to make any required milestone or royalty payments, or (ii) if we become bankrupt or if a petition in bankruptcy or insolvency is filed and not dismissed within 60 days or if we become subject to a receiver or trustee for the benefit of creditors. Each party may terminate the agreement upon 30 days' written notice and an opportunity to cure in the event the other party committed a material breach or default. We may also terminate the agreement for any reason upon 90 days' notice to NovaDel.

#### **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 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 we will be responsible.

The IGI sublicense agreement requires us to make certain milestone payments as follows: \$300,000 payable upon the commencement of a Phase II clinical trial; \$500,000 upon the commencement of a Phase III 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 III 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.

In addition, we are 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, we are obligated to pay IGI, Inc. an annual royalty of 9% on such excess. Through December 31, 2006, none of the milestones have been reached and sales have not commenced, therefore, we have not paid any such milestones or 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.

## **Research and Development Projects**

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

In January 2005, the FDA accepted our filed investigational new drug application, or "IND" for the human clinical testing of Oleoyl-estrone. We completed Phase Ia and Phase Ib clinical trials in May 2005 and July 2005 and released data on both trials in October 2005. Both trials were completed in Basel, Switzerland after obtaining formal approval from the Swiss medical authority, Swissmedic, however only the Phase Ia trial was conducted pursuant to the IND accepted by the FDA. The objective of both dose-escalation studies was to determine the safety and tolerability of defined doses of orally administered Oleoyl-estrone in obese adult volunteers as well as the pharmacokinetic profile (i.e. the manner in which the drug is absorbed, distributed, metabolized and excreted by the body) of Oleoyl-estrone in both men and women.

The Phase Ia study involved 36 obese volunteers. Twelve of the 36 patients received placebo and 24 received a single dose in one of six strengths ranging from 1 mg to 150 mg. Oleoyl-estrone was shown to be safe with no serious adverse events noted in this study.

The Phase Ib study was a seven day repeat dose study involving 24 obese volunteers in four cohorts of 6 patients each who received either placebo or Oleoyl-estrone in doses ranging from 10 mg to 150 mg once daily for seven consecutive days. The results indicated that Oleoyl-estrone was generally well-tolerated at all doses and no serious adverse events were reported. There were also no clinically significant changes in the physical exams, vital signs, ECGs, coagulation and liver function tests. The study demonstrated evidence of greater weight loss among the treated groups compared with the placebo group as well as evidence of reduction in desire to eat, hunger levels, fasting glucose and LDL cholesterol. Important clinical laboratory findings included reversible, dose-dependent elevations in estrone and estradiol levels, as well as reductions in testosterone levels.

In March 2006, we entered into a research and development agreement with Swiss Pharma Contract Ltd., or Swiss Pharma, to perform a Phase IIa clinical study in 100 obese patients of our Oleoyl-estrone product candidate for the treatment of obesity. The contract requires us to pay up to \$2,152,000 to Swiss Pharma for conducting the study.

In the fourth quarter of 2006, we expanded this ongoing Phase IIa clinical trial of Oleoyl-estrone in obesity into two new clinical sites in the United States. Because the size of the study has not been expanded beyond the 100 obese patients, we do not anticipate the addition of the two new sites to materially increase our total financial commitment of up to \$2,152,000. Such financial commitment will now be paid to three clinical centers rather than one. Enrollment in this study was completed in February 2007 and we expect this study to conclude mid-year 2007.

In the fourth quarter of 2006, we commenced a Phase IIa study in the morbidly obese led by St.Lukes/Roosevelt hospital in New York in conjunction with Columbia University. The financial commitment for this study is approximately \$685,000. The study is expected to conclude mid-year 2007.

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

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

Expenses associated with the ongoing clinical trials are recognized on this activity based basis, therefore, the expense recognition differs from the payment schedules. Approximately \$937,000 was paid on this basis in 2006 and \$764,000 of expense was recognized in 2006. Because the amounts paid were greater than the related research and development costs recognized as of December 31, 2006, we recognized a prepaid expense of approximately \$173,000.

To date, we have incurred \$12,301,000 of project costs related to our development of oleoyl-estrone, including milestone payments triggered under our license agreement for oleoyl-estrone, of which \$4,311,000 was incurred in fiscal 2006. Since oleoyl-estrone is regarded by the FDA as a new entity, it is not realistic to predict the size and the design of future studies at this time.

Based on the resources available to us at December 31, 2006 and the net proceeds from the March 2007 private placement management believes we have sufficient capital to fund the development of Oleoyl-estrone through the end of 2007. We will need to raise additional capital in order to complete our planned R&D activities for oleoyl-estrone and its continued development beyond 2007. If we are unable to raise such additional capital, we may have to sublicense our rights to oleoyl-estrone to a third party as a means of continuing development, or, although less likely, we may be required to abandon further development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

In addition to raising further capital, whether we are successful in developing oleoyl-estrone is dependent on numerous other factors, including unforeseen safety issues, lack of effectiveness, significant unforeseen delays in the clinical trial and regulatory approval process, both of which could be extremely costly, and inability to monitor patients adequately before and after treatments. See also "Item 1. Description of Business - Risk Factors" in this Form 10-KSB. The existence of any of these factors could increase our development costs or make successful completion of development impractical, which would have a material adverse affect on the prospects of our business.

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

We are developing PTH (1-34) as a topical treatment for psoriasis. In August 2003, researchers, led by Michael Holick, MD, Professor of Medicine, Physiology, and Biophysics at Boston University Medical Center, reported positive results from a US Phase I and II clinical trial evaluating the safety and efficacy of PTH (1-34) as a topical treatment for psoriasis. This double-blind, controlled trial in 15 patients compared PTH (1-34) formulated in the Novasome® Technology versus the Novasome® vehicle alone. Following 8 weeks of treatment, the topical application of 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 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 PTH (1-34) we believe that it may have an important clinical advantage over current topical psoriasis treatments. A follow on physician IND Phase IIa trial involving 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 IIa clinical study of topical PTH (1-34) due to a formulation issue. We believe we have identified and resolved this issue. In conjunction with formulation experts, we have produced several alternative formulations of PTH (1-34) that have successfully completed preliminary testing and have shown high levels of activity in preclinical models. These formulations will now advance into the final stages of testing. Based on discoveries made during this formulation effort, the Company is preparing several patent applications.

Our rights to PTH (1-34) were acquired as a result of our April 2005 acquisition of Tarpan Therapeutics, Inc. PTH (1-34) is being developed as a topical treatment for psoriasis. To date, we have incurred \$2,696,000 of project costs related to our development of PTH (1-34). These project costs have been incurred since April 1, 2005, the date of the Tarpan Therapeutics acquisition. During 2006 \$1,726,000 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 PTH (1-34) beyond 2007. We will, therefore, need to raise additional capital in order to complete our planned R&D activities for PTH (1-34) and its continued development beyond 2007. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to 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.

***Lingual spray propofol***

We are developing propofol lingual spray, the right to which we license from NovaDel Pharma, Inc., for light to medium sedation on a Section 505b2 bioequivalence regulatory pathway toward FDA approval. In January 2005, the FDA accepted our IND for propofol lingual spray, allowing us to commence clinical trials. The FDA has indicated to us in discussions that we may proceed to a pivotal Phase III trial of propofol lingual spray following completion of Phase I trials. We are planning the next steps for the clinical development of this product candidate, meeting with our scientific advisors, NovaDel and other formulation partners regarding formulation, reviewing existing data, developing trial design and evaluating plans to re-enter the clinic. See also "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Research and Development

Projects - Lingual Spray Propofol.

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To date, we have incurred \$2,956,837 of project costs related to our development of propofol lingual spray, of which \$135,651 was incurred in fiscal 2006. As with the development of our other product candidates, we do not currently have sufficient capital to fund our planned development activities of propofol lingual spray beyond 2007. We will, therefore, need to raise additional capital in order to complete our planned R&D activities for propofol lingual spray and its continued development beyond 2007. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to propofol lingual spray or abandon our development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

## Summary of Contractual Commitments

### *Employment Agreements*

We have employment agreements with three employees for the payment of aggregate annual base salaries of \$805,000 as well as performance based bonuses. All of these agreements have terms of three years and have a remaining obligation of \$1,492,000 as of December 31, 2006.

### *Leases*

Rent expense for the years ended December 31, 2006 and 2005 was \$141,012 and \$120,209, respectively. Future minimum rental payments subsequent to December 31, 2006 under an operating lease for the Company's office facility are as follows:

| Years Ending December 31, | Commitment |
|---------------------------|------------|
| 2007                      | \$ 141,600 |
| 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 year ended December 31, 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 July 2006, the FASB issued Interpretation No. 48 (“FIN No. 48”), Accounting for Uncertainty in Income Taxes. FIN No. 48 prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise’s financial statements in accordance with FASB Statement No. 109 (“FAS No. 109”), Accounting for Income Taxes . Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN No. 48 and in subsequent periods. FIN No. 48 will be effective for fiscal years beginning after December 15, 2006 and the provisions of FIN No. 48 will be applied to all tax positions accounted for under FAS No. 109 upon initial adoption. The cumulative effect of applying the provisions of FIN No. 48 will be reported as an adjustment to the opening balance of retained earnings for that fiscal year. The Company currently believes that the adoption of FIN 48 will have no material impact on its consolidated financial position or results of operations.

In December 2006, the FASB issued FASB Staff Position EITF 00-19-2 (“FSP 00-19-2”), Accounting for Registration Payment Arrangements. FSP 00-19-2 addresses an issuer’s accounting for registration payment arrangements by specifying that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, Accounting for Contingencies. FSP 00-19-2 will be effective for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company currently believes that the adoption of FSP 00-19-2 will have no material impact on its consolidated financial position or results of operations.

**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. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

As of December 31, 2006, 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, 2006 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.

**\_PART III**

**ITEM DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS;  
9. COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT**

Information in response to this Item is incorporated herein by reference to our 2007 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-KSB.

**ITEM 10. EXECUTIVE COMPENSATION**

Information in response to this Item is incorporated herein by reference to our 2007 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-KSB.

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

Information in response to this Item is incorporated herein by reference to our 2007 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-KSB.

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

Information in response to this Item is incorporated herein by reference to our 2007 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-KSB.

### ITEM 13. EXHIBITS LIST

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         | Warrant issued to John Prendergast to purchase 37,500 shares of Registrant's common stock (incorporated by reference from Exhibit 10.24 to the Registrant's Form 10-QSB for the quarter ended March 31, 1997).   |
| 4.3         | 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).                               |
| 4.4         | 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)). |
| 4.5         | 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).   |
| 4.6         | 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)).
- 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 Employment Agreement between the Registrant and Alan G. Harris January 26, 2006 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-QSB for the quarter ended March 31, 2006).
- 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 Separation Agreement dated July 7, 2006 between the Registrant and Nicholas J. Rossettos (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed July 12, 2006).

- 10.14 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).
- 10.15 Form of Stock Option Agreement issued under the Registrant's 2003 Stock Option Plan.
- 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**

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, 2006 and 2005:

| Fee Category           | J.H. Cohn LLP    |                  |
|------------------------|------------------|------------------|
|                        | Fiscal 2006 Fees | Fiscal 2005 Fees |
| Audit Fees             | \$ 100,111       | \$ 101,911       |
| Audit-Related Fees (1) | 22,943           | 9,430            |
| Tax Fees (2)           | 21,165           | 18,622           |
| All Other Fees (3)     | -                | -                |
| Total Fees             | \$ 144,219       | \$ 129,963       |

(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 2006 was obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act, Manhattan Pharmaceuticals, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on April 2, 2007.

Manhattan Pharmaceuticals, Inc.

By: /s/ Douglas Abel

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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<br>Douglas Abel                   | Chief Executive Officer, President and<br>Director (principal executive officer)         | April 2, 2007 |
| /s/ Michael G. McGuinness<br>Michael G. McGuinness | Secretary and Chief Financial Officer<br>(principal accounting and financial<br>officer) | April 2, 2007 |
| /s/ Neil Herskowitz<br>Neil Herskowitz             | Director   | April 2, 2007 |
| /s/ Malcolm Hoenlein<br>Malcolm Hoenlein           | Director   | April 2, 2007 |
| /s/ Timothy McInerney<br>Timothy McInerney         | Director   | April 2, 2007 |
| /s/ Joan Pons Gimbert<br>Joan Pons Gimbert         | Director   | April 2, 2007 |
| /s/ Richard Steinhart<br>Richard Steinhart         | Director   | April 2, 2007 |
| /s/ Michael Weiser<br>Michael Weiser               | Director   | April 2, 2007 |



**Index to Consolidated Financial Statements**

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| Consolidated Statements of Cash Flows for the Years Ended December 31, 2006 and 2005 and the cumulative period from August 6, 2001 (inception) to December 31, 2006                       | F-6         |
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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, 2006 and 2005, 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, 2006. 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, 2006 and 2005, 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, 2006, in conformity with accounting principles generally accepted in the United States of America.

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 2, 2007, except for Notes 2 and 12 which are as of March 30, 2007

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

Consolidated Balance Sheets

|   | <b>December 31,<br/>2006</b> | <b>December 31,<br/>2005</b> |
|---|------------------------------|------------------------------|
| <b>Assets</b>   |                              |                              |
| Current assets:   |                              |                              |
| Cash and cash equivalents   | \$ 3,029,118                 | \$ 9,826,336                 |
| Short-term investments, available for sale, at market   | —                            | 1,007,818                    |
| Prepaid expenses  | 264,586                      | 194,776                      |
| <b>Total current assets</b>   | <b>3,293,704</b>             | <b>11,028,930</b>            |
| Property and equipment, net   | 83,743                       | 106,877                      |
| Other assets  | 70,506                       | 70,506                       |
| <b>Total assets</b>   | <b>\$ 3,447,953</b>          | <b>\$ 11,206,313</b>         |
| <b>Liabilities and Stockholders' Equity</b>   |                              |                              |
| Current liabilities:  |                              |                              |
| Accounts payable  | \$ 1,393,296                 | \$ 1,617,489                 |
| Accrued expenses  | 550,029                      | 48,328                       |
| <b>Total liabilities</b>  | <b>1,943,325</b>             | <b>1,665,817</b>             |
| Commitments and contingencies   |                              |                              |
| Stockholders' equity:   |                              |                              |
| Preferred stock, \$.001 par value. Authorized 1,500,000 shares;<br>no shares issued and outstanding at December 31, 2006 and 2005   |                              |                              |
| Common stock, \$.001 par value. Authorized 150,000,000 shares;<br>60,120,038 and 60,092,697 shares issued and outstanding<br>at December 31, 2006 and December 31, 2005, respectively |                              |                              |
|   | 60,120                       | 60,093                       |
| Additional paid-in capital  | 44,411,326                   | 42,751,111                   |
| Deficit accumulated during the development stage  | (42,966,818)                 | (33,271,695)                 |
| Accumulated other comprehensive income  | —                            | 987                          |
| <b>Total stockholders' equity</b>   | <b>1,504,628</b>             | <b>9,540,496</b>             |
| <b>Total liabilities and stockholders' equity</b>   | <b>\$ 3,447,953</b>          | <b>\$ 11,206,313</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<br>period<br>from<br>August 6,<br>2001<br>(inception)<br>to<br>2006 |
|---|--------------------------|---------------------|--|
|   | 2006                     | 2005                |  |
| Revenue   | \$ —                     | \$ —                | —  |
| <b>Costs and expenses:</b>  |                          |                     |  |
| Research and development<br>(including stock based compensation<br>expense of<br>\$528,723 for the year ended<br>December 31, 2006<br>and for the cumulative period from<br>August 6, 2001<br>(inception) to December 31, 2006)     | 6,172,845                | 5,178,077           | 17,953,356   |
| General and administrative<br>(including stock based compensation<br>expense of<br>\$1,146,776 for the year ended<br>December 31, 2006<br>and for the cumulative period from<br>August 6, 2001<br>(inception) to December 31, 2006) | 3,827,482                | 2,291,121           | 10,244,093   |
| In-process research and development<br>charge   | —                        | 11,887,807          | 11,887,807   |
| Impairment of intangible assets   | —                        | —                   | 1,248,230  |
| Loss on disposition of intangible<br>assets   | —                        | —                   | 1,213,878  |
| <b>Total operating expenses</b>   | <b>10,000,327</b>        | <b>19,357,005</b>   | <b>42,547,364</b>  |
| <b>Operating loss</b>   | <b>(10,000,327)</b>      | <b>(19,357,005)</b> | <b>(42,547,364)</b>  |
| <b>Other (income) expense:</b>  |                          |                     |  |
| Interest and other income   | (307,871)                | (210,156)           | (709,716)  |
| Interest expense  | 1,665                    | —                   | 25,558   |
| Realized (gain)/loss on sale of<br>marketable equity securities   | 1,002                    | (5,852)             | (76,032)   |
| <b>Total other income</b>   | <b>(305,204)</b>         | <b>(216,008)</b>    | <b>(760,190)</b>   |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| Net loss  | (9,695,123)    | (19,140,997)    | (41,787,174)    |
| Preferred stock dividends (including imputed amounts) | —              | (175,663)       | (1,179,644)     |
| Net loss applicable to common shares                  | \$ (9,695,123) | \$ (19,316,660) | \$ (42,966,818) |
| Net loss per common share:                            |                |                 |                 |
| Basic and diluted                                     | \$ (0.16)      | \$ (0.44)       |                 |
| Weighted average shares of common stock outstanding:  |                |                 |                 |
| Basic and diluted                                     | 60,112,333     | 43,544,206      |                 |

See accompanying notes to consolidated financial statements.

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

Consolidated Statement of Stockholder's Equity (Deficiency)

|  | Series A convertible preferred stock |        | Common stock |           | Additional paid-in capital | Subscription receivable | Deficit accumulated during development stage | Dividends payable in Series A preferred shares | Accumulated other comprehensive income (loss) | Unearned consulting services |
|--|--------------------------------------|--------|--------------|-----------|----------------------------|-------------------------|--|--|---|------------------------------|
|  | Shares                               | Amount | Shares       | Amount    |                            |                         |  |  |   |                              |
| Stock issued at \$0.0004 per share for subscription receivable | —                                    | \$ —   | 10,167,741   | \$ 10,168 | (6,168)                    | (4,000)                 | \$ —   | \$ —   | \$ —  |                              |
| Net loss   | —                                    | —      | —            | —         | —                          | —                       | (56,796)                                     | —  | —   |                              |
| 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                   | —                                    | —      | —            | —         | —                          | —                       | —  | —  | —   | 22,700                       |
| 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)                                  | —  | —   | (37,889)                     |
| Common stock issued at \$0.63 per share, net of                | —                                    | —      | 1,321,806    | 1,322     | 742,369                    | —                       | —  | —  | —   | —                            |

|   |           |       |            |        |            |   |             |           |   |         |
|---|-----------|-------|------------|--------|------------|---|-------------|-----------|---|---------|
| expenses  |           |       |            |        |            |   |             |           |   |         |
| Effect of reverse acquisition                                     | —         | —     | 6,287,582  | 6,287  | 2,329,954  | — | —           | —         | — | —       |
| Amortization of unearned consulting costs                         | —         | —     | —          | —      | —          | — | —           | —         | — | 37,8    |
| Unrealized loss on short-term investments                         | —         | —     | —          | —      | —          | — | —           | —         | — | (7,760) |
| Payment for fractional shares for stock combination               | —         | —     | —          | —      | (300)      | — | —           | —         | — | —       |
| Preferred stock issued at \$10 per share, net of expenses         | 1,000,000 | 1,000 | —          | —      | 9,045,176  | — | —           | —         | — | —       |
| Imputed preferred stock dividend                                  |           |       |            |        | 418,182    | — | (418,182)   | —         | — | —       |
| Net loss  | —         | —     | —          | —      | —          | — | (5,960,907) | —         | — | —       |
| Balance at December 31, 2003                                      | 1,000,000 | 1,000 | 23,362,396 | 23,362 | 14,289,535 | — | (7,473,205) | —         | — | (7,760) |
| Exercise of stock options   | —         | —     | 27,600     | 27     | 30,073     | — | —           | —         | — | —       |
| Common stock issued at \$1.10, net of expenses                    | —         | —     | 3,368,952  | 3,369  | 3,358,349  | — | —           | —         | — | —       |
| Preferred stock dividend accrued                                  | —         | —     | —          | —      | —          | — | (585,799)   | 585,799   | — | —       |
| Preferred stock dividends paid by issuance of shares              | 24,901    | 25    | —          | —      | 281,073    | — | —           | (282,388) | — | —       |
| Conversion of preferred stock to common stock at \$1.10 per share | (170,528) | (171) | 1,550,239  | 1,551  | (1,380)    | — | —           | —         | — | —       |

|   |           |       |            |        |            |   |              |           |        |        |
|---|-----------|-------|------------|--------|------------|---|--------------|-----------|--------|--------|
| Warrants issued for consulting services   | —         | —     | —          | —      | 125,558    | — | —            | —         | —      | (120,9 |
| Amortization of unearned consulting costs   | —         | —     | —          | —      | —          | — | —            | —         | —      | 100,8  |
| 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 | (20,1  |
| Common stock issued at \$1.11 and \$1.15, net of expenses   | —         | —     | 11,917,680 | 11,918 | 12,238,291 | — | —            | —         | —      | —      |
| Common stock issued to vendor at \$1.11 per share in satisfaction of accounts payable               | —         | —     | 675,675    | 676    | 749,324    | — | —            | —         | —      | —      |
| Exercise of stock options   | —         | —     | 32,400     | 33     | 32,367     | — | —            | —         | —      | —      |
| Exercise of warrants  | —         | —     | 279,845    | 279    | 68,212     | — | —            | —         | —      | —      |
| Preferred stock dividend accrued  | —         | —     | —          | —      | —          | — | (175,663)    | 175,663   | —      | —      |
| Preferred stock dividends paid by issuance of shares  | 41,781    | 42    | —          | —      | 477,736    | — | —            | (479,074) | —      | —      |
| Conversion of preferred stock to common stock   | (896,154) | (896) | 8,146,858  | 8,147  | (7,251)    | — | —            | —         | —      | —      |



at \$1.10 per  
share

|  |     |             |           |               |           |     |     |     |     |                        |
|--|-----|-------------|-----------|---------------|-----------|-----|-----|-----|-----|------------------------|
| Share-based compensation   | —   | —           | —         | —             | 66,971    | —   | —   | —   | —   | 20,1                   |
| 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    | —         | —   | —   | —   | —   | —                      |
| Net loss   | —   | —           | —         | —             | —         | —   | —   | —   | —   | (19,140,997)           |
| Balance at December 31, 2005   | —   | —60,092,697 | 60,093    | 42,751,111    | —         | —   | —   | —   | —   | (33,271,695) 987       |
| Cashless exercise of warrants  | —   | —           | 27,341    | 27            | (27)      | —   | —   | —   | —   | —                      |
| Share-based compensation   | —   | —           | —         | —             | 1,675,499 | —   | —   | —   | —   | —                      |
| Unrealized loss on short-term investments                                | —   | —           | —         | —             | —         | —   | —   | —   | —   | (987)                  |
| Costs associated with private placement                                  | —   | —           | —         | —             | (15,257)  | —   | —   | —   | —   | —                      |
| Net loss   | —   | —           | —         | —             | —         | —   | —   | —   | —   | (9,695,123)            |
| Balance at December 31, 2006   | —\$ | —60,120,038 | \$ 60,120 | \$ 44,411,326 | \$        | —\$ | —\$ | —\$ | —\$ | —\$ (42,966,818)\$ 987 |

See accompanying notes to consolidated financial statements.

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

Consolidated Statements of Cash Flows

|  | Years ended December 31, |                         | Cumulative<br>period from<br>August 6,<br>2001<br>(inception)<br>to<br>December<br>31, 2006 |
|--|--------------------------|-------------------------|---|
| Cash flows from operating activities:  |                          |                         |   |
| Net loss   | \$ 2006<br>(9,695,123)   | \$ 2005<br>(19,140,997) | \$ (41,787,174)   |
| Adjustments to reconcile net loss to<br>net cash used in operating activities: |                          |                         |   |
| Share-based compensation   | 1,675,499                | 87,139                  | 1,924,027   |
| Amortization of intangible assets  | —                        | —                       | 145,162   |
| (Gain)/loss on sale of marketable equity<br>securities                         | 1,002                    | (5,852)                 | (76,032)  |
| Depreciation   | 60,186                   | 53,734                  | 147,480   |
| Non cash portion of in-process research and<br>development charge              | —                        | 11,721,623              | 11,721,623  |
| Loss on impairment of intangible assets  | —                        | —                       | 1,248,230   |
| Loss on disposition of intangible assets                                       | —                        | —                       | 1,213,878   |
| Other  | —                        | —                       | 5,590   |
| Changes in operating assets and liabilities, net of<br>acquisitions:           |                          |                         |   |
| Increase in prepaid expenses and other current<br>assets                       | (69,810)                 | (154,650)               | (206,341)   |
| Increase in other assets   | —                        | —                       | (70,506)  |
| Increase (decrease) in accounts payable  | (224,193)                | 1,197,835               | 1,793,510   |
| Increase (decrease) in accrued expenses  | 501,701                  | (3,774)                 | 9,708   |
| Net cash used in operating activities  | (7,750,738)              | (6,244,942)             | (23,930,845)  |
| Cash flows from investing activities:  |                          |                         |   |
| Purchase of property and equipment   | (37,052)                 | (39,555)                | (221,501)   |
| Cash paid in connection with acquisitions                                      | —                        | —                       | (32,808)  |
| Purchase of short-term investments   | —                        | —                       | (5,000,979)   |
| Proceeds from sale of short-term investments                                   | 1,005,829                | 3,499,999               | 5,436,917   |
| Proceeds from sale of license  | —                        | —                       | 200,001   |
| Cash acquired in acquisition   | —                        | 6,777                   | 6,777   |
| Net cash provided by (used in) investing<br>activities                         | 968,777                  | 3,467,221               | 388,407   |
| Cash flows from financing activities:  |                          |                         |   |
| Repayments of notes payable to stockholders                                    | —                        | (651,402)               | (884,902)   |
| Payment for fractional shares for Preferred stock<br>dividends                 | —                        | (1,296)                 | (2,286)   |
| (Costs) proceeds related to sale of common<br>stock, net                       | (15,257)                 | 12,250,209              | 18,044,077  |

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|  |              |              |              |
|--|--------------|--------------|--------------|
| Proceeds from sale of preferred stock, net                               | —            | —            | 9,046,176    |
| Proceeds from exercise of stock options                                  | —            | 32,400       | 62,500       |
| Proceeds from exercise of warrants                                       | —            | 68,490       | 68,491       |
| Other, net   | —            | —            | 237,500      |
| Net cash (used in) provided by financing activities                      | (15,257)     | 11,698,401   | 26,571,556   |
| Net (decrease) increase in cash and cash equivalents                     | (6,797,218)  | 8,920,680    | 3,029,118    |
| Cash and cash equivalents at beginning of period                         | 9,826,336    | 905,656      | —            |
| Cash and cash equivalents at end of period                               | \$ 3,029,118 | \$ 9,826,336 | \$ 3,029,118 |
| Supplemental disclosure of cash flow information:                        |              |              |              |
| Interest paid  | \$ 1,665     | \$ —         | \$ 25,558    |
| Supplemental disclosure of noncash investing and financing activities:   |              |              |              |
| Common stock issued in satisfaction of accounts payable                  | \$ —         | \$ 750,000   | \$ 750,000   |
| Imputed preferred stock dividend   | —            | —            | 418,182      |
| Preferred stock dividends accrued  | —            | 175,663      | 761,462      |
| Conversion of preferred stock to common stock                            | —            | 896          | 1,067        |
| Preferred stock dividends paid by issuance of shares                     | —            | 477,736      | 759,134      |
| Issuance of common stock for acquisitions                                | —            | 11,052,984   | 13,389,226   |
| Marketable equity securities received in connection with sale of license | —            | —            | 359,907      |
| Net liabilities assumed over assets acquired in business combination     | —            | (675,416)    | (675,416)    |
| Cashless exercise of warrants  | 27           | —            | 27           |

See accompanying notes to consolidated financial statements.

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

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. (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.

***Business and Operations***

As described above, the Company resulted from the February 21, 2003 reverse merger between Atlantic Technology Ventures, Inc., 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 Development.

The Company is a development stage biopharmaceutical company that holds an exclusive world-wide, royalty-free license to certain intellectual property related to oleoyl-estrone, which is owned by Oleoyl-Estrone Developments, SL (“OED”) of Barcelona, Spain. Oleoyl-estrone is an orally administered small molecule that has been shown to cause significant weight loss in pre-clinical animal studies regardless of dietary modifications. In addition, the Company has exclusive, world-wide proprietary rights to a technology for the clinical uses of PTH (1-34) relating to the regulation of cell differentiation and proliferation for treatment of skin disorders including psoriasis. The Company also holds the worldwide, exclusive rights to proprietary lingual spray technology to deliver the drug propofol for preprocedural sedation prior to diagnostic, therapeutic or endoscopic procedures.

***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  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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). Results of operations of Tarpan are included in the consolidated financials since April 1, 2005.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A summary of the allocation of the purchase price is as follows:

|  |               |
|--|---------------|
| Assets purchased:                            |               |
| Cash   | \$ 6,777      |
| Property and equipment                       | 2,037         |
| Acquired in-process research and development | 11,887,807    |
| Total  | 11,896,621    |
| Liabilities assumed:                         |               |
| Accounts payable                             | 26,051        |
| Notes payable - related parties              | 651,402       |
| Total  | 677,453       |
| Net purchase price                           | \$ 11,219,168 |

The following unaudited pro forma financial information presents the condensed consolidated results of operations of the Company and Tarpan, as if the acquisition had occurred on January 1, 2005 instead of April 1, 2005, after giving effect to certain adjustments, including the issuance of the Company's common stock as part of the purchase price. The unaudited pro forma information does not necessarily reflect the results of operations that would have occurred had the entities been a single company during this period.

|  |  |
|--|--|
|  | <b>Twelve months<br/>ended<br/>December 31,<br/>2005</b> |
| Net loss   | \$ (19,268,258)  |
| Weighted average number of common shares outstanding | 46,219,619   |
| Loss per common share - basic and diluted            | \$ (0.42)  |

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

***Liquidity***

The Company incurred 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 and a net loss of \$19,140,997 and negative cash flows from operating activities of \$6,244,942 for the year ended December 31, 2005. The net loss from date of inception, August 6, 2001, to December 31, 2006 amounts to \$41,787,174.

The Company received approximately \$8 million net from a private placement of common stock and warrants in March 2007. This private placement is more fully described in Note 12.

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Management believes that the Company will continue to incur net losses through at least December 31, 2007 and for the foreseeable future thereafter. Based on the resources of the Company available at December 31, 2006 and the net proceeds received from the March 2007 private placement management believes that the Company has sufficient capital to fund its operations through 2007. 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 beyond 2007. 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.

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.

***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***

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.



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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 13,383,229 and 12,841,159 shares at December 31, 2006 and 2005, respectively.

***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.”



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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 year ended December 31, 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 recognized compensation expense related to stock option grants on a straight-line basis over the vesting period. For the year ended December 31, 2006, the Company recognized share-based employee compensation cost of \$1,670,661 in accordance with Statement 123(R). \$1,500,690 of this expense resulted from the grants of stock options to officers, directors and employees of the Company on or prior to December 31, 2005. The balance of \$169,971 relates 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, 2006, net of amortization, the Company recognized 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:

**2006**

General and administrative expense:

|  |    |           |
|--|----|-----------|
| Share-based employee compensation cost       | \$ | 1,176,618 |
| Share-based consultant and non-employee cost |    | (29,842)  |
|  | \$ | 1,146,776 |

Research and development expense

|  |    |         |
|--|----|---------|
| Share-based employee compensation cost       | \$ | 494,043 |
| Share-based consultant and non-employee cost |    | 34,680  |
|  | \$ | 528,723 |

|                        |    |           |
|------------------------|----|-----------|
| Total share-based cost | \$ | 1,675,499 |
|------------------------|----|-----------|

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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.

The net loss for the year ended December 31, 2005 does not include any compensation charges related to options granted to employees since the Company used the intrinsic value method for employee options and the exercise price of the options granted through December 31, 2005 was not less than the fair value at the date of grant. The following table illustrates the pro forma effect on net loss and loss per share assuming the Company had applied the fair value recognition provisions of SFAS No. 123 instead of the intrinsic value method under APB 25 to stock-based employee compensation:

|  | <b>2005</b>     |
|--|-----------------|
| Net loss applicable to common shares, as reported  | \$ (19,316,660) |
| Deduct: Total stock-based employee compensation expense determined under fair value method | (1,089,814)     |
| Net loss applicable to common shares, pro forma  | \$ (20,406,474) |
| Net loss per common share – basic  |                 |
| As reported  | \$ (0.44)       |
| Pro forma  | (0.47)          |

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. Under the 1995 Plan at December 31, 2006 options to purchase 1,137,240 shares were outstanding and no shares were reserved for future stock option grants.

To compute compensation expense in 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.

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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 2006 and the pro forma charges in 2005:

|                          | 2006         | 2005        |
|--------------------------|--------------|-------------|
| Expected Volatility      | 84% - 98%    | 70% - 72%   |
| Dividend yield           | —            | —           |
| Expected term (in years) | 5 - 10       | 4 - 5       |
| Risk-free interest rate  | 4.45% - 5.1% | 3.4% - 4.4% |
| Forfeiture rate          | 4%           | N/A         |

***Financial Instruments***

At December 31, 2006 and 2005, the fair values of cash and cash equivalents, short-term investments 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, 2006. At December 31, 2005 the Company had short-term investments with a market value of \$1,007,818, a cost basis of \$1,006,831 and an unrealized gain of \$987. Unrealized gain (and loss, if any) is excluded from operations and included in accumulated other comprehensive income (loss). The Company's comprehensive loss (net loss adjusted for changes in unrealized gains/losses on short-term investments) for 2005 was \$19,153,247.

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*New Accounting Pronouncements*

In July 2006, the FASB issued Interpretation No. 48 (“FIN No. 48”), Accounting for Uncertainty in Income Taxes. FIN No. 48 prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise’s financial statements in accordance with FASB Statement No. 109 (“FAS No. 109”), Accounting for Income Taxes. Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN No. 48 and in subsequent periods. FIN No. 48 will be effective for fiscal years beginning after December 15, 2006 and the provisions of FIN No. 48 will be applied to all tax positions accounted for under FAS No. 109 upon initial adoption. The cumulative effect of applying the provisions of FIN No. 48 will be reported as an adjustment to the opening balance of retained earnings for that fiscal year. The Company currently believes that the adoption of FIN 48 will have no material impact on its consolidated financial position or results of operations.

In December 2006, the FASB issued FASB Staff Position EITF 00-19-2 (“FSP 00-19-2”), Accounting for Registration Payment Arrangements. FSP 00-19-2 addresses an issuer’s accounting for registration payment arrangements by specifying that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, Accounting for Contingencies. FSP 00-19-2 will be effective for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company currently believes that the adoption of FSP 00-19-2 will have no material impact on its consolidated financial position or results of operations.

The FASB and the Securities and Exchange Commission had issued certain other accounting pronouncements as of December 31, 2006 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, 2006 and 2005 and for the period from August 6, 2001 (inception) to December 31, 2006 or that will have a significant effect at the time they become effective.

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(4) **Property and Equipment**

Property and equipment consists of the following at December 31:

|                               | 2006       | 2005       |
|-------------------------------|------------|------------|
| Property and equipment        | \$ 244,040 | \$ 206,988 |
| Less accumulated depreciation | (160,297)  | (100,111)  |
| Net property and equipment    | \$ 83,743  | 106,877    |

(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.

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.

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. 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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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.

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.

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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.

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.

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

**(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 and 2005, 7,400,000 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 534,500 shares of common stock at an exercise price of \$1.35, 50,000 shares of common stock at an exercise price of \$0.89 and 220,000 shares of common stock at an exercise price of \$0.70 during the year ended December 31, 2006.

At December 31, 2006 there were 1,536,736 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, 2006 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, 2006 and 2005 and changes during the years then ended is presented below:

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|  | 2006      |  |  |                                 | 2005      |  |
|--|-----------|--|--|---------------------------------|-----------|--|
|  | Shares    | Weighted<br>average<br>exercise<br>price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(years) | Aggregate<br>Intrinsic<br>Value | Shares    | Weighted<br>average<br>exercise<br>price |
| Outstanding at beginning of year                               | 6,328,754 | \$ 1.33                                  |  |                                 | 2,822,140 | \$ 1.17                                  |
| Granted  | 804,500   | 1.12                                     |  |                                 | 3,641,180 | 1.45                                     |
| Exercised  | -         |  |  |                                 | (32,400)  | 1.00                                     |
| Cancelled  | (132,750) | 1.20                                     |  |                                 | (102,166) | 1.31                                     |
| Outstanding at end of year                                     | 7,000,504 | \$ 1.31                                  | 7.71   | \$ 262,937                      | 6,328,754 | \$ 1.33                                  |
| Options exercisable at year-end                                | 4,822,372 |  | 7.37   | \$ 262,937                      | 3,472,745 |  |
| Weighted-average fair value of options granted during the year | \$ 0.50   |  |  |                                 | \$ 0.89   |  |

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

Included in the options granted during 2005 are options for 350,000 shares issued to consultants which are subject to variable accounting pursuant to EITF 96-18. As a result, the Company recorded expense for the increase in the fair value of those options of \$4,838 and \$66,971 for the years ended December 31, 2006 and December 31, 2005, respectively.

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The following table summarizes the information about stock options outstanding at December 31, 2006:

| Exercise price | Number outstanding | Remaining contractual life (years) | Number of options exercisable |
|----------------|--------------------|------------------------------------|-------------------------------|
| \$0.400        | 876,090            | 6.16                               | 876,090                       |
| 0.430          | 400                | 6.15                               | 400                           |
| 0.700          | 220,000            | 9.53                               | —                             |
| 0.890          | 50,000             | 9.38                               | —                             |
| 0.970          | 440,000            | 8.75                               | 415,000                       |
| 1.000          | 312,364            | 8.04                               | 195,522                       |
| 1.000          | 65,000             | 5.24                               | 65,000                        |
| 1.250          | 12,000             | 5.08                               | 12,000                        |
| 1.250          | 163,750            | 5.14                               | 153,750                       |
| 1.350          | 130,000            | 9.08                               | —                             |
| 1.350          | 300,000            | 9.09                               | —                             |
| 1.350          | 60,000             | 9.53                               | —                             |
| 1.500          | 2,923,900          | 8.25                               | 1,949,277                     |
| 1.500          | 250,000            | 3.58                               | 25,000                        |
| 1.600          | 100,000            | 8.46                               | 33,333                        |
| 1.650          | 1,077,000          | 7.08                               | 1,077,000                     |
| 4.375          | 10,000             | 4.14                               | 10,000                        |
| 20.938         | 10,000             | 3.28                               | 10,000                        |
|                | 7,000,504          |                                    | 4,822,372                     |

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**(7) Stock Warrants**

The following table summarizes the information about warrants to purchase shares of our common stock outstanding at December 31, 2006:

| Exercise price | Number outstanding | Remaining contractual life (years) | Number of warrants exercisable |
|----------------|--------------------|------------------------------------|--------------------------------|
| 0.700          | 353,013            | 1.00                               | 353,013                        |
| 0.700          | 1,252,752          | 2.21                               | 1,252,752                      |
| 0.780          | 10,000             | 2.98                               | 10,000                         |
| 1.100          | 909,090            | 1.85                               | 909,090                        |
| 1.100          | 326,499            | 2.08                               | 326,499                        |
| 1.440          | 2,702,216          | 3.65                               | 2,702,216                      |
| 1.440          | 135,135            | 3.65                               | 135,135                        |
| 1.490          | 276,741            | 3.67                               | 276,741                        |
| 1.900          | 100,000            | 2.21                               | 100,000                        |
| 6.690          | 185,601            | 1.10                               | 185,601                        |
| 8.000          | 101,678            | 1.00                               | 101,678                        |
| 22.500         | 30,000             | 0.01                               | 30,000                         |
|                | 6,382,725          |                                    | 6,382,725                      |

**(8) Related-Party Transactions**

**Oleoylstrone Developments, SL**

Pursuant to the terms of a license agreement dated February 15, 2002 by and between Manhattan Research Development, Inc., the Company's wholly owned subsidiary and OED, the Company has an exclusive, worldwide license to U.S. and foreign patents and patent applications relating to certain technologies. Although the Company is not obligated to pay royalties to OED, the license agreement requires the Company to make certain performance-based milestone payments. See Note 10. OED currently owns approximately 7 percent of the Company's outstanding common stock. Additionally, Mr. Pons, a member of the Company's board of directors, is chief executive officer of OED.

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 will terminate when the license agreement terminates. The fees associated with the consulting agreement are expensed as incurred. OED agreed to serve as a member of the Company's Scientific Advisory Board and to render consultative and advisory services to the Company. Such services include research, development and clinical testing of the Company's technology as well as the reporting of the findings of such tests, assistance in the filing of patent applications and oversight and direction of efforts in regards to personnel for clinical development.

Total milestone payments under the license agreement of \$250,000, \$250,000 and \$675,000 and consulting fees of \$75,000, \$75,000 and \$362,500 are included in the accompanying consolidated statements of operations for the years ended December 31, 2006, 2005 and for the cumulative period from August 6, 2001 to December 31, 2006.

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**NovaDel Pharma Inc.**

As discussed in Note 10, pursuant to the terms of a license agreement dated April 4, 2003 by and between the Company and NovaDel Pharma Inc. ("NovaDel"), the Company has the rights to develop NovaDel's proprietary lingual spray technology to deliver propofol for preprocedural sedation. The license agreement with NovaDel requires the Company to make certain license and milestone payments, as well as pay royalties. During 2003, the Company paid aggregate license fees of \$500,000 to NovaDel under the license agreement. In 2005 and 2006, no milestones were reached and no payments were made to NovaDel. Lindsay A. Rosenwald, who beneficially owns more than 10 percent of the Company's common stock, also beneficially owns in excess of 20 percent of the common stock of NovaDel and may therefore be deemed to be an affiliate of that company.

**Paramount BioCapital, Inc.**

One member of the Company's board of directors, Timothy McInerney, is also an employees of Paramount BioCapital, Inc. or one of its affiliates ("Paramount"). 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 BioCapital through August 2004 and were directors of the Company until September 2005. The sole shareholder of Paramount BioCapital, Inc. ("Paramount BioCapital") is Lindsay A. Rosenwald, M.D. Dr. Rosenwald beneficially owns more than 5 percent of the Company's common stock as of December 31, 2006 and various trusts established for Dr. Rosenwald's or his family's benefit, held in excess of 14% of the Company's common stock as of December 31, 2006. In November 2003, the Company paid to Paramount BioCapital 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 BioCapital 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 BioCapital 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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**(9) Income Taxes**

There was no current or deferred tax expense for the years ended December 31, 2006 and 2005 because of the Company's operating losses.

The components of deferred tax assets as of December 31, 2006 and 2005 are as follows:

|                                  | 2006              | 2005              |
|----------------------------------|-------------------|-------------------|
| Deferred tax assets:             |                   |                   |
| Tax loss carryforwards           | \$ 18,265,000     | \$ 14,860,000     |
| Research and development credit  | 1,263,000         | 1,174,000         |
| Other                            | 29,000            | (5,000)           |
| <b>Gross deferred tax assets</b> | <b>19,557,000</b> | <b>16,029,000</b> |
| Less valuation allowance         | (19,557,000)      | (16,029,000)      |
| Net deferred tax assets          | \$ —              | \$ —              |

The reasons for the difference between actual income tax benefit for the years ended December 31, 2006 and 2005 and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit are as follows:

|  | 2006           |                        | 2005           |                        |
|--|----------------|------------------------|----------------|------------------------|
|  | Amount         | % of<br>pretax<br>loss | Amount         | % of<br>pretax<br>loss |
| Federal income tax benefit at statutory rate | \$ (3,296,000) | (34.0%)                | \$ (6,508,000) | (34.0%)                |
| State income taxes, net of federal tax       | (659,000)      | (6.8%)                 | (1,302,000)    | (6.8%)                 |
| Research and development credits             | (90,000)       | (0.9%)                 | (233,000)      | (1.2%)                 |
| Other  | (165,000)      | (1.7%)                 | —              | —                      |
| Stock based compensation                     | 682,000        | 7.0%                   | —              | —                      |
| In-process research and development charge   | —              | —                      | 4,850,000      | 25.3%                  |
| Change in valuation allowance                | 3,528,000      | 36.4%                  | 3,193,000      | 16.7%                  |
|  | \$ -           | —                      | \$ -           | —                      |

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, 2006 and 2005 was an increase of \$3,528,000 and \$3,193,000, 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.



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At December 31, 2006, the Company had unused federal and state net operating loss carryforwards of approximately \$46,432,000 and \$38,412,000, respectively. The net operating loss carryforwards expire in various amounts through 2026 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 in reducing any future year's taxable income. At December 31, 2006, the Company also had research and development credit carryforwards of approximately \$1,263,000 for federal income tax purposes which expire in various amounts through 2026.

(10) **License and Consulting 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.

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 will terminate when the License Agreement terminates. The fees associated with the consulting agreement are expensed as incurred. OED agreed to serve as a member of the Company's Scientific Advisory Board and to render consultative and advisory services to the Company. Such services include research, development and clinical testing of the Company's technology as well as the reporting of the findings of such tests, assistance in the filing of patent applications and oversight and direction of efforts in regards to personnel for clinical development.

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:

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(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, 2006, the Company paid a total of \$675,000 in licensing fees and milestone payments.

**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. Holders of a significant portion of the Company's common stock own a significant portion of the common stock of NovaDel. (See Note 8.)

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).

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, 2006, the Company has incurred, and paid a total of \$500,000 under the NovaDel license agreement, the initial license fee paid in 2003.

NovaDel may terminate the agreement (i) upon 10 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 or insolvency is filed and not dismissed within 60 days or if the Company becomes subject to a receiver or trustee for the benefit of creditors. Each party may terminate the agreement upon 30 days' written notice and an opportunity to cure in the event the other party committed a material breach or default. The Company may also terminate the agreement for any reason upon 90 days' notice to NovaDel.

### **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 II clinical trial; \$500,000 upon the commencement of a Phase III 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 III 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.

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, 2006, the Company has not paid any such milestones or 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.

## **(11) Commitments and Contingencies**

### ***Research and Development Agreement***

On March 27, 2006, the Company entered into a research and development agreement with Swiss Pharma Contract Ltd. ("Swiss Pharma") to perform a Phase IIa study in 100 obese patients of the Company's Oleoyl-estrone product for the treatment of obesity. The terms of the contract call for the Company to pay Swiss Pharma up to \$2,151,840. The payment terms are: 20%, or \$430,368, upon signing the agreement, 20% after the first patient has received the initial dose, 20% after half the patients have received the initial dose, 20% after all patients have completed dosing, 10%, on receipt of statistical analyses and 10% on acceptance by the Company of the Phase IIa study.

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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.

The contract with Swiss Pharma contains a list of the fees to be charged by Swiss Pharma for the provision of specific services under the contract. The maximum fees to be charged under the contract are \$2,151,840. The Company recognizes expense as per this list as the specific services are performed by Swiss Pharma. In the fourth quarter of 2006, we expanded this ongoing Phase IIa clinical trial of Oleoyl-estrone in obesity into two clinical sites in the United States. Because the size of the study has not been expanded beyond the 100 obese patients, we do not anticipate the addition of the two new sites to materially increase our total financial commitment of up to \$2,152,000. Such financial commitment will now be paid to three clinical centers rather than one. As of December 31, 2006, the Company had paid an aggregate of \$1,168,755 to the three clinical sites and recognized \$1,012,333 of research and development expense for the Phase IIa study. The remainder, \$156,422, is included in prepaid expenses.

In the fourth quarter of 2006 the Company commenced a Phase IIa clinical trial in the morbidly obese at St. Lukes/Roosevelt Hospital in New York City. The financial commitment for this study is approximately \$685,000. The study is expected to conclude mid year 2007.

***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.

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***Employment Agreement***

The Company has employment agreements with three employees for the payment of aggregate annual base salary of \$805,000 as well as performance based bonuses. These agreements have three year terms and have a remaining obligation of \$1,492,000 as of December 31, 2006.

***Leases***

The Company leases office space under a non-cancellable lease terminating in September 2008. Rent expense for the years ended December 31, 2006 and 2005 was \$141,012 and \$120,209, respectively.

Future minimum rental payments subsequent to December 31, 2006 under an operating lease for the Company's office facility are as follows:

| Years Ending December 31, | Commitment |
|---------------------------|------------|
| 2007                      | \$ 141,600 |
| 2008                      | \$ 100,000 |
| 2009 and subsequent       | \$ 0       |

**(12) Subsequent Events**

On March 30, 2007, the Company completed a private placement of our common stock and warrants to purchase shares of our common stock. We received net proceeds of approximately \$8.0 million from this private placement. The Company issued approximately 10.2 million shares of common stock at a price of \$0.84 per share and 5-year warrants to purchase an additional 3.6 million shares of our common stock at \$1.00 per share to the investors and warrants to purchase approximately 510,000 shares of our common stock at \$1.00 per share to the placement agent, Paramount Biocapital, Inc., a related party. In connection with this private placement the Company paid approximately \$600,000 to Paramount as a placement fee. As a result of this private placement, the Company believes it now has sufficient capital to fund its operations through the end of 2007.

**Index to Exhibits Filed with this Report**

| Exhibit No. | Description  |
|-------------|--|
| 10.15       | Form of Stock Option Agreement issued under the Registrant's 2003 Stock Option Plan. |
| 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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