MANHATTAN PHARMACEUTICALS INC
Form 10KSB
March 31, 2006
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

x Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2005

o 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, 4th 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. o

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 x No o

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. o

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, 2005 were$0.

The aggregate market value of the common stock of the issuer held by non-affiliates of the issuer on March 24, 2006 based on the closing price of the common stock as reported on the American Stock Exchange on such date was $54,939,388 .

As of March 24, 2006 there were 60,092,697 outstanding shares of common stock, par value $.001 per share.

Traditional Small Business Disclosure Format: Yes o No x

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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 state 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 engaged in the business of developing and commercializing biomedical and pharmaceutical technologies. We aim to acquire proprietary rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually bringing the technologies to market. We do not have any drugs or other products available for sale, but we are currently researching and developing three biomedical technologies:

- Oleoyl-estrone, an orally administered hormone attached to a fatty-acid that has been shown to cause significant weight loss in preclinical animal studies regardless of dietary modifications;

- PTH (1-34), a peptide that regulates epidermal cell growth and differentiation currently under development as a topical treatment for psoriasis and additional hyperproliferative skin disorders.

- Lingual spray propofol, a proprietary lingual spray technology is used to deliver propofol for pre-procedural sedation prior to diagnostic, therapeutic or endoscopic procedures.

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Although we are primarily focused on developing these technologies, we continue to seek to acquire proprietary rights to other biomedical and pharmaceutical technologies, by licensing or acquiring an ownership interest, funding their research and development and bringing the technologies to market.

Pursuant to an Agreement and Plan of Merger dated April 1, 2005 (the "Agreement") between us, Tarpan Therapeutics, Inc., a Delaware corporation ("Tarpan"), and Tarpan Acquisition Corp., a Delaware corporation and our wholly-owned subsidiary ("TAC"), TAC merged with and into Tarpan, with Tarpan remaining as the surviving corporation and our wholly-owned subsidiary. Tarpan was a privately-held, New York based biopharmaceutical company developing dermatological therapeutics. Through the merger, we acquired Tarpan's primary product candidate, PTH (1-34), a peptide believed to be a regulator of epidermal cell growth and differentiation. In consideration for their shares of Tarpan capital stock and in accordance with the Agreement, the stockholders of Tarpan received an aggregate of approximately 10,731,000 shares, representing approximately 20% of our then outstanding common stock. This transaction was accounted for as a purchase of Tarpan by the Company. As a result of the merger, we assumed Tarpan's outstanding indebtedness of approximately $651,000, which resulted 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 amended at the time of the merger to provide that one-half of the outstanding indebtedness was payable upon completion of the merger and the remaining one-half will be payable at such time as we raise at least $5 million in new financing. As a result of our August 2005 private placement, we have now satisfied the remaining balance of this indebtedness.

Several of Tarpan's former stockholders are directors or significant stockholders of our company. At the time of the merger, 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 our common stock (Dr. Rosenwald disclaims beneficial ownership of shares held by such trusts, except to the extent of any pecuniary interest). In addition, Joshua Kazam, David Tanen, Dr. Michael Weiser and Timothy McInerney, all of whom were then members of our board of directors, collectively owned approximately 13.4 percent of Tarpan's outstanding common stock. Dr. Weiser and Mr. McInerney are also employed by Paramount BioCapital, Inc., an entity owned and controlled by Dr. Rosenwald. As a result of such relationships between us and Tarpan, our board of directors established a special committee to consider and approve the merger. The special committee consisted of three disinterested directors, none of whom had any prior relationship with Tarpan.

We were incorporated in Delaware in May 1993 under the name "Atlantic Pharmaceuticals, Inc." and, in March 2000, we changed our name to "Atlantic Technology Ventures, Inc." On February 21, 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. with the impact of the "acquisition" of Atlantic Technology Ventures, Inc. as of February 21, 2003.

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Oleoyl-estrone

We acquired the rights to develop and commercialize oleoyl-estrone, a hormone modified by an attachment to a fatty acid, pursuant to a February 2002 license agreement with Oleoylestrone Development, SL., a Spanish corporation. Oleoyl-estrone is an orally administered small molecule that has been shown to cause significant weight loss in preclinical animal studies regardless of dietary modifications.

Oleoyl-estrone was initially developed by researchers at the University of Barcelona ("UB") in Spain. Through a decade of research, scientists of the Nitrogen-Obesity Research Group at UB noted that hormones that effect metabolism play a significant role in body weight regulation. At the same time, the obesity research community suggested that weight is regulated by the ponderostat, a central mechanism in the hypothalamus of the brain believed to set the point of ideal weight. Researchers at UB believe that a hormone controls the ponderostat, raising or lowering body weight by changing the central set point for the entire body.

We consider 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. The potential for out-licensing oleoyl-estrone may also create an opportunity for non-dilutive financing based on both up-front and ongoing milestone payments as the drug advances through development.

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 laboratories findings included reversible, dose-dependent elevations in estrone and estradiol levels, as well as reductions in testosterone levels. We plan to initiate a follow on Phase IIa study using low doses of Oleoyl-estrone in the first half of 2006.

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Results from both Phase I studies are being used, in conjunction with extensive preclinical work, to establish the protocol and obtain approval from the relevant regulatory authority to begin Phase II clinical trials. Under our license agreement with Oleoylestrone Developments, we made a $250,000 milestone payment upon the treatment of the first patient in the Phase I trial. Upon initiation of the Phase IIa trial, an additional milestone payment of $250,000 will be made. In preparation for beginning the phase IIa clinical trial, the clinical study protocol is currently in the regulatory review cycle in Switzerland, having received local ethics committee review and approval. The trial will begin immediately following receipt of final regulatory approval from Swissmedic, the Swiss Medical Authority.

PTH(1-34)

We acquired our rights to PTH (1-34) in connection with our acquisition of Tarpan Therapeutics in April 2005. Tarpan acquired an exclusive, worldwide license to develop and commercialize this drug compound pursuant to an April 2004 agreement with IGI, Inc.

In August 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. Patient recruitment is ongoing; dosing has not yet begun.

Lingual Spray Propofol

On April 4, 2003, we entered into a License and Development Agreement (the “Propofol License”) with NovaDel Pharma Inc. (“NovaDel”) for the worldwide, exclusive rights to NovaDel’s proprietary lingual spray technology to deliver propofol for preprocedural 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 office-based and other ambulatory uses. Accordingly, we have filed a patent application for this new method of use. 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.

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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. NovaDel refers to its delivery system as Immediate-Immediate Release (I2R ™) because its delivery system is designed to provide therapeutic benefits within minutes of administration. 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 June 2003.

In July 2004, we released the 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 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 the propofol spray 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 min 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 January 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 Propofol LS under the 505b2 regulatory pathway. Section 505b2 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 505b2 to proceed directly to a pivotal Phase III trial for lingual spray propofol following completion of Phase I trials. We are actively planning the next steps of the development process for Propofol LS, particularly meeting with scientific advisors, NovaDel and other formulation partners regarding optimum formulation development. 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.

Although we have the sole right and obligation to develop and commercialize lingual spray propofol on a worldwide basis, NovaDel has undertaken to perform certain development activities on our behalf. NovaDel's responsibilities include formulation development, formulation stability testing, formulation analytic method development and testing and manufacture of clinical trial material for the pre-clinical and early clinical development. We are also working with other formulation partners to develop an optimal formulation. We will oversee pre-clinical testing, as necessary, and have responsibility for overall product development and product management. In addition, we will design and oversee clinical trials and be responsible for regulatory filings and meetings. The license agreement provides that these development activities are to be performed under the supervision of a development committee, which is comprised of an equal number of appointees of us and NovaDel. Within 30 days of the end of each calendar quarter in which any agreed-upon development activities are to be performed, each of us and NovaDel are to provide a written progress report to the development committee, which should describe the activities that have been performed and evaluate the work performed in relation to the goals of the development plan and budget. The NovaDel license agreement also provides that NovaDel will manufacture and supply us with lingual spray propofol for use in clinical development and for commercial purposes pursuant to a manufacturing agreement to be entered into between us and NovaDel.

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Market and Competition

Obesity

According to estimates, the market for prescription anti-obesity drugs is in excess of $10 billion, or roughly equal to that of diabetes. It is estimated that 65 percent of Americans are overweight and that 30 percent are obese. According to the Center for Disease Control and Prevention (CDC), the medical costs attributed to both overweight and obesity accounted for 9.1 percent of the total U.S. medical expenditures in 1998 and may have reached as high as $78.5 billion. The U.S. Department of Health and Human Services has estimated that in 2000 the total costs for the treatment of obesity had reached $117 billion. Meridia® and Xenical®, two currently approved anti-obesity medications, together accounted for approximately $700 million in worldwide sales in 2004. We believe that the disease currently lacks a treatment that is safe and effective for most patient groups, and that oleoyl-estrone has the potential to meet the needs of this market.

Competition in the pharmaceutical industry, and the anti-obesity drug market in particular, is intensely competitive. 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 GlaxoSmithKline PLC, Johnson & Johnson, Inc., Bristol-Myers Squibb Company, Regeneron Pharmaceutical, Inc., Phytopharm, PLC, 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.

Psoriasis

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 intend to achieve market share as a monotherapy at the expense of existing and established products to be used 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," and prescription topical treatments, Dovonex, phototherapies, laser treatment, methotrexate, cyclosporine, Johnson & Johnson (Remicade), Amgen (Enbrel), BiogenIdec (Amevive) and Genentech (Raptiva).

Topical treatments include numerous OTC ointments that help to reduce inflammation, soothe skin and enhance the efficacy of other therapies. Additionally, steroids are prescribed as an adjunct therapy for pain and anti-inflammation. One of the most frequently prescribed topical treatments is Calcipotriene (Dovonex), 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 become resistant to treatment in 6-12 months. Dovonex achieved $700 million in sales in its first two years after launch but sales have now declined to $130 million due to high incidence of resistance.

There are two main types of phototherapy, Ultra-violet A, or "UVA" and Ultra-violet B, or "UVB." UVA penetrates deeper into the skin but requires the use of photo-sensitizing agent and carries a higher risk of skin cancer. UVB, on the other hand, is 1,000 times more powerful than UVA in producing sunburn. UV treatments are often combined with other treatments such as topicals and methotrexate. Phototherapy treatments have been shown to clear the disease and induce remission but they require frequent doctor visits, making treatment expensive and inconvenient.

Systemic treatments are generally reserved for severe patients due to their harsh side effect profiles. The most effective systemic treatments are methotrexate and cyclosponine. Methotrexate is a classical antifolate commonly used for the treatment of widespread plaque psoriasis the psoriatic arthritis and other autoimmune diseases. The low cost and effectiveness of methotrexate is counter balanced by the significant risk of liver and kidney toxicity and

inability to be used by pregnant women. Cyclosporine inhibits Nuclear Factor of Activated T-Cells (NFAT), which requires the transcription of cytokines and the immune response. It is only indicated in patients who have failed prior systemic therapies and carries the risk of impaired renal function and severe immunosuppression. Unlike methotrexate, cyclosporine is relatively expensive and costs over $6,000 per year.

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Biologics are likely to play a large role in the treatment of patients with moderate to severe psoriasis but due to their high cost, use will likely be limited to patients that have failed all other treatments or have experienced intolerable side effects or toxicity with other therapies. Therefore the market will likely be limited to the patient population that can no longer be treated with methotrexate or cyclosporine. Amgen's TNF-a inhibitor, Enbrel, recently received marketing approval for psoriasis and is expected to have strong sales due to physician familiarity and efficacy data. However, Enbrel has been shown to cause serious infections and sepsis. Genentech and Serono's Raptiva received FDA approval in 2003 for the treatment of chronic moderate to severe plaque psoriasis in adults. Raptiva is a humanized monoclonal antibody that binds to CD11a, leading to inhibition of T-cell activation and migration to sites of inflammation. Clinical trials show Raptiva to have a fast onset of action and to be relatively effective, however, the companies are required to conduct post market safety and efficacy studies. There are other biologics that are either approved or in clinical studies for psoriasis, including BiogenIdec's Amevive and Johnson & Johnson's Remicade. Use of many of these will be limited by their side effect profiles, cost and method of delivery.

Pre-procedural Sedation

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 propofol lingual spray 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.

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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 Oleoylestrone Developments. 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, 2005, we have paid the initial license fee of $175,000 and $250,000 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. Oleoylestrone 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.

On April 1, 2005 as part of the acquisition of Tarpan Therapeutics, Inc., we acquired a Sublicense Agreement with IGI, Inc. (the "IGI Agreement") dated April 14, 2004. We currently 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.

2. U.S. Patent No. 5,840,690, entitled "Regulation of cell proliferation and differentation using peptides." M.F. Holick, Inventor. Application filed June 6, 1995. Patent issued November 24, 1998.

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.

4. European Patent Specification PCT/US88/03639

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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, 2005, 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 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.

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.

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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 upon the completion of our $10 million private placement of Series A Convertible Preferred Stock in November 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). 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.

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 "Good Manufacturing Process" (GMP) 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.

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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, the Company 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.

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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 505b2 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.

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 postmarketing 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.

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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 8 employees, including 3 persons devoted to research and development and 5 persons in administration and finance, including our senior management.

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.

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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, 2005, we had $9,826,336 of cash and cash equivalents and $1,007,818 of short-term investments. We will have to raise 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. For each of the fiscal years ended December 31, 2005, 2004, 2003 and 2002 and from August 6, 2001 (inception) through December 31, 2001, we incurred net losses of $19,140,997, $5,896,031, $5,960,907, $1,037,320, and $56,796, respectively. Even if we succeed in developing and commercializing one or both 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.

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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. Assuming formulation work is completed satisfactorily, we expect to conduct a Phase I clinical study for propofol lingual spray following formulation. 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 our planned Phase I trials. Accordingly, we currently anticipate that development of propofol lingual spray may be completed as early as 2007. 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.

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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 our product candidate. Failure to obtain FDA approval of any of our product candidate 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.

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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 DEA, 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.

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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 approval, 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.

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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.

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We currently do not directly own the rights to any patents or patent applications. We license the exclusive rights to two issued patents relating to oleoyl-estrone, which expire in 2016, and three patent applications. We also license the exclusive rights to three issued patents relating to lingual spray propofol, which expire from 2016 to 2017. In addition, our license for propofol lingual spray covers one pending patent application. See “Business - Intellectual Property and License Agreements.” There are no other pending patent applications relating to either of our product candidates, although we anticipate the need to file additional patent applications both in the U.S. and in other countries, as appropriate.

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.

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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.

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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 $2,000,000, 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 $0.65 (in the fourth quarter of 2004) to a high of $2.48 (in the second quarter of 2004). 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.

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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 never paid dividends.

We have never paid dividends on our capital 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.

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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 for a term of four years 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 210 West 55th Street, New York, New York on November 18, 2005. 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:

Nominee	Votes For	Votes Withheld
Douglas Abel	40,968,529	54,074
Neil Herskowitz	40,935,131	88,372
Malcolm Hoenlein	40,935,131	88,372
Timothy McInerney	40,966,301	57,202
Joan Pons Gimbert	40,966,301	57,202
Richard I. Steinhart	40,967,848	55,655
Michael Weiser	40,941,697	81,806

(ii) The stockholders ratified and approved and amendment to our 2003 Stock Option Plan, increasing the number of shares of our common stock available for issuance thereunder to 7,400,000. 33,214,320 votes were cast for the proposal; 327,255 votes were cast against the proposal; 116,498 votes abstained; and there were 7,365,430 broker non-votes.

(iii) The stockholders ratified the appointment of J.H. Cohn LLP as our independent registered public accounting firm for fiscal 2005. 41,010,443 votes were cast for the proposal; 11,500 votes were cast against the proposal, shares representing 1,560 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:

	Price Range			
	2005		2004	
Quarter Ended	**High**	**Low**	**High**	**Low**
March 31	$ 2.100	$ 0.850	$ 2.000	$ 1.350
June 30	1.640	1.200	2.480	1.270
September 30	1.600	1.110	1.600	0.700
December 31	1.520	1.040	1.050	0.650

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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 14, 2006 was 581.

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 2005.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OR PLAN OF OPERATIONS.

Overview

We were incorporated in Delaware in May 1993 under the name "Atlantic Pharmaceuticals, Inc." and, in March 2000, we changed our name to "Atlantic Technology Ventures, Inc." On February 21, 2003, we completed a "reverse" acquisition of privately-held Manhattan Research Development, Inc. (formerly Manhattan Pharmaceuticals, Inc.), a Delaware corporation. To effect this transaction, we caused Manhattan Pharmaceuticals Acquisition Corp., our wholly-owned subsidiary, to merge with and into Manhattan Research Development, with Manhattan Research Development surviving as our wholly owned subsidiary. In accordance with the terms of the merger, the outstanding common stock of Manhattan Research Development automatically converted into the right to receive an aggregate of approximately 80 percent of our outstanding common stock (after giving effect to the transaction). In connection with the merger, we also changed our name to "Manhattan Pharmaceuticals, Inc." The financial statements reflect the activities of Manhattan Research Development, Inc. since its inception, as the "accounting acquirer".

Pursuant to an Agreement and Plan of Merger dated April 1, 2005 (the "Agreement") among us, Tarpan Therapeutics, Inc., a Delaware corporation ("Tarpan"), and Tarpan Acquisition Corp., a Delaware corporation and our wholly-owned subsidiary ("TAC"), TAC merged with and into Tarpan, with Tarpan remaining as the surviving corporation and our wholly-owned subsidiary. Tarpan was a privately-held, New York based biopharmaceutical company developing dermatological therapeutics. Through the merger, we acquired exclusive rights to develop and commercialize Tarpan's primary product candidate, PTH (1-34), a peptide believed to be a regulator of epidermal cell growth and differentiation. In consideration for their shares of Tarpan capital stock and in accordance with the Agreement, the stockholders of Tarpan received an aggregate of approximately 10,731,000 shares or approximately 20% of our then outstanding common stock. This transaction was accounted for as a purchase of Tarpan by the Company. As a result of the merger, we assumed Tarpan's outstanding indebtedness of approximately $651,000, which resulted 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 amended at the time of the merger to provide that one-half of the outstanding indebtedness was payable upon completion of the merger and the remaining one-half will be payable at such time as we raise at least $5 million in new financing. Further, the remaining one-half of indebtedness would no longer be interest bearing. As a result of our August 2005 private placement, discussed above, we have now satisfied the remaining balance of this indebtedness.

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We are engaged in the business of developing and commercializing early-stage technologies, particularly biomedical and pharmaceutical technologies. We aim to acquire proprietary rights to these technologies, by license or acquisition of an ownership interest, fund their research and development and eventually bring the technologies to market. We currently are researching and developing three biomedical technologies: oleoyl-estrone, an orally administered hormone which we believe can be used to treat obesity; PTH (1-34), a topical treatment for psoriasis; and lingual spray propofol, a proprietary lingual spray technology to deliver propofol for pre-procedural sedation prior to diagnostic, therapeutic or endoscopic procedures.

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

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. We do not expect to have revenues relating to our technologies prior to December 31, 2006.

For the year ended December 31, 2005 research and development expense was $5,178,077 as compared to $4,152,994 for the year ended December 31, 2004. The increase of $1,025,083 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 $969,508. As we enter Phase IIa clinical trials in Oleoyl-estrone and PTH (1-34), we expect research and development to continue to increase in 2006.

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For the year ended December 31, 2005, general and administrative expense was $2,291,121as compared to $1,989,829 for the year ended December 31, 2004. The increase of $301,292 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 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. As a result of the acquisition of Tarpan and continued expansion of our infrastructure required to support the planned growth, we expect general and administrative expenses to continue to increase in 2006.

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 $216,008 as compared to $246,792 for the year ended December 31, 2004. The decrease of $30,784 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 $19,140,997 as compared to $5,896,031 for the year ended December 31, 2004. This increase in net loss is attributable primarily to the in-process research and development charge of $11,887,807 related to the acquisition of Tarpan. Additionally, there were increases in research and development expenses of $1,025,083 and general and administrative expenses of $301,292. Additionally, there was a decrease in interest and other income of $30,784.

Preferred stock dividends of $175,663 and $585,799 reduced earnings per share for the years ended December 31, 2005 and 2004 by $0.00 and $0.02, respectively.

2004 Versus 2003

During each of the years ended December 31, 2004 and 2003, we had no revenue.

For the year ended December 31, 2004, research and development expense was $4,152,994 as compared to $1,724,043 for the year ended December 31, 2003. The increase of $2,428,951 is due primarily to an acceleration of pre-clinical development of our Oleoyl-estrone drug to the pre-clinical and clinical development of our Propofol Lingual Spray.

For the year ended December 31, 2004, general and administrative expense was $1,989,829 as compared to $1,786,080 for the year ended December 31, 2003. The increase of $203,749 is due primarily to investor relations expenses of approximately $160,000 and consulting expenses of approximately $67,000. In addition, we had increases in expenses associated with travel of approximately $85,000 and meetings and conferences of approximately $54,000 as well as rent and other expenses of approximately $19,000 and $55,000, respectively. These increases are partially offset by a net reduction in legal and accounting fees of approximately $91,000. Finally, in 2003 we had amortization of intangible assets of approximately $145,000 which we did not have in the current year.

For the year ended December 31, 2004, interest and other income was $246,792 as compared to $11,324 for the year ended December 31, 2003. The increase of $235,468 is a result of an increase in cash balances and a gain on sale of short-term investments.

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Net loss for the year ended December 31, 2004, was $5,896,031 as compared to $5,960,907 for the year ended December 31, 2003. This decrease in net loss is attributable primarily to losses in 2003 on the disposition of intangible assets as a result of our sale of our remaining rights to CT-3 to Indevus Pharmaceuticals, Inc. of $1,213,878 as well as an impairment of intangible assets of $1,248,230 as a result of a decision by Bausch & Lomb not to pursue the Avantix cataract removal technology. This decrease in net loss is partially offset by an increase in research and development expenses of $2,428,951 and an increase in general and administrative expenses of $203,749. These expense increases are partially offset by an increase in interest and other income of $235,468.

Preferred stock dividends of $585,799 increased loss per common share for the year ended December 31, 2004 by $0.02. There were no preferred stock dividend requirements in 2003.

Liquidity and Capital Resources

From inception to December 31, 2005, we incurred a deficit during the development stage of $33,271,695 primarily as a result of our net losses, and we expect to continue to incur additional losses through at least December 31, 2006 and for the foreseeable future. The acquisition of Tarpan will increase these losses. 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 and our licensing and sale of residual royalty rights of CT-3 to Indevus. During the year ended December 31, 2005, we had a net increase in cash and cash equivalents of $8,920,680. This increase resulted from net cash provided by financing activities, substantially all of which was from the net proceeds of $12,250,209 from the August 2005 private placement of 11,917,680 shares of common stock at $1.11 and $1.15 per share and investing activities, and also included proceeds from the sale of short-term investments of $3,499,999. These increases are partially offset by net cash used in operating activities of $6,244,942. Total liquid resources including short term investments as of December 31, 2005 were $10,834,154 compared to $5,419,872 at December 31, 2004.

Our current liabilities as of December 31, 2005 were $1,665,817 compared to $1,195,705 at December 31, 2004, an increase of $470,112. The increase was primarily due to an increase in expenditures associated with our Phase I clinical trial for our Oleoyl-estrone product candidate and commencement of Phase II clinical trial for our PTH (1-34) product candidate. As of December 31, 2005, we had working capital of $9,363,113 compared to $4,264,293 at December 31, 2004.

In August 2005, we completed a private placement offering of units consisting of shares of our common stock and warrants to purchase additional shares of common stock. The private placement was completed in two separate closings held on August 26, 2005 and August 30, 2005. In the August 26 closing, we sold a total of 10,808,971 shares of common stock and five-year warrants to purchase 2,161,767 shares for total gross proceeds of $11,997,954. The warrants issued at the August 26 closing are exercisable at a price of $1.44 per share. On August 30, 2005, we closed on the sale of an additional 1,108,709 shares of common stock and warrants to purchase 221,741 common shares, which resulted in gross proceeds of $1,275,016. The warrants issued in connection with the August 30 closing are exercisable at a price of $1.49 per share. After payment of all related commissions and expenses totaling $1,022,761, we realized total net proceeds of $12,250,209.

We engaged Paramount BioCapital, Inc. an affiliate of a significant stockholder of the Company, as placement agent and paid total cash commissions and expenses of $879,418, of which $121,625 was paid to certain selected dealers engaged by Paramount in connection with the August 26 closing 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, we paid cash commissions to Paramount of $88,550 and issued an additional five-year warrant to purchase 55,000 common shares at a price of $1.49 per share. Timothy McInerney and Dr. Michael Weiser, each a director of the Company, are employees of Paramount BioCapital, Inc.

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The terms of the Company's Series A Preferred Stock, which was originally issued in November 2003, provided for its automatic conversion upon the Company's completion of a financing that results in gross proceeds to of at least $10 million at a pre-money valuation of the Company of at least $30 million. Accordingly, as a result of the August 26, 2005 closing of the Company's private placement discussed above, all of the remaining outstanding shares of the Company's Series A Preferred Stock automatically converted into shares of the Company's common stock. As of such date, there were 729,626 shares of Series A Preferred Stock outstanding, which, upon the closing of the private placement, converted into an aggregate of 6,632,957 shares of common stock (at a rate of 9.0909 common shares per share of preferred stock).

On October 21, 2005, the Company issued 675,675 shares of common stock to Cato BioVentures, an affiliate of Cato Research, Inc., in exchange for the satisfaction of $750,000 of accounts payable owed by the Company to Cato Research, Inc. The transaction was completed on the same terms as the private placement described earlier which closed on August 26, 2005.

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned pre-clinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in our existing collaborative and licensing relationships, the resources that we devote to 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, 2005, 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. Management believes that we will continue to incur net losses and negative cash flows from operating activities for the foreseeable future. Based on the resources available to us at December 31, 2005, 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 2006 to be able to sustain our operations beyond 2006 and we will need additional financing thereafter until we can achieve profitability, if ever.

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We have reported net losses of $19,140,997 and $5,896,031 for the years ended December 31, 2005 and 2004, respectively. The net loss from date of inception, excluding preferred stock dividends, August 6, 2001 to December 31, 2005, amounts to $32,092,051. Management believes that we will continue to incur net losses through at least December 31, 2006. 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. These matters raise substantial doubt about our ability to continue as a going concern.

The report of our independent registered public accounting firm on our consolidated financial statements includes an explanatory paragraph which states that our recurring losses and cash used in operating activities raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Development Commitments

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 which is included in 2002 research and development expense. 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"); (ii) $250,000 upon the treatment of the first patient in a Phase II clinical trial under a Company-sponsored IND; (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, 2005, we have paid $425,000 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.

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In April 2003, we entered into a license and development agreement with NovaDel Pharma, Inc. ("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. Accordingly, upon completion of our sale of $10,000,000 of our Series A Convertible Preferred Stock in November 2003, we paid and expensed the $375,000 balance of the license fee. We paid and expensed the first $125,000 in June 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).

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.

Through our April 2005 acquisition of Tarpan Therapeutics, Inc., we acquired a Sublicense Agreement with IGI, Inc. (the "IGI Agreement") dated April 14, 2004. Under the IGI Agreement we received the exclusive, world-wide, royalty bearing sublicense to develop and commercialize the licensed technology. Under the terms of the IGI 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.

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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% on such excess. Through December 31, 2005, 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 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 laboratories findings included reversible, dose-dependent elevations in estrone and estradiol levels, as well as reductions in testosterone levels. We will initiate a follow on Phase IIa study using lower doses of Oleoyl-estrone in the first half of 2006. In preparation for beginning the phase IIa clinical trial, the clinical study protocol is currently in the regulatory review cycle in Switzerland, having received local ethics committee review and approval. The trial will begin immediately following receipt of final regulatory approval from Swissmedic, the Swiss Medical Authority.

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To date, we have incurred $7,989,816 of project costs related to our development of oleoyl-estrone, including milestone payments triggered under our license agreement for oleoyl-estrone, of which $4,004,322 was incurred in fiscal 2005. Currently, we anticipate that we will need to expend approximately an additional $5,000,000 in development costs 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 futues studies at this time.

Although we currently have sufficient capital to fund our anticipated 2006 R&D expenditures relating to oleoyl-estrone, we will need to raise additional capital in order to complete the anticipated five or six year development program for the product. 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).

PTH (1-34), which we acquired as a result of our April 2005 acquisition of Tarpan Therapeutics, Inc., is being developed 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 (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. Patient recruitment is ongoing; dosing has not yet begun.

To date, we have incurred $969,508 of project costs related to our development of PTH (1-34), which has been incurred since April 1, 2005, the date of the Tarpan Therapeutics, Inc. acquisition. Currently, we anticipate that we will need to expend approximately an additional $3,300,000 in development costs in fiscal 2006. A phase IIa clinical trial involving PTH (1-34) was initiated in late 2005 under the auspices of Boston University. As with the development of our other product candidates, we believe we currently have sufficient capital to fund our development activities of PTH (1-34) in their entirety during 2006. 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.

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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 actively 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.

To date, we have incurred $2,821,187 of project costs related to our development of propofol lingual spray, of which $204,247 was incurred in fiscal 2005. Currently, we anticipate that we will need to expend approximately an additional $100,000 in development costs in fiscal 2006 and at least an aggregate of approximately $3,000,000 to $5,000,000 until we receive FDA approval for propofol, should we opt to continue development until then, including anticipated 2006 costs. As with our development of oleoyl-estrone, we believe we currently have sufficient capital to fund our development activities of propofol lingual spray during 2005 and 2006. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2006. We expect to raise such additional capital through debt financings or by selling shares of our capital stock. 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 Committments

Employment Agreements

We have employment agreements with three employees for the payment of aggregate base salary of $775,000 as well as performance based bonuses. Two of these agreements have terms ranging from two to three years and have a remaining obligation of $825,000 as of December 31, 2005. The third agreement effective February 1, 2006 has a term of three years and a remaining obligation of $875,000.

Leases

Rent expense for the years ended December 31, 2005 and 2004 was $120,209 and $112,176, respectively.

Future minimum rental payments subsequent to December 31, 2005 under an operating lease for the Company’s office facility are as follows:

Years Ending December 31,	Commitment
2006	$ 141,600
2007	$ 141,600
2008	$ 100,000

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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

Research and development expenses are expensed as incurred. In process research and development, deemed to have no future use, is expensed as incurred as well.

Stock-based Compensation

Options, warrants and stock awards issued to non-employees and consultants are recorded at their fair value as determined in accordance with Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," and EITF No. 96-18, "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" and recognized as expense over the service period. The fair value of the options issued to consultants or others which require "variable accounting" are remeasured at each reporting period and the resultant change in fair value of the vested options is recorded as a charge or credit in the consolidated statement of operations.

Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R) (revised 2004), "Share-Based Payment", which amends SFAS Statement No. 123 and will be effective for our quarter ending March 31, 2006. The new standard will require us to expense employee stock options and other share-based payments over the vesting period. The new standard may be adopted in one of three ways - the modified prospective transition method, a variation of the modified prospective transition method or the modified retrospective transition method. We are will adopt SFAS 123(R) in the first quarter of 2006.

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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, 2005, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of that date are effective to ensure that information required to be disclosed in the reports we file under the Securities and Exchange Act is recorded, processed, summarized and reported on an accurate and timely basis. During the fourth quarter of 2005, we hired the accounting firm of Amper, Politziner & Mattia to review and consult on non-routine transactions and our periodic SEC filings. We expect that this will improve our internal controls over financial reporting subsequent to such evaluation.

As a non-accelerated filer with a fiscal year end of December 31, we must first begin to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 for the fiscal year ending December 31, 2007. We believe that our present internal control program has been effective at a reasonable assurance level to ensure that our financial reporting has not been materially misstated. Nonetheless, during the remaining periods through December 31, 2007, we will review, and where necessary, enhance our internal control design and documentation, management review, and ongoing risk assessment as part of our internal control program, including implementing the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Controls

In connection with the preparation of our quarterly report on Form 10-QSB for the quarter ended September 30, 2005, as part of its review of this report, our independent registered public accounting firm identified material weaknesses, as of September 30, 2005, in our internal controls over financial reporting relating to the recording and disclosures of stock options that we have granted to non-employee consultants in accordance with Emerging Issues Task Force (“EITF”) 96-18 and SFAS 123. Specifically, in accordance with EITF 96-18, we should have been accounting for an option issued to a non-employee consultant using variable accounting, instead of fixed accounting. In addition, we improperly applied SFAS 123 in accounting for a stock option granted to a different non-employee consultant. In connection with its review of such Form 10-QSB, our independent registered accounting firm also identified certain errors made in the calculation of our weighted average number of shares outstanding. Our independent registered public accounting firm advised management and our Audit Committee that it considered each of these situations to be a material weakness in our internal controls. Since such material weaknesses were identified by our independent registered accounting firm in connection with its review of this Form 10-QSB and because they relate only to the quarter ended September 30, 2005, the items subject to these issues are correctly presented on our historical financial statements, including the September 30, 2005 Form 10-QSB, and no restatement of any previously filed financial

statements was required.

As a result of the material weakness discussed above, however, we implemented a change in our internal controls over financial reporting during the fourth quarter of the year ended December 31, 2005. Specifically, we have instituted additional procedures in the review process for the financial statement recording and disclosures of options in order to remediate this issue. Additionally, we engaged a public accounting firm separate and unrelated to our independent registered public accounting firm, to consult with from time to time concerning the appropriate accounting treatment of such stock options, as well as other accounting matters. We have also increased our emphasis on continuing education for our accounting personnel and increase our emphasis on reviewing applicable accounting literature, all relating to the selection and application of accounting principles pertaining to stock options. We believe these enhancements to our system of internal control and our disclosure controls and procedures are adequate to provide reasonable assurance that our internal controls are effective in alerting management on a timely basis to material information required to be disclosed in our periodic reports to the Securities and Exchange Commission.

ITEM 8B. OTHER INFORMATION

As discussed above, at our annual stockholder meeting held on November 18, 2005, our stockholders approved an amendment to our 2003 Stock Option Plan, increasing the number of shares of our common stock available for issuance under such plan from 5,400,000 to 7,400,000.

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PART III

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

Information Concerning Directors and Executive Officers

Name	Age	Position
Douglas Abel	44	President and Chief Executive Officer and Director
Alan G. Harris, M.D.	55	Chief Medical Officer
Nicholas J. Rossettos, C.P.A.	40	Chief Financial Officer, Chief Operating Officer and Secretary
Neil Herskowitz	48	Director
Malcolm Hoenlein	61	Director
Timothy McInerney	44	Director
Joan Pons	55	Director
Richard I. Steinhart	48	Director
Michael Weiser, M.D., Ph.D.	42	Director

Douglas Abel has been our President and Chief Executive Officer since April 2005, when we completed our acquisition of Tarpan Therapeutics, where Mr. Abel had been President and CEO since November 2004. Prior to joining Tarpan, Mr. Abel served as Vice President of the Dermatology Business Unit at Biogen Idec where he worked from August 2000 to November 2004. While at Biogen, he led the creation of the U.S. dermatology commercial operation, building the team from two to more than 100 employees to support the launch of AMEVIVE®. Before that, Mr. Abel was at Allergan Pharmaceuticals from December 1987 to August of 2000, with his most recent position being Director of BOTOX® Marketing. Mr. Abel received his A.B. in chemistry from Lafayette College and an M.B.A. from Temple University.

Alan G. Harris has been our Chief Medical Officer since February 2006. Prior to joining Manhattan, from January 2004, Dr. Harris was head of the Worldwide Medical Endocrine Care group at Pfizer, Inc. (New York, NY), where he was responsible for the clinical development of the growth hormone Genotropin®, the growth hormone antagonist Somavert®, and the leading international medical outcomes database containing information about growth hormone treatment in children (KIGS) and adults (KIMS). Prior to that he served in a number of capacities at Schering-Plough Corporation (Kenilworth, NJ) from 1995 to 2004, most recently as vice president, Global Healthcare Research & Outcomes. Dr. Harris received an MD degree cum laude from the Louis Pasteur Faculty of Medicine, University of Strasbourg, France and a Ph.D. in Endocrinology from Erasmus University, Rotterdam, The Netherlands. He is currently an adjunct professor of medicine at New York University Medical School and visiting professor of medicine in the Department of Endocrinology at Liege University Medical School, Belgium and in the department of Pharmacology and Clinical Toxicology at the University Hospital of Lausanne, Switzerland. Dr. Harris is a Fellow of the American College of Physicians, the Royal College of Physicians (UK), and the American College of Clinical Pharmacology.

Nicholas J. Rossettos has been our Chief Financial Officer and Treasurer since April 2000 and our Chief Operating Officer since February 2003. From February 1999 until joining our company, Mr. Rossettos was Manager of Finance for Centerwatch, a pharmaceutical trade publisher headquartered in Boston, Massachusetts, that is a wholly owned subsidiary of Thomson Corporation of Toronto, Canada. Prior to that, from 1994, he was Director of Finance and

Administration for EnviroBusiness, Inc., an environmental and technical management-consulting firm headquartered in Cambridge, Massachusetts. Mr. Rossettos is a certified public accountant and holds an M.S. in Accounting and M.B.A. from Northeastern University.

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Neil Herskowitz was appointed to our board of directors in July 2004. Since 1998, Mr. Herskowitz has co-owned the ReGen Group of companies. Currently he is a managing member of ReGen Partners I L.P., an investment fund based in New York City, and President of Riverside Claims LLC an investment vehicle for ReGen. Mr. Herskowitz also serves as a member of the Board of Directors of Chelsea Therapeutics, Inc. (OTCBB: CHTP) a publicly traded specialty pharmaceutical development company, and as a director of Starting Point Services for Children, a not-for-profit corporation. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College.

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

Timothy McInerney has been a director of our company since July 2004. Since 1992, Mr. McInerney has been a Managing Director of Paramount BioCapital, Inc. where he oversees the overall distribution of Paramount's private equity product. Prior to 1992, Mr. McInerney was a research analyst focusing on the biotechnology industry at Ladenburg, Thalman & Co. Prior to that, Mr. McInerney held equity sales positions at Bear, Stearns & Co. and Shearson Lehman Brothers, Inc. Mr. McInerney also has worked in sales and marketing for Bristol-Myers Squibb. He received his B.S. in pharmacy from St. John's University at New York. He also completed a post-graduate residency at the New York University Medical Center in drug information systems.

Joan Pons has been a director of our company since February 21, 2003, the date of our merger with Manhattan Research Development. Prior to the merger, he served as a director of Manhattan Research Development from 2002. Since 2002, Mr. Pons has served chief executive officer of Oleoylestrone Development S.L., a spin-off of the University of Barcelona. Pursuant to a January 2002 license agreement, we hold an exclusive worldwide license to several patents and patent applications relating to oleoyl-estrone, which are owned by Oleoylestrone Developments. From 1999 until joining Oleoylestrone Developments, Mr. Pons has served as Director of Franchising of Pans & Company, a fast-food company. From 1972 until 1999, Mr. Pons was employed in various finance and sales capacities by Gallina Blanca Purina S.A., a joint venture between St. Louis, Missouri based Ralston Purina Co. and Spanish based Agrolimen S.A., most recently serving as its National Sales & Marketing Director.

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

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Michael Weiser, M.D., Ph.D., has been a director of our company since the completion of our merger transaction with Manhattan Research Development, Inc. in February 2003. He served as a director of Manhattan Research Development since December 2001 and as its Chief Medical Officer from its inception until August 2001. Dr. Weiser is currently also the Director of Research of Paramount BioCapital Asset Management and he is a director of Hana Biosciences, Inc. (AMEX:HBX), a South San Francisco, California-based technology company focused on oncology therapeutics, Chelsea Therapeutics International, Ltd. (OTCBB:CHTP) and VioQuest Pharmaceuticals, Inc. (OTCBB:VQPH). Dr. Weiser is also a member of Orion Biomedical GP, LLC, and serves on the board of directors of several privately held companies. Dr. Weiser received an M.D. from New York University School of Medicine and a Ph.D. in Molecular Neurobiology from Cornell University Medical College. Dr. Weiser completed a Postdoctoral Fellowship in the Department of Physiology and Neuroscience at New York University School of Medicine and performed his post-graduate medical training in the Department of Obstetrics and Gynecology and Primary Care at New York University Medical Center.

There are no family relationships among our executive officers or directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers, directors and persons who are the beneficial owners of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Officers, directors and beneficial owners of more than 10% of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on a review of the copies of the Forms 3, 4 and 5 and amendments that we received with respect to transactions during 2005, we believe that all such forms were filed on a timely basis, except for those items listed in the table below:

Name of Filer	Description of Transaction	Transaction Date	Filing Date
Douglas Abel	Initial Form 3	4/1/05	4/25/05
Neil Herskowitz	Director Stock Option Grant	1/11/05	2/22/05
Malcolm Hoenlein	Director Stock Option Grant	1/11/05	4/20/05
Joshua A. Kazam	Director Stock Option Grant	1/11/05	3/29/05
Timothy McInerney	Director Stock Option Grant	1/11/05	4/5/05
Joan Pons Gimbert	Option Grant	1/24/04	4/26/05
	Director Stock Option Grant	1/11/05	4/26/05
Nicholas J. Rossettos	Grant of options	1/11/05	8/19/05
Richard I. Steinhart	Director Stock Option Grant	1/11/05	2/22/05
David M. Tanen	Director Stock Option Grant	1/11/05	3/29/05
Michael Weiser	Director Stock Option Grant	1/11/05	4/5/05

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Code of Business Conduct and Ethics

Our Board of Directors adopted a Code of Business Conduct and Ethics to be applicable to all officers, directors and employees. The Code of Business Conduct and Ethics is intended to be designed to deter wrong-doing and promote honest and ethical behavior, full, fair, timely, accurate and understandable disclosure, and compliance with applicable laws. The Board adopted the Code of Business Conduct and Ethics in July 2004. A copy of the Code of Business Conduct and Ethics can be obtained and will be provided to any person without charge upon written request to our Secretary at our executive offices, 810 Seventh Avenue, 4th Floor, New York, New York 10019.

Audit Committee Financial Expert

We have an audit committee comprised of Richard Steinhart, Neil Herskowitz and Malcolm Hoenlein. Richard Steinhart satisfies the “audit committee financial expert” as that term is defined by SEC regulations. Further, all of our audit committee members are independent, as defined by the listing standards of the American Stock Exchange.

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ITEM 10. EXECUTIVE COMPENSATION

The following table sets forth, for the last three fiscal years, the compensation earned for services rendered in all capacities by our chief executive officer and the other highest-paid executive officers serving as such at the end of 2005 whose compensation for that fiscal year was in excess of $100,000. The individuals named in the table will be hereinafter referred to as the "Named Officers." No other executive officer of Manhattan received compensation in excess of $100,000 during fiscal year 2005.

Summary Compensation Table

		Annual Compensation			Long-Term Compensation Awards	All Other Compensation ($)
Name and Principal Position	**Year**	**Salary($)**	**Bonus($)**	**Other Annual Compensation ($)**	**Securities Underlying Options/SARs(#)**	
Douglas Abel [1]						
Chief Executive	2005	243,750	200,000	57,648[3]	2,923,900	—
Officer and	2004	—	—	—	—	—
President	2003	—	—	—	—	—
Nicholas J. Rossettos	2005	175,000	22,500	7,170[4]	50,000	—
Chief Operating	2004	150,000	22,500	7,500[4]	150,000	—
Officer, Chief Financial Officer,						
Treasurer & Secretary	2003	142,788	25,000	22,397[2]	292,030	—

(1) Mr. Abel was appointed our chief executive officer on April 1, 2005 following the merger with Tarpan Therapeutics, Inc.

(2) Represents salary deferred from the prior fiscal year and prior to February 24, 2003.

(3) Represents matching contributions by us pursuant to our company's 401(k) retirement plan of $8,400 and reimbursement of certain business related travel expenses of $49,248.

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

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Options and Stock Appreciation Rights

The following table contains information concerning the grant of stock options under our stock option plans and otherwise to the executive officers identified below during the 2005 fiscal year. No stock appreciation rights were granted during the 2005 fiscal year.

Option Grants in Last Fiscal Year (Individual Grants)

Name	Number of Securities Underlying Options/SARs Granted (#)	Percent of Total Options/SARs Granted to Employees in Fiscal Year	Exercise or Base Price ($/Share)[1]	Expiration Date
Mr. Abel	2,923,900[2]	80	1.50	4/1/2015
Mr. Rossettos	50,000[3]	1	1.00	1/11/2015

(1) Exercise price is based on the closing sale price of our common stock on the last trading day preceding the grant date.
(2) One-third of the option vested as of November 2005; the remaining two-thirds vests in equal annual amounts in November 2006 and November 2007.
(3) One-half of the option vested as of January 2006; the remaining one-half vests in January 2007.

Option Exercise and Holdings

The following table provides information with respect to the executive officers named below concerning the exercisability of options during the 2005 fiscal year and unexercisable options held as of the end of the 2005 fiscal year. No stock appreciation rights were exercised during the 2005 fiscal year, and no stock appreciation rights were outstanding at the end of that fiscal year.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

Name	Shares Acquired on Exercise	Value Realized [1]	No. of Securities Underlying Unexercised Options/SARs at FY-End (#)		Value of Unexercised In-the-Money Options/SARs at FY-End (Market price of shares at FY-End less exercise price) ($)[2]	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Mr. Abel	—	—	974,634	1,949,266	—	—
Mr. Rossettos	—	—	457,030	110,000	254,476	12,500

(1) Equal to the fair market value of the purchased shares at the time of the option exercise over the exercise price paid for those shares.
(2) Based on the fair market value of our common stock on December 30, 2005, the last trading day of fiscal 2005, of $1.25 per share, the closing sale price per share on that date on the American Stock Exchange.

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Long Term Incentive Plan Awards

No long term incentive plan awards were made to any of our executive officers during the last fiscal year.

Compensation of Directors

Non-employee directors are eligible to participate in an automatic stock option grant program pursuant to the 2003 stock option plan. Non-employee directors are granted an option for 50,000 shares of common stock upon their initial election or appointment to the board and an option for 25,000 shares of common stock annually thereafter. For members of a sub-committee, the annual grant is an option for 30,000 shares and for a Chairman of the Board, the annual grant is an option for 35,000 shares. During 2005 our board members received an aggregate of $11,500 in cash compensation for their services as directors. Directors are reimbursed for reasonable expenses incurred in connection with attending meetings of the board and of committees of the board.

Employment Contracts and Termination of Employment and Change of Control Arrangements

Douglas Abel

We entered into an Employment Agreement with Douglas Abel dated April 1, 2005 whereby Mr. Abel will serve as our President and Chief Executive Officer for a period of three years in exchange for (i) an annual base salary of $300,000, subject to a retroactive increase in the amount of $25,000 in the event we complete a financing transaction of at least $5,000,000, (ii) a signing bonus in the amount of $200,000 payable in two installments of $100,000 in May and November 2005, respectively, (iii) a discretionary performance-based bonus in an amount equal to up to 50% of Mr. Abel’s base salary, and (iv) an option to purchase 2,923,900 shares of our common stock at $1.50 per share with three-year annual vesting, purchasable for a 10-year term. As a result of the private placement that we completed in August 2005, Mr. Abel’s salary was increased to $325,000 retroactive to April 1, 2005. The employment agreement contains customary provisions relating to confidentiality, work-product assignment, non-competition and non-solicitation. In the event Mr. Abel’s employment is terminated by us (other than for cause) during the term of the agreement, including a termination upon a change of control (as defined in the agreement), we are required to pay a severance payment ranging from between 6 and 12 month of base salary, depending upon the circumstances of such termination.

Alan G. Harris

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

Nicholas J. Rossettos

Mr. Rossettos' employment with us is pursuant to a January 2005 employment agreement. This agreement has a two-year term ending on January 3, 2007, which may be extended for additional one (1) year periods thereafter. Under the agreement, Mr. Rossettos is entitled to an annual salary of $175,000 in addition to health, disability insurance and other benefits. Pursuant to his employment agreement, on January 3, 2005, Mr. Rossettos was granted an option to purchase an aggregate of 50,000 shares of common stock at a price of $1.00 per share. The option vests in two equal installments on each of January 3, 2006 and January 3, 2007. Mr. Rossettos and his dependents are eligible to receive paid medical and long term disability insurance and such other health benefits as we make available to other senior officers and directors. In the event Mr. Rossettos' employment with the Company is terminated other than for "cause" or upon a "change of control" (as such terms are defined in the employment agreement), he is entitled to continue receiving his base salary until the end of the term of the agreement or 1 year from such termination, whichever occurs first, and the portions of his stock options scheduled to vest in the calendar year of such termination shall accelerate and be deemed vested as of the date of termination. If Mr. Rossettos' employment is terminated upon a change of control, he is entitled to continue receiving his base salary for a period of 6 months from termination and the vesting of all his stock options shall accelerate and be deemed vested as of such termination.

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ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTER

The following table sets forth certain information regarding beneficial ownership of the our common stock as of March 1, 2006, by (i) each person known by us to be the beneficial owner of more than 5 percent of the outstanding Common Stock, (ii) each director, (iii) each executive officer, and (iv) all executive officers and directors as a group. The number of shares beneficially owned is determined under rules promulgated by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire within 60 days of the date hereof, through the exercise or conversion of any stock option, convertible security, warrant or other right. Inclusion of shares in the table does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares. Unless otherwise indicated, each person or entity named in the table has sole voting power and investment power (or shares that power with that person's spouse) with respect to all shares of capital stock listed as owned by that person or entity. Unless otherwise indicated, the address of each of the following persons is 810 Seventh Avenue, 4th Floor, New York, New York 10019.

Name	Shares Beneficially Owned	Percent of Class
Douglas Abel (1)	999,634	1.6
Alan G. Harris	0	*
Nicholas J. Rossettos(2)	532,030	*
Michael Weiser(3)	2,431,092	4.0
Joan Pons Gimbert(4)	4,048,704	6.7
Neil Herskowitz (5)	126,541	*
Malcolm Hoenlien (6)	60,673	*
Timothy McInerney (7)	811,338	1.3
Richard I. Steinhart (6)	60,673	*
All directors and officers as a group (8)	9,070,685	14.6
Oleoylestrone Developments, SL(9)	3,957,037	6.6
Josep Samitier 1-5, Barcelona Science Park		
08028 Barcelona Spain		
Lester E. Lipschutz(10)	8,918,354	14.8
1650 Arch Street - 22nd Floor		
Philadelphia, PA 19103		
Lindsay A. Rosenwald(11)	3,444,506	6.6