

MANHATTAN PHARMACEUTICALS INC  
Form 10KSB  
March 31, 2005

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

FORM 10-KSB

Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2004

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 0-27282

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.)

(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:**

None

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

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

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

The issuer's revenues for the fiscal year ended December 31, 2004 were \$0.

As of March 21, 2005 there were 29,608,883 outstanding shares of common stock, par value \$.001 per share.

The aggregate market value of the voting common stock of the issuer held by non-affiliates of the issuer on March 21, 2005 based on the closing price of the common stock as quoted by the NASD Over-the-Counter Bulletin Board on such date was \$47,966,390.

Transitional Small Business Disclosure Format: Yes  No



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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 statements that are not historical but are forward-looking in nature, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. In particular, the “Risk Factors” section following Item 1 and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section in Item 6 of this annual report include 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 in the subsection entitled “Risk Factors” following Item 1 in this Annual Report, and should not unduly rely on these 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 two 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; and
- Lingual spray propofol, a proprietary lingual spray technology to deliver propofol for pre-procedural sedation prior to diagnostic, therapeutic or endoscopic procedures.

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. We have signed a letter of intent to acquire Tarpan Therapeutics, Inc. (“Tarpan”), a privately-held, New York-based biopharmaceutical company developing dermatological therapeutics, in an all stock transaction. Upon consummation of the transaction, Tarpan shareholders will own approximately 20% of the shares of Manhattan on a fully-diluted basis. Upon the close of the Tarpan transaction, our expanded therapeutic portfolio will consist of three product candidates having the potential to address various large, underserved medical markets. Through the acquisition, we will acquire Tarpan’s primary product candidate, PTH (1-34), a peptide believed to be a regulator of epidermal cell growth and differentiation.

Several of Tarpan’s stockholders are directors or significant stockholders of our company. For example, Joshua Kazam, Timothy McInerney, David Tanen and Dr. Michael Weiser, all directors of our company, collectively hold approximately 13.4 percent of Tarpan’s outstanding common stock. In addition, Dr. Lindsay Rosenwald and various trusts established for the benefit of Dr. Rosenwald and members of his immediate family collectively beneficially own approximately 46 percent of Tarpan’s common stock and beneficially own approximately 26 percent our common stock. Because of these relationships, our board has established a committee of disinterested directors to consider the Tarpan transaction. Although not yet closed, we anticipate completing the transaction with Tarpan in the near future.



We were incorporated originally 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 known as Manhattan Pharmaceuticals, Inc.), a Delaware corporation. To effect this transaction, Manhattan Pharmaceuticals Acquisition Corp., a wholly-owned subsidiary of Atlantic Technology Ventures, merged with and into Manhattan Research Development, with Manhattan Research Development surviving as a wholly owned subsidiary of Atlantic Technology Ventures. In accordance with the terms of the merger, the outstanding shares of common stock of Manhattan Research Development automatically converted into an aggregate of approximately 80 percent of the outstanding common stock of Atlantic Technology Ventures (after giving effect to the transaction). While in connection with the merger, Atlantic Technology Ventures changed its name to “Manhattan Pharmaceuticals, Inc.”, for accounting purposes, Manhattan Research Development was treated as the acquiring company. Accordingly, when we refer to our business or financial information for periods prior to the merger, we are referring to the business and financial information of Manhattan Research Development, unless the context indicates otherwise.

### **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, S.L., 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. We believe that oleoyl-estrone causes weight loss in two ways. First, the scientific community believes that weight loss is regulated by a part of the hypothalamus, located in the brain, called the ponderostat. It is believed that the ponderostat regulates the body’s weight in a manner similar to the way in which a thermostat regulates a room’s temperature. Preclinical studies suggest that oleoyl-estrone resets the ponderostat, telling the body that a lower weight is normal. We believe that this signal then decreases appetite, which leads to weight loss that may be maintained even after oleoyl-estrone treatment is discontinued. Second, fat cells that have been treated with oleoyl-estrone appear to shrink in size, indicating a local effect of oleoyl-estrone acting directly on cells. The apparent dual effect of oleoyl-estrone leads us to believe that the drug has the potential to cause weight loss in a variety of obese and overweight patients.

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.

After examining the available work related to estrogens, changes in body weight and body fat percentage (such as during pregnancy), researchers at UB noted that the estrogen-like hormone, estrone, was elevated in the blood of both obese men and women. Initially thought to be a simple estrogen, UB researchers noticed that although estrone levels were elevated, very few obese men manifest the effects of elevated estrogen levels. Further testing revealed that oleoyl-estrone was the main form of estrone that existed in obese patients. The researchers suggested that when cells become filled with fat they produce oleoyl-estrone, signaling the brain to lose weight. They further suggested that fat cells in obese people do not produce sufficiently high levels of oleoyl-estrone to signal the ponderostat to suppress appetite and cause weight loss. Based on this concept, investigators at UB believed that they could induce weight loss by increasing levels of oleoyl-estrone in obese individuals. When oleoyl-estrone was given to rats, the rats lost weight in a dose-dependent manner, supporting the idea that oleoyl-estrone is a primary weight loss signal produced by fat cells. At the doses employed, no side effects were observed in the rats and, in female rats, uterine size remained unchanged, indicating that oleoyl-estrone did not act as an estrogen.



In January 2005, the United States Food and Drug Administration (“FDA”) accepted our filed Investigational New Drug Application (“IND”) for the human clinical testing of oleoyl estrone. This IND allowance moves us forward into the next stage of oleoyl-estrone’s development and was granted on the preclinical chemistry, manufacturing, and safety data which we submitted to the FDA.

In February 2005, we began dosing patients in our first Phase I trial of oleoyl-estrone in Basel, Switzerland to evaluate the safety and tolerability of defined doses of orally administered oleoyl-estrone in obese adults, in accordance with FDA guidelines. The objective of this human Phase I dose-escalation study is to determine the pharmacokinetic profile of oleoyl-estrone, as well as its safety and tolerability in obese adult volunteers of both genders. In total, 36 obese volunteers will be randomized to receive a single dose of either OE or a placebo, in a dose-escalating manner. The Swiss medical regulatory authority, SwissMedic, issued its formal approval to initiate such a trial last month. The trial is being conducted under the IND Application recently accepted by the FDA in February 2005 and the results will be used as a part of the U.S. regulatory approval process.

### **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 in an oily emulsion for intravenous infusion for induction and maintenance of general anesthesia or “monitored anesthesia care” in operating rooms, or deep sedation in intensive care units. Propofol has previously not 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 non-oily, novel formulation.

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



Novadel's delivery systems (both patented and patent-pending) are lingual sprays, enabling drug absorption through the oral mucosa and more rapid absorption into the bloodstream than presently available oral delivery systems. 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 required for FDA approval of Propofol Lingual Spray (Propofol LS). We continue to pursue FDA approval of Propofol LS under 505(b)2 regulatory pathway. Section 505(b)2 of the U.S. Food, Drug & Cosmetic Act allows the FDA to approve a drug on the basis of existing data in the scientific literature or data used by the FDA in the approval of other drugs. Accordingly, the FDA has indicated to us that we will be able to utilize Section 505(b)2 to proceed directly to a pivotal Phase III trial for lingual spray propofol following completion of Phase 1 trials. We are actively planning the next steps of the clinical development process for Propofol LS, meeting with scientific advisors and Novadel regarding formulation, reviewing existing data, developing trial design, and evaluating plans to re-enter the clinic in mid-2005. 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 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. Currently, a proprietary formulation has been prepared and is undergoing one, two, three and six month stability tests, as well as specification analysis. 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.

## **Market and Competition**

According to estimates, the market for prescription anti-obesity drugs is approximately \$10 billion, or equal to that of diabetes. It is estimated that 61 percent of Americans are overweight and that 26 percent are obese. According to the National Institute of Health's estimate, direct costs for the treatment of obesity in 1988 were in excess of \$45 billion and accounted for nearly 8 percent of the total national cost of health care in the United States. By 1999, direct costs for the treatment of obesity had reached \$102.2 billion dollars. Meridia® and Xenical®, two currently approved anti-obesity medications, together accounted for approximately \$800 million in sales in 2001. 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.

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 midazolam's 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.

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.

## **Intellectual Property and License Agreements**

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

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

*Oleoyl-estrone License Agreement*

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

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

The U.S. and European patents have numerous, detailed, and specific claims for both the composition of oleoyl-estrone, and its method of use for weight loss. Our rights to these patents are subject to the terms of a February 2002 license agreement between us and 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.

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.

*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. 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.
4. U.S. Patent Application No. 10/834815 entitled “Buccal, Polar and Non-Polar Sprays Containing Propofol.” H.A. Dugger and M.A. El-Shafy, Inventors. Application filed April 27, 2004.

These issued patents have numerous, detailed, and specific claims relating to the formulation for lingual spray applications and their method of use. We have the right to use the technology in connection with one application - delivering propofol. Our success in developing lingual spray propofol depends substantially on the maintenance and enforcement of NovaDel’s patents covering its proprietary spray technology. In consideration for our rights under the NovaDel license agreement, we paid NovaDel an initial license fee of \$500,000 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 IND 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. or a member of the European Union). 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. The license agreement also provided that NovaDel could terminate the license agreement in the event we did not raise \$5 million in financing on or before March 31, 2004; however, we satisfied that condition in November 2003 in connection with the \$10 million private placement of our Series A Convertible Preferred Stock. We may terminate the license agreement for any reason upon 90 days’ notice to NovaDel.

## **Manufacturing**

We do not have any manufacturing capabilities. We have been in contact with several contract “Good Manufacturing Process” (GMP) manufacturers for the supply of both oleoyl-estrone and lingual spray propofol that will be necessary to conduct Phase I 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. Bids are being received from multiple providers, so that provider redundancy can be maintained during product launch.

## Government Regulation

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

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

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

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

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

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily 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.

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

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

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

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.

**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.





## **Tarpan Product Candidate**

Pending a planned merger with Tarpan Therapeutics, Inc., Manhattan Pharmaceuticals, Inc. will have a third biomedical technology under development:

- PTH (1-34), a peptide believed to be a regulator of epidermal cell growth and differentiation currently under development as a topical treatment for psoriasis and additional dermatological indications.

To date, researchers, led by Michael Holick, MD, PhD, Professor of Medicine, Physiology, and Biophysics at Boston University Medical Center, recently 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-blinded, controlled trial in 15 patients comparing PTH (1-34) formulated in the Novasome® Technology versus the Novasome® vehicle alone showed PTH (1-34) to be a potentially safe and effective treatment for plaque psoriasis. Following 8 weeks of treatment, the 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. No patients experienced any significant adverse events.

Due to the high response rate seen in psoriasis patients in the initial trial PTH (1-34) may have an important clinical advantage over current topical psoriasis treatments. Following the acquisition, Manhattan intends to initiate additional clinical activities with PTH (1-34) in 2005. Through the transaction with Tarpan, Manhattan obtains rights to issued and pending patents for all topical uses of PTH (1-34) as well as access to the Novasome® technology and patents for these applications. Novasome® is a registered trademark of IGI, Inc., Buena Park, NJ.

## **Market and Competition**

The efficacy and safety profile of PTH (1-34) will 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 not 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 cyclosporine. 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.

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, which leads to the inhibition of T-cell activation and migration to sites of inflammation. Clinical trials showed 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.

### **Intellectual Property**

1. PTH (1-34): In April 2004, Tarpan entered into an exclusive worldwide royalty bearing License Agreement with IGI, Inc., for the rights to the intellectual property and know-how relating to all topical uses of PTH (1-34). The topical application of PTH (1-34) for the treatment of hyperproliferative skin disorders (including psoriasis) is protected by US patents 5,527,772, 5,840,690, and 6,066,618 and European Patent Specification PCT/US88/03639.
2. Novasome Delivery Technology: In April 2004, Tarpan entered into a non-exclusive, non-royalty bearing, world-wide License Agreement with IGI Inc., for the rights to use the Novasome delivery technology for the development, commercialization and sale of PTH (1-34). IGI will supply product utilizing the Novasome Technology at IGI's cost.

## Employees

We currently have 7 employees, including 3 persons devoted to research and development and 4 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.*

### 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, 2004, we had \$905,656 of cash and cash equivalents and \$4,514,216 of short-term investments. We will have to raise a significant amount of additional funds to complete the development of our drug candidates and to bring them to market. 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, 2004, 2003 and 2002 and from August 6, 2001 (inception) through December 31, 2001, we incurred net losses of \$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.

**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 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 IND's for both our Oleoyl-estrone and Propofol LS product candidates. We have not yet filed an IND for PTH (1-34). In February 2005, we began dosing patients in our first Phase I trial in Basel, Switzerland to evaluate the safety and tolerability of defined doses of orally administered oleoyl-estrone in obese adults, in accordance with FDA guidelines. Pending completion of formulation work, we expect to conduct a Phase I clinical study for propofol lingual spray as early as 2005 assuming formulation work is completed satisfactorily. 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 2006. See "Business - Lingual Spray Propofol." We are unable to estimate the size and timing of all the Phase II and Phase III programs for oleoyl-estrone at this time and, accordingly, cannot estimate the time when development of that product candidate will be completed.

When the clinical testing for our product candidates is complete, we will submit to the FDA a New Drug Application, or “NDA,” demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA’s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for 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 and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. We expect that our clinical trials will only involve a small sample size. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

**Physicians and patients may not accept and use our drugs.**

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

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

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

**Our drug-development program depends upon third-party researchers who are outside our control.**

We currently are collaborating with NovaDel Pharma, from which we license our rights to lingual spray propofol, in the development of that product candidate in the pre-clinical and early clinical trial stages. Under our agreement with NovaDel, it has agreed to perform certain development on our behalf and at our expense, including formulation stability testing, formulation analytic method development and testing and manufacture of clinical trial material for the pre-clinical and early clinical development of propofol lingual spray. Beyond those limited activities, we need to engage independent investigators and other third party collaborators to conduct pre-clinical and clinical trials for lingual spray propofol. We are not currently collaborating with any third party with respect to the development of oleoyl-estrone, but we intend to engage third party independent investigators and collaborators, which may include universities and medical institutions, to conduct our pre-clinical and clinical trials for that product candidate, as well. Accordingly, the successful development of our product candidates will depend on the performance of these third parties. These collaborators will not be our employees, however, and we cannot control the amount or timing of resources that they will devote to our programs. Our collaborators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

**We rely exclusively on third parties to formulate and manufacture our product candidates.**

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

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the 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.

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.

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 our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of its proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

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

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

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

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



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

Companies that currently sell both generic and proprietary anti-obesity compounds formulations include among others Abbot Laboratories, Inc., Amgen, Inc., and Regeneron Pharmaceuticals, Inc. Alternative technologies are being developed to treat obesity and overweight disease, several of which are in advanced clinical trials. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.

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

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

We currently do not directly own the rights to any patents 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.

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

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

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
  - other healthcare payers.

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

**We may not successfully manage our growth.**

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

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

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

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

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. We currently carry clinical trial insurance in an amount up to \$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 47 percent of our outstanding voting stock and, including shares underlying outstanding options and warrants, this group beneficially owns approximately 51 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**

**Trading of our common stock is limited.**

Trading of our common stock is conducted on the National Association of Securities Dealers' Over-the-Counter Bulletin Board, or "OTC Bulletin Board." This has adversely effected the liquidity of our securities, not only in terms of the number of securities that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock.

**Because it is a "penny stock," it will be more difficult for you to sell shares of our common stock.**

In addition, our common stock is a "penny stock." Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny-stock market. A broker must also give a purchaser, orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser, and obtain the purchaser's written agreement to the purchase. The penny stock rules may make it difficult for you to sell your shares of our stock. Because of the rules, there is less trading in penny stocks. Also, many brokers choose not to participate in penny-stock transactions. Accordingly, you may not always be able to resell shares of our common stock publicly at times and prices that you feel are appropriate.



**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 \$0.25 (in the first quarter of 2003) to a high of \$2.50 (in the third quarter of 2003), as adjusted for our 1-for-5 reverse stock split in September 2003. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

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

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

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

**We have 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.

**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.**

During the fourth quarter of our fiscal year ended December 31, 2004, there were no matters submitted to a vote of our stockholders.

**PART II****ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market for Common Stock**

Our common stock is quoted on the Over-the-Counter Bulletin Board, or “OTC Bulletin Board” under the symbol “MHTT.OB.” The following table lists the high and low price for our common stock as quoted, in U.S. dollars, on the OTC Bulletin Board during each quarter within the last two fiscal years:

Quarter Ended	Price Range			
	2004		2003	
	High	Low	High	Low
March 31	\$ 2.000	\$ 1.350	\$ 0.900	\$ 0.250
June 30	2.480	1.270	1.650	0.600
September 30	1.600	0.700	2.500	1.000
December 31	1.050	0.650	2.000	1.200

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 23, 2005 was 314.

**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 2004.

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

### **Overview**

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

We are a development stage biopharmaceutical company that holds an exclusive world-wide, royalty-free license to certain intellectual property related to oleoyl-estrone, which is owned by Oleoyl-Estrone Developments, SL ("OED") of Barcelona, Spain. Oleoyl-estrone is an orally administered small molecule that has been shown to cause significant weight loss in pre-clinical animal studies regardless of dietary modifications. We also hold the worldwide, exclusive rights to proprietary lingual spray technology to deliver the drug propofol for procedural sedation prior to diagnostic, therapeutic or endoscopic procedures.

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. We have signed a letter of intent to acquire Tarpan Therapeutics, Inc. ("Tarpan"), a privately-held, New York-based biopharmaceutical company developing dermatological therapeutics, in an all stock transaction. Upon consummation of the transaction, Tarpan shareholders will own approximately 20% of the shares of Manhattan on a fully-diluted basis. Assuming the completion of the Tarpan transaction, through the acquisition we will acquire Tarpan's primary product candidate, PTH (1-34), a peptide believed to be a regulator of epidermal cell growth and differentiation, which is being developed for the treatment of psoriasis.

Several of Tarpan's stockholders are directors or significant stockholders of our company. For example, Joshua Kazam, Timothy McInerney, David Tanen and Dr. Michael Weiser, all directors of our company, collectively hold approximately 13.4 percent of Tarpan's outstanding common stock. In addition, Dr. Lindsay Rosenwald and various trusts established for the benefit of Dr. Rosenwald and members of his immediate family collectively beneficially own approximately 46 percent of Tarpan's common stock and beneficially own approximately 26 percent our common stock. Because of these relationships, our board has established a committee of disinterested directors to consider the Tarpan transaction. Although not yet closed, we anticipate completing the transaction with Tarpan in the near future.

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**

#### ***2004 Versus 2003***

During each of the years ended December 31, 2004 and 2003, we had no revenue. We do not expect to have revenues relating to our technologies prior to December 31, 2005.

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.

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.

### ***2003 Versus 2002***

During each of the years ended December 31, 2003 and 2002, we had no revenue.

For the year ended December 31, 2003, research and development expense was \$1,724,043 as compared to \$700,798 for the year ended December 31, 2002. The increase of \$1,023,245 is due in part to an acceleration of pre-clinical and clinical development for product candidates, oleoyl-estrone and propofol lingual spray of approximately \$256,000. Related research and development consulting increased by approximately \$267,000. In addition, in connection with our license agreement with NovaDel Pharma Inc., we made license payments of \$500,000 in 2003 which we did not have in 2002.

For the year ended December 31, 2003, general and administrative expense was \$1,786,080 as compared to \$317,384 for the year ended December 31, 2002. The increase of \$1,468,696 is due primarily to expenses associated with hiring full time employees and consultants of approximately \$572,000 and \$261,000, respectively. In addition, we had increases in legal and accounting fees of approximately \$220,000 associated with becoming subject to the reporting obligations under the Exchange Act following completion of the Atlantic Technology Ventures, Inc. - Manhattan Research Development, Inc. merger in February 2003. Insurance, recruiters fees, travel, transfer agent fees and other expenses increased by approximately \$144,000, \$46,000, \$32,000, \$28,000 and \$21,000, respectively. Finally, in 2003, we had amortization of intangible assets of approximately \$145,000.

Net loss for the year ended December 31, 2003, was \$5,960,907 as compared to \$1,037,320 for the year ended December 31, 2002. This increase in net loss is attributable to the factors described above and to a loss 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.

### **Liquidity and Capital Resources**

From inception to December 31, 2004, we incurred a deficit during the development stage of \$13,955,035 primarily as a result of losses, and we expect to continue to incur additional losses and negative cash flows from operating activities through the year ending December 31, 2005 and for the foreseeable future. These losses have been incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity financing and our licensing and sale of residual royalty rights of CT-3 to Indevus. During the year ended December 31, 2004, we had a net decrease in cash and cash equivalents of \$6,508,147. This decrease resulted from net cash provided by financing activities of \$3,390,528, substantially all of which was from the private placement of 3,368,952 shares of common stock at \$1.10 per share and from net cash used in investing activities of \$4,208,230 primarily for the purchase of short-term investments offset by proceeds from the sale of these investments of \$931,089, offset by net cash used in operating activities of \$5,690,445 for the year ended December 31, 2004. Total cash resources as of December 31, 2004 were \$905,656 compared to \$7,413,803 at December 31, 2003.

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 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 IND 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. or a member of the European Union).

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.

Our current liabilities as of December 31, 2004 were \$1,195,705 compared to \$966,020 at December 31, 2003, an increase of \$229,685. The increase was primarily due to an increase in expenditures associated with the commencement of our Phase I clinical trial for our Oleoyl-estrone product candidate. As of December 31, 2004, we had working capital of \$4,264,293 compared to \$6,824,911 at December 31, 2003.

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, technological advances, 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, 2004, 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, 2004, management believes that we will need additional equity or debt financing or will need to generate revenues during 2005 through licensing our products or entering into strategic alliances to be able to sustain our operations through 2005 and we will need additional financing thereafter until we can achieve profitability, if ever.

We have reported net losses of \$5,896,031 and \$5,960,907 for the years ended December 31, 2004 and 2003, respectively. The net loss from date of inception, excluding preferred stock dividends, August 6, 2001 to December 31, 2004, amounts to \$12,951,054. Management believes that we will continue to incur net losses through at least December 31, 2005. 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.

## Research and Development Projects

### *Oleoyl-estrone*

In January 2005, The United States Food and Drug Administration (FDA) accepted our filed Investigational New Drug Application (IND) for the human clinical testing of oleoyl estrone. This IND allowance moves Manhattan forward into the next stage of oleoyl-estrone's development and was granted on the preclinical chemistry, manufacturing, and safety data submitted to the FDA by the Company.

In February 2005, we began dosing patients in our first Phase I trial in Basel, Switzerland to evaluate the safety and tolerability of defined doses of orally administered oleoyl-estrone in obese adults, in accordance with FDA guidelines. The objective of this human Phase I dose-escalation study is to determine the pharmacokinetic profile of oleoyl-estrone, as well as its safety and tolerability in obese adult volunteers of both genders. In total, 36 obese volunteers will be randomized to receive a single dose of either OE or a placebo, in a dose-escalating manner. The Swiss medical regulatory authority, SwissMedic, issued its formal approval to initiate such a trial last month. The trial is being conducted under the Investigational New Drug Application recently accepted by the U.S FDA and the results will be use as a part of the U.S. regulatory approval process. Under our license agreement with Oleoyl-Estrone Developments, we made a \$250,000 milestone payment upon the treatment of the first patient in the Phase I trial. Given the uncertainties inherent in early human clinical trials, it is difficult to predict with accuracy when the Phase I program will be completed.

To date, we have incurred \$3,260,097 of project costs related to our development of oleoyl-estrone, of which \$2,605,766 was incurred in fiscal 2004. Currently, we anticipate that we will need to expend approximately an additional \$1,500,000 to \$2,500,000 in development costs in fiscal 2005. Since oleoyl-estrone is regarded by the FDA as a new entity, it is not realistic to predict the size and the design of the study at this time.

Although we currently have sufficient capital to fund our anticipated 2005 R&D expenditures relating to oleoyl-estrone, we will need additional raise capital from debt financings or by selling shares of our capital stock 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 much 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 additional 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.

### ***Lingual spray propofol***

We are currently working with NovaDel to develop, manufacture and commercialize a propofol lingual spray. In July of 2004, we released the results of the first human trial for our proprietary lingual spray formulation of propofol. In January of 2005, the U.S. Food and Drug Administration accepted our Investigational New Drug Application (IND) for the initiation of the human clinical trials in the United States required for FDA approval of Propofol Lingual Spray (Propofol LS). We continue to pursue FDA approval of Propofol LS under 505(b)2 regulatory pathway. Section 505(b)2 of the U.S. Food, Drug & Cosmetic Act allows the FDA to approve a drug on the basis of existing data in the scientific literature or data used by the FDA in the approval of other drugs. Accordingly, the FDA has indicated to us that we will be able to utilize Section 505(b)2 to proceed directly to a pivotal Phase III trial for lingual spray propofol following completion of Phase 1 trials. We are actively planning the next steps of the clinical development process for Propofol LS, meeting with scientific advisors and Novadel regarding formulation, reviewing existing data, developing trial design, and evaluating plans to re-enter the clinic in mid-2005. 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 \$2,616,940 of project costs related to our development of propofol lingual spray, of which \$1,547,228 was incurred in fiscal 2004. Currently, we anticipate that we will need to expend an additional \$1,000,000 to \$1,500,000 in development costs in fiscal 2005 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 2005 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 2004 and 2005. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2005. 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.

### **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.

### ***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 related vesting period.

### **Recently Issued Accounting Standards**

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet.

SFAS No. 150 affects the issuer's accounting for three types of freestanding financial instruments. One type is mandatory redeemable shares, which the issuing company is obligated to buy back in exchange for cash or other assets. A second type included put options and forward purchase contracts, which involves instruments that do or may require the issuer to buy back some of its shares in exchange for cash or other assets. The third type of instruments that are liabilities under SFAS No. 150 are obligations that can be settled with shares, the monetary value of which is fixed, tied solely or predominantly to a variable such as market index, or varies inversely with the value of the issuers' shares. SFAS No. 150 does not apply to features embedded in a financial instrument that is not a derivative in its entirety.

Most of the provisions of SFAS No. 150 are consistent with the existing definition of liabilities in FASB Concepts Statement No. 6, "Elements of Financial Statements." The remaining provisions of SFAS No. 150 are consistent with the FASB's proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own shares. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003 and otherwise was effective at the beginning of the first interim period beginning after June 15, 2003. There was no effect on the Company's financial statements from adopting this statement.

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 small business issuers for interim or annual periods beginning after December 15, 2005. 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 currently evaluating how we will adopt the standard and evaluating the effect that the adoption of SFAS 123(R) will have on our financial position and results of operations.



**ITEM 7.**

**CONSOLIDATED FINANCIAL STATEMENTS**

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

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

None.

**ITEM 8A. CONTROLS AND PROCEDURES**

As of December 31, 2004, 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 are effective in alerting them on a timely basis to material information required to be disclosed in our periodic reports to the Securities and Exchange Commission. During the fourth quarter of 2004, there were no significant changes in our internal controls over financial reporting that have significantly affected, or are reasonably likely to significantly affect, 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, 2006. 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, 2006, 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.

**ITEM 8B. OTHER INFORMATION**

None.

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**PART III****ITEM DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS;  
9. COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT****Information Concerning Directors and Executive Officers**

<b>Name</b>	<b>Age</b>	<b>Position</b>
Nicholas J. Rossettos, C.P.A.	39	Chief Financial Officer, Chief Operating Officer and Secretary
Neil Herskowitz	47	Director
Malcolm Hoenlein	60	Director
Joshua Kazam	27	Director
Timothy McInerney	43	Director
Joan Pons	55	Director
Richard I. Steinhart	47	Director
David M. Tanen	33	Director
Michael Weiser, M.D., Ph.D.	41	Director

**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.

**Neil Herskowitz** was appointed to our board of directors in July 2004. Since 1998, Mr. Herskowitz has been a Managing Member of ReGen Partners LLC, an New York investment fund, and is also President of its affiliate, Riverside Claims LLC. Mr. Herskowitz currently serves on the board of directors of Starting Point Services for Children a not-for-profit corporation, and on the board of directors of Vacation Village, a 220-unit development in Sullivan County, New York. Mr. Herskowitz holds 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.

**Joshua Kazam** 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. Since September 2004, Mr. Kazam has been a partner of Two River Group Holdings, a New York-based [venture capital and investment bank focused on biotechnology companies], which he co-founded. Since 2001, Mr. Kazam has been the Director of Investment for the Orion Biomedical Fund, a New York based private equity fund focused on biotechnology investments. Mr. Kazam holds a Bachelors degree from the Wharton School of 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 Oleoyl-Estrone 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 Oleoyl-Estrone Development. From 1999 until joining Oleoyl-Estrone Development, 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.

**David M. Tanen** has been a director of our company since January 2002. Since September 2004, Mr. Tanen has been a partner of Two River Group Holdings, a New York-based [venture capital and investment bank focused on biotechnology companies], which he co-founded. From 1996 to August 2004, Mr. Tanen served as an associate director of Paramount Capital, where he was involved in the founding of a number of biotechnology start-up companies. Since February 2003, Mr. Tanen has also served as a director of VioQuest Pharmaceuticals, Inc. (OTC: VQPH) and he also serves as an officer or director of several other privately held development-stage biotechnology companies. Mr. Tanen holds a law degree from Fordham University School of Law.

**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. (OTC: HNAB), a South San Francisco, California-based technology company focused on oncology therapeutics. 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. Dr. Weiser dedicates only a portion of his time to our business.

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 2004, we believe that all such forms were filed on a timely basis, except for those items listed in the table below.

The following table shows the transactions for 2004 that were not in compliance.

Name of Filer	Description of Transaction	Transaction Date	Filing Date
Lindsay A. Rosenwald, M.D.	Purchase of shares between 8/17/04 and 9/3/04	8/17/04 - 9/3/04	9/10/04
Neil Herskowitz	Initial Form 3	7/21/04	9/8/04
Timothy McInerney	Initial Form 3	7/21/04	9/8/04
Richard I. Steinhart	Initial Form 3	7/21/04	9/2/04
Malcolm Hoenlein	Initial Form 3	7/21/04	9/2/04

Joan Pons Gimbert	Sale of shares by Company of which Mr. Gimbert is CEO	2/26/04	3/29/04
Michael Weiser	Issued Warrants and Options in a private placement	1/27/04	2/5/04
Nicholas J. Rossettos	Grant of options	1/28/04	2/4/04
Leonard Firestone, M.D.	Grant of options on 1/1/04 and 1/28/04	1/1/04	2/2/04
Joshua A. Kazam	Issued Warrants and Options in a private placement	1/27/04	2/4/04
Joan Pons Gimbert	Grant of options	1/28/04	2/2/04

### 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; he has practiced as a CPA and in various financial reporting capacities. Further, all of our audit committee members are independent, as defined by applicable regulation.

**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 2004 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 2004.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation Awards	All Other Compensation (\$)
		Salary(\$)	Bonus(\$)	Other Annual Compensation (\$)	Securities Underlying Options/SARs(#)	
Leonard Firestone <sup>(1)</sup> Chief Executive Officer and President	2004	325,000	73,750	12,300	600,000	--
	2003	250,000	200,000	--	584,060	--
	2002	--	--	--	--	--
Nicholas J. Rossettos Chief Operating Officer, Chief Financial Officer, Treasurer & Secretary	2004	150,000	22,500	7,500	150,000	--
	2003	142,788	25,000	22,397	292,030	--
	2002	107,645	25,000	10,000(3)	55,000	--
				(2)		
				(3)		

(1) Dr. Firestone became chief executive officer of Manhattan Research Development, Inc. in January 2003 and, following the merger with Atlantic Technology Ventures, Inc. on February 21, 2003, he was appointed chief executive officer of the Registrant. The above table reflects Dr. Firestone's combined compensation received from Manhattan Research Development and our company during fiscal 2003. Dr. Firestone's employment with the Company ended in January 2005.

(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) and SAR-SEP retirement plans.

## 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 2004 fiscal year. No stock appreciation rights were granted during the 2004 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) <sup>(1)</sup>	Expiration Date
Dr. Firestone	600,000	36	1.65	1/28/2014
Mr. Rossettos	150,000 <sup>(2)</sup>	9	1.65	1/28/2014

(1) Exercise price is based on the closing sale price of our common stock on the last trading day preceding the grant date.

(2) Two-thirds of the option vested as of January 2005; the remaining one-third vests in January 2006.

## Option Exercise and Holdings

The following table provides information with respect to the executive officers named below concerning the exercisability of options during the 2004 fiscal year and unexercisable options held as of the end of the 2004 fiscal year. No stock appreciation rights were exercised during the 2004 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 <sup>(1)</sup>	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) (\$) <sup>(2)</sup>	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Dr. Firestone						
(3)	--	--	584,060	600,000	379,639	--
Mr. Rossettos	--	--	258,515	258,515	96,160	94,910

(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, 2004, the last trading day of fiscal 2004, of \$1.05 per share, the closing sale price per share on that date on the OTC Bulletin Board.

(3)



Although the presentation in the above table reflects options exercisable as of the end of fiscal 2004, 600,000 shares subject to an option held by Dr. Firestone became exercisable on January 1, 2005.

### **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 30,000 shares and for a Chairman of the Board, the annual grant is 35,000 shares. During 2004 our board members did not receive any cash compensation for their services as directors, although 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**

#### ***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. Mr. Rossettos reports to the Board of Directors of the Company with primary direction being given by the Chief Executive Officer and President.

**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 26, 2004, 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. Including those shares in the tables 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 787 Seventh Avenue, 48th Floor, New York, New York 10019.

Name	Shares Beneficially Owned	Percent of Class
Nicholas J. Rossettos(1)	457,030	1.6
Joshua Kazam(2)	362,532	1.3
Michael Weiser(3)	1,520,215	5.3
Joan Pons Gimbert(4)	4,015,371	14.2
David M. Tanen(5)	440,980	1.6
Neil Herskowitz (6)	77,005	*
Malcolm Hoenlien (7)	30,337	*
Timothy McInerney (8)	608,695	2.1
Richard I. Steinhart (7)	30,337	*
All directors and officers as a group(9)	8,726,562	28.5
Lindsay A. Rosenwald(10)	3,374,023	11.9
Oleoylestrone Developments, SL(11) Josep Samitier 1-5, Barcelona Science Park 08028 Barcelona Spain	3,957,037	14.0
Lester E. Lipschutz(12) 1650 Arch Street - 22 <sup>nd</sup> Floor Philadelphia, PA 19103	3,982,368	14.0
Atlas Fund, LLC (13) 181 West Madison, Suite 3600 Chicago, IL 60602	1,818,182	6.4

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- \* Less than 1.0%
- (1) Includes 457,030 shares issuable upon the exercise of options that are currently exercisable or will be exercisable within 60 days.
  - (2) Includes 58,334 shares issuable upon the exercise of an option, and 60,173 shares issuance upon exercise of a warrant.
  - (3) Includes 60,000 shares issuable upon the exercise of an option, and 103,655 shares issuance upon exercise of a warrant.
  - (4) Includes 3,957,037 shares held by Oleoylestrone Developments, SL, of which Mr. Pons is chief executive officer, and 58,334 shares issuable upon the exercise of options.
  - (5) Includes 72,400 shares issuable upon the exercise of options that are currently exercisable, or will be exercisable within 60 days.
  - (6) Includes 44,168 shares issuable upon conversion of Series A Convertible Preferred Stock and 30,337 shares issuable upon exercise of options. Also includes 2,500 shares held by Riverside Contracting, LLC, a limited liability company of which Mr. Herskowitz is a member holding 50%.
  - (7) Includes 30,337 shares issuable upon exercise of options.
  - (8) Includes 41,667 shares issuable upon exercise of options; and 58,642 shares issuable upon exercise of warrants.
  - (9) Includes 2,022,836 shares issuance upon exercise of options; 222,470 shares issuable upon exercise of warrants; and 44,168 shares issuable upon conversion of Series A Convertible Preferred Stock.
  - (10) Includes 831,213 shares held by certain trusts for the benefit of Dr. Rosenwald, 80 shares owned by his spouse, 33 shares owned by Dr. Rosenwald's children and 76 shares held by certain corporation of which Dr. Rosenwald is a shareholder. Based on a Form 4 filed by Dr. Rosenwald on March 22, 2005.
  - (11) Mr. Pons is the chief executive officer of Oleoylestrone Developments, SL.
  - (12) Includes 3,761,513 shares of common stock held by eight separate trusts with respect to which Mr. Lipschutz is either trustee or manager and in either case has investment and voting power, including 220,855 shares of common stock issuable upon conversion of 24,294 shares of Series A Convertible Preferred Stock.
  - (13) Based on an Amendment to Schedule 13G filed February 11, 2005.

**Equity Compensation Plan Information**

The following table summarizes outstanding options under our 1995 Stock Option Plan, as amended and our 2003 Stock Option Plan, as well as outstanding options that we have issued to certain officers, directors and employees of our company outside of any plan.

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b> <b>(a)</b>	<b>Weighted average exercise price of outstanding options, warrants and rights</b> <b>(b)</b>	<b>Number of securities remaining available for future issuance (excluding securities reflected in column (a))</b> <b>(c)</b>
Equity compensation plans approved by stockholders (1)	1,652,500	\$ 1.44	3,747,500
Equity compensation plans approved by stockholders (2)	32,400	\$ 8.28	489,991
Equity compensation plans not approved by stockholders (3)	1,137,240	\$ 0.57	--

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(1) Represent shares of common stock issuable upon outstanding options issued to employees and directors under our 2003 Stock option Plan.

(2) Represent shares of common stock issuable upon outstanding options issued to employees and directors under our 1995 Stock Option Plan, as amended.

(3) Represent shares of common stock issuable upon outstanding options issued to employees and directors outside of any stock option plan.

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

### **Oleoylstrone Developments, SL**

Pursuant to the terms of a license agreement dated February 15, 2002 by and between Manhattan Research Development, Inc., our wholly owned subsidiary, and Oleoylstrone Developments, SL (“OED”), we have an exclusive, worldwide license to U.S. and foreign patents and patent applications relating to certain technologies. Although we are not obligated to pay royalties to OED, the license agreement requires us to make certain performance-based milestone payments. See “Item 1 - Intellectual Property.” OED currently owns approximately 16 percent of our outstanding common stock. Additionally, Mr. Pons, a member of our board of directors, is chief executive officer of OED.

### **NovaDel Pharma Inc.**

As discussed above, pursuant to the terms of a license agreement dated April 4, 2003 by and between us and NovaDel Pharma Inc., we have the rights to develop NovaDel’s proprietary lingual spray technology to deliver propofol for preprocedural sedation. The license agreement with NovaDel requires us to make certain license and milestone payments, as well as pay royalties. See “Item 1. Business - Lingual Spray Propofol.” During 2003, we paid aggregate license fees of \$500,000 to NovaDel under the license agreement, but during 2004 did not make any payments to NovaDel under the agreement. Lindsay A. Rosenwald, who beneficially owns more than 10 percent of our common stock, also beneficially owns in excess of 20 percent of the common stock of NovaDel and may therefore be deemed to be an affiliate of that company.

### **Paramount BioCapital, Inc.**

Two members of our board of directors, Timothy McInerney and Michael Weiser, are also employees of Paramount BioCapital, Inc. or one of its affiliates. In addition, two members of our board of directors, Joshua Kazam and David Tanen were employed by Paramount BioCapital through August 2004. The sole shareholder of Paramount BioCapital, Inc. is Lindsay A. Rosenwald, M.D. Dr. Rosenwald beneficially owns approximately 12 percent of our common stock. In November 2003, we paid to Paramount BioCapital approximately \$460,000 as commissions earned in consideration for placement agent services rendered in connection with the private placement of our Series A Convertible Preferred Stock, which amount represented 7 percent of the shares sold by Paramount BioCapital in the offering. In connection with the November 2003 private placement, we did not engage Paramount BioCapital directly, but rather Paramount BioCapital was engaged as a sub-agent of Maxim Group, the broker-dealer we engaged for the offering. In addition, in January 2004, we paid approximately \$260,000 as commissions earned in consideration for placement agent services rendered by Paramount BioCapital in connection with a private placement of our common stock, which amount represented 7 percent of the shares sold by Paramount BioCapital in the private placement. The engagement of Paramount BioCapital in connection with the January 2004 private placement was approved by all of our disinterested directors. In connection with both private placements and as a result of their employment with Paramount BioCapital, Mr. Kazam, Mr. McInerney and Dr. Weiser were allocated 5-year placement agent warrants to purchase 60,174, 58,642 and 103,655 shares of our common stock, respectively, at a price of \$1.10 per share.

We believe that all the transactions described above were made on terms no less favorable to us than could have been obtained from unaffiliated third parties.

### ITEM 13. EXHIBITS LIST

The following documents are included or referenced in this report.

<u>Exhibit No.</u>	<u>Description</u>
2.1	Agreement and Plan of Merger among the Company, Manhattan Pharmaceuticals Acquisition Corp. and Manhattan Research Development, Inc. (formerly Manhattan Pharmaceuticals, Inc.) dated December 17, 2002 (incorporated by reference to Exhibit 2.1 from Form 8-K filed March 5, 2003).
3.1	Certificate of incorporation, as amended through September 25, 2003 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-QSB for the quarter ended September 30, 2003).
3.2	Bylaws, as amended to date (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
3.3	Certificate of Designations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (File No. 333-111897)).
4.1	Form of unit certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.2	Specimen common stock certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.3	Form of redeemable warrant certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.4	Form of redeemable warrant agreement between the Registrant and Continental Stock Transfer & Trust Company (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.5	Form of underwriter's warrant certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.6	Form of underwriter's warrant agreement between the Registrant and Joseph Stevens & Company, L.P. (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.7	Form of bridge warrant (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.8	Warrant issued to John Prendergast to purchase 37,500 shares of Registrant's common stock (incorporated by reference from Exhibit 10.24 to the Registrant's Form 10-QSB for the quarter ended March 31, 1997).

- 4.9 Warrant No. 2 issued to Joseph Stevens & Company, Inc. to purchase 150,000 shares of Registrant's Common Stock exercisable January 4, 2001 (incorporated by reference to Exhibit 10.29 to the Registrant's Form 10-KSB for the year ended December 31, 1999).
- 4.10 Warrant No. 3 issued to Joseph Stevens & Company, Inc. to purchase 150,000 shares of Registrant's Common Stock exercisable January 4, 2002 (incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-KSB for the year ended December 31, 1999).
- 4.11 Form of stock purchase warrants issued on September 28, 2000 to BH Capital Investments, L.P., exercisable for shares of common stock of the Registrant (incorporated by reference to Exhibit 10.6 to the Registrant's Form 10-QSB for the quarter ended September 30, 2000).
- 4.12 Form of stock purchase warrants issued on September 28, 2000 to Excalibur Limited Partnership, exercisable for shares of common stock of the Registrant (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-QSB for the quarter ended September 30, 2000).
- 4.13 Warrant certificate issued March 8, 2001 by the Registrant to Dian Griesel (incorporated by reference to Exhibit 10.56 to the Registrant's Form 10-QSB for the quarter ended March 31, 2001).
- 4.14 Form of warrant issued by Manhattan Research Development, Inc., which automatically converted into warrants to purchase shares of the Registrant's common stock upon the merger transaction with such company (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
- 4.15 Form of warrant issued to placement agents in connection with the Registrant's November 2003 private placement of Series A Convertible Preferred Stock and the Registrant's January 2004 private placement (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (File No. 333-111897)).
- 4.16 Form of subscription agreement between Registrant and the selling stockholders (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
- 10.1 1995 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-QSB for the quarter ended September 30, 1996).
- 10.2 Common stock purchase agreement dated March 16, 2001, between Registrant and Fusion Capital Fund II, LLC (incorporated by reference from Exhibit 10.55 of the Registrant's Form 10-QSB for the quarter ended March 31, 2001).
- 10.3 Third Amendment to Employment Agreement dated February 21, 2003 between the Registrant and Nicholas J. Rossettos (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
- 10.4 Employment Agreement dated January 2, 2003, between Manhattan Research Development, Inc. and Leonard Firestone, as assigned to the Registrant effective as of February 21, 2003 (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).



10.5 Employment Agreement dated February 28, 2003, between the Registrant and Nicholas J. Rossettos (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).

10.6 License Agreement dated on or about February 28, 2002 between Manhattan Research Development, Inc. (f/k/a Manhattan Pharmaceuticals, Inc.) and Oleoyl-Estrone Developments SL (incorporated by reference to Exhibit 10.6 to the Registrant's Amendment No. 2 to Form 10-QSB/A for the quarter ended March 31, 2003 filed on March 12, 2004).

10.7 License Agreement dated April 4, 2003 between the Registrant and NovaDel Pharma, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to Form 10-QSB/A for the quarter ended June 30, 2003 filed on March 12, 2004).++

10.8 Employment Agreement dated January 2, 2004 between the Registrant and Leonard Firestone (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (No. 333-111897)).

10.9 2003 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed February 17, 2004).

23.1 Consent of J.H. Cohn LLP.

31.1 Certification of Principal Executive and Financial Officer.

32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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

The following is a summary of the fees billed to us by J.H. Cohn LLP, our independent registered public accounting firm for professional services rendered for fiscal years ended December 31, 2004 and 2003:

Fee Category	J.H. Cohn LLP	
	Fiscal 2004 Fees	Fiscal 2003 Fees
Audit Fees	\$ 73,146	\$ 88,400
Audit-Related Fees (1)	40,627	8,800
Tax Fees (2)	17,832	5,400
All Other Fees (3)	683	--
Total Fees	\$ 132,288	\$ 102,600

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

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

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

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

At present, our audit committee approves each engagement for audit or non-audit services before we engage our independent registered public accounting firm to provide those services. Our audit committee has not established any pre-approval policies or procedures that would allow our management to engage our independent registered public accounting firm to provide any specified services with only an obligation to notify the audit committee of the engagement for those services. None of the services provided by our independent registered public accounting firm for fiscal 2004 was obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

**SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act, Manhattan Pharmaceuticals, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2005.

**MANHATTAN PHARMACEUTICALS, INC.**

By: /s/ Nicholas J. Rossettos

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Nicholas J. Rossettos  
 Treasurer, Secretary, Chief Financial Officer and Chief Operating Officer

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Nicholas J. Rossettos Nicholas J. Rossettos	Treasurer, Secretary, Chief Financial Officer and Chief Operating Officer (principal executive, accounting and financial officer)	March 31, 2005
/s/ Neil Herskowitz Neil Herskowitz	Director	March 31, 2005
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 31, 2005
/s/ Joshua Kazam Joshua Kazam	Director	March 31, 2005
/s/ Timothy McInerney Timothy McInerney	Director	March 31, 2005
/s/ Joan Pons Joan Pons	Director	March 31, 2005
/s/ Richard Steinhart Richard Steinhart	Director	March 31, 2005
/s/ David M. Tanen	Director	March 31,

2005

David M. Tanen

/s/ Michael Weiser

Director

March 31,  
2005

Michael Weiser

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
Manhattan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Manhattan Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended, and for the period from August 6, 2001 (date of inception) to December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Manhattan Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2004 and 2003, and their consolidated results of operations and cash flows for the years then ended and for the period from August 6, 2001 (date of inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2, the Company incurred a net loss of \$5,896,031 and used \$5,690,445 of cash in operating activities during the year ended December 31, 2004 and, as of that date, it had a loss from inception of \$12,951,054. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/J.H. Cohn LLP

Roseland, New Jersey  
March 18, 2005

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

Consolidated Balance Sheets

Assets	December 31, 2004	December 31, 2003
<b>Current assets:</b>		
Cash and cash equivalents	\$ 905,656	\$ 7,413,803
Short-term investments, available for sale, at market	4,514,216	352,147
Prepaid expenses	40,126	24,981
<b>Total current assets</b>	<b>5,459,998</b>	<b>7,790,931</b>
Property and equipment, net	119,017	8,021
Other assets	70,506	—
<b>Total assets</b>	<b>\$ 5,649,521</b>	<b>\$ 7,798,952</b>
 <b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,143,603	\$ 548,595
Accrued expenses	52,102	417,425
<b>Total liabilities</b>	<b>1,195,705</b>	<b>966,020</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Series A convertible preferred stock, \$.001 par value.		
Authorized 1,500,000 shares; 854,373 and 1,000,000 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively (liquidation preference aggregating \$8,973,730 and \$10,000,000 at December 31, 2004 and 2003, respectively)		
	854	1,000
Common stock, \$.001 par value. Authorized 150,000,000 shares; 28,309,187 and 23,362,396 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively		
	28,309	23,362
Additional paid-in capital	18,083,208	14,289,535
Deficit accumulated during development stage	(13,955,035)	(7,473,205)
Dividends payable in Series A preferred shares	303,411	—
Accumulated other comprehensive income (loss)	13,237	(7,760)
Unearned consulting costs	(20,168)	—
<b>Total stockholders' equity</b>	<b>4,453,816</b>	<b>6,832,932</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 5,649,521</b>	<b>\$ 7,798,952</b>

See accompanying notes to consolidated financial statements.

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

Consolidated Statements of Operations

	Years ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2004
	2004	2003	
Revenue	\$	—	\$
			—
<b>Costs and expenses:</b>			
Research and development	4,152,994	1,724,043	6,602,434
General and administrative	1,989,829	1,786,080	4,125,490
Impairment of intangible assets	—	1,248,230	1,248,230
Loss on disposition of intangible assets	—	1,213,878	1,213,878
Total operating expenses	6,142,823	5,972,231	13,190,032
Operating loss	(6,142,823)	(5,972,231)	(13,190,032)
<b>Other (income) expense:</b>			
Interest and other income	(175,610)	(16,079)	(191,689)
Interest expense	—	4,755	23,893
Realized gain on sale of short-term investments	(71,182)	—	(71,182)
Total other income	(246,792)	(11,324)	(238,978)
Net loss	(5,896,031)	(5,960,907)	(12,951,054)
Preferred stock dividends (including imputed amounts)	(585,799)	(418,182)	(1,003,981)
Net loss applicable to common shares	\$ (6,481,830)	\$ (6,379,089)	\$ (13,955,035)
Net loss per common share:			
Basic and diluted	\$ (0.24)	\$ (0.28)	
Weighted average shares of common stock outstanding:			
Basic and diluted	26,936,658	22,389,755	

See accompanying notes to consolidated financial statements.



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

Consolidated Statement of Stockholders' Equity (Deficiency)

	Series A	convertible preferred stock Shares	Common stock Shares	Additional paid-in capital	Subscription receivable	development stage	Dividends Deficit accumulated	Dividends payable accumulated	Series A other	earned income/(loss)	consulting fees	Total stock- holders' equity (deficiency)
Stock issued at \$0.0004 per share for subscription receivable	—	10,167,741	\$ 10,168	\$ (6,168)	\$ (4,000)	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(56,796)	—	—	—	—	(56,796)
Balance at December 31, 2001												
												10,167,741
												10,168
)												(6,168)
)												(4,000)
)												(56,796)
)												—
)												—
)												—
)												(56,796)

Proceeds from subscription receivable

—  
—  
—  
—  
—  
4,000  
—  
—  
—  
—  
4,000

Stock issued at \$0.0004 per share for  
license rights

—  
—  
2,541,935  
2,542  
(1,542

)

—  
—  
—  
—  
—  
1,000

Stock options issued for consulting services

—  
—  
—  
—  
60,589

)

(60,589)

Amortization of unearned consulting services

—  
—  
—  
—  
—  
—  
—  
—  
—  
—  
22,721

22,721

Sales of common stock at \$0.63 per share through private placement,

net of expenses

—  
—  
3,043,332  
3,043  
1,701,275  
—  
—  
—  
—  
—  
1,704,318

Net loss

—  
—  
—  
—  
—  
—  
(1,037,320

)

—  
—  
—  
(1,037,320

)  
Balance at December 31, 2002

	—
	15,753,008
	15,753
	1,754,154
	—
)	(1,094,116
	—
	—
)	(37,868
	637,923
Common stock issued at \$0.63 per share, net of expenses	—
	—
	1,321,806
	1,322
	742,369
	—
	—
	—
	—
	—
	743,691
Effect of reverse acquisition	—

	—
	6,287,582
	6,287
	2,329,954
	—
	—
	—
	—
	—
	2,336,241
Amortization of unearned consulting costs	—
	—
	—
	—
	—
	—
	—
	—
	—
	—
	37,868
	37,868
Unrealized loss on short-term investments	—
	—
	—

	—
	—
	—
	—
	—
)	(7,760)
	—
)	(7,760)
Payment for fractional shares for stock combination	
	—
	—
	—
	—
)	(300)
	—
	—
	—
	—
)	(300)
Preferred stock issued at \$10 per share, net of expenses	
	1,000,000
	1,000
	—

	—
	9,045,176
	—
	—
	—
	—
	9,046,176
Imputed preferred stock dividend	
	418,182
	—
)	(418,182)
	—
	—
Net loss	
	—
	—
	—
	—
	—
	—
)	(5,960,907)
	—
	—
	—



	(5,960,907
)	
Balance at December 31, 2003	
	1,000,000
	1,000
	23,362,396
	23,362
	14,289,535
	—
	(7,473,205
)	
	—
	(7,760
)	
	—
	6,832,932
Exercise of stock options	
	—
	—
	27,600
	27
	30,073
	—
	—
	—
	—

	30,100
Common stock issued through private placement at \$1.10 per share, net of expenses per share, net of expenses	—
	—
	3,368,952
	3,369
	3,358,349
	—
	—
	—
	—
	—
	3,361,718
Conversion of preferred stock to common stock	(170,528
)	)
	(171
)	)
	1,550,239
	1,551
	(1,380
)	)
	—
	—
	—
	—

	—
	—
Preferred stock dividends paid by issuance of shares	
	24,901
	25
	—
	—
	281,073
	—
	—
)	(282,388
	—
	—
)	(1,290
Preferred stock dividend accrued	
	—
	—
	—
	—
	—
	—
)	(585,799
	585,799
	—
	—
	75

	—
Warrants issued for consulting services	—
	—
	—
	—
	—
	125,558
	—
	—
	—
	—
)	(120,968)
	4,590
Amortization of unearned consulting costs	—
	—
	—
	—
	—
	—
	—
	—
	100,800
	100,800

Reversal of unrealized loss on short-term investments and unrealized gain  
on short-term investments

—  
—  
—  
—  
—  
—  
—  
—  
—  
—  
20,997

20,997

Net loss

(5,896,031

)

(5,896,031

)		
Balance at December 31, 2004		
		854,373
\$		854
		28,309,187
\$		28,309
\$		18,083,208
\$		—
\$		(13,955,035)
)		
\$		303,411
\$		13,237
\$		(20,168)
)		
\$		4,453,816

See accompanying notes to consolidated financial statements.

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

Condensed Consolidated Statements of Cash Flows

	<b>Years ended December 31,</b>		<b>Cumulative</b>
	<b>2004</b>	<b>2003</b>	<b>period from</b>
			<b>August 6, 2001</b>
			<b>(inception) to</b>
			<b>December 31,</b>
			<b>2004</b>
Cash flows from operating activities:			
Net loss	\$ (5,896,031)	\$ (5,960,907)	\$ (12,951,054)
Adjustments to reconcile net loss to net cash used in operating activities:			
Common stock issued for license rights			—
			—
			1,000
Amortization of unearned consulting costs			100,800
			37,868
			161,389
Warrants issued for consulting services			4,590
			—
			4,590
Amortization of intangible assets			—
			145,162
			145,162
Gain on sale of short-term investments			

)	(71,182)
	—
)	(71,182)
Depreciation	
	27,344
	6,216
	33,560
Loss on impairment of intangible assets	
	—
	1,248,230
	1,248,230
Loss on disposition of intangible assets	
	—
	1,213,878
	1,213,878
Changes in operating assets and liabilities, net of acquisition:	
(Increase)/decrease in prepaid expenses and other current assets	
)	(15,145)
	33,264
	18,119
Increase in other assets	
)	(70,506)
	—
)	(70,506)



Increase in accounts payable	595,008
	59,961
	819,868
Decrease in accrued expenses	(365,323)
)	
	(138,869)
)	
	(488,219)
)	
Decrease in due affiliate	—
	(96,328)
)	
	—
Net cash used in operating activities	(5,690,445)
)	
	(3,451,525)
)	
	(9,935,165)
)	
Cash flows from investing activities:	
Purchase of property and equipment	(138,340)
)	
	(6,554)
)	
	(144,894)
)	
Cash paid in connection with acquisition	

	—
)	(32,808
)	(32,808
Purchase of short-term investments	(5,000,979
)	—
)	(5,000,979
Proceeds from sales of short-term investments	931,089
	—
Proceeds from sale of license	931,089
	—
	200,000
	200,001
Net cash provided by (used in) investing activities	(4,208,230
)	160,638
)	(4,047,591
Cash flows from financing activities:	
Proceeds from issuances of notes payable to stockholders	—
	—
	233,500

Repayments of notes payable to stockholders

	—
)	(206,000
)	(233,500
Proceeds from issuance of note payable to bank	—
	—
	600,000
Repayment of note payable to bank	—
)	(600,000
)	(600,000
Proceeds from subscriptions receivable	—
	—
	4,000
Payment for fractional shares for stock combination	(1,290
)	(300
)	(990
Proceeds from sale of common stock, net	3,361,718
	743,691
	5,809,126

Proceeds from sale of preferred stock, net	—
	9,046,176
	9,046,176
Proceeds from exercise of stock options	
	30,100
	—
	30,100
Net cash provided by financing activities	
	3,390,528
	8,983,567
	14,888,412
Net increase (decrease) in cash and cash equivalents	
)	(6,508,147
	5,692,680
	905,656
Cash and cash equivalents at beginning of period	
	7,413,803
	1,721,123
	—
Cash and cash equivalents at end of period	
\$	905,656
\$	7,413,803
\$	

	905,656
Supplemental disclosure of cash flow information:	
Interest paid	
\$	—
\$	502
\$	26,934
Supplemental disclosure of noncash investing and financing activities:	
Stock options/warrants issued for consulting services	
\$	120,968
\$	—
\$	181,557
Preferred stock dividends accrued	
	585,799
	—
	585,799
Conversion of preferred stock to common stock	
	171
	—
	171
Preferred stock dividends paid by issuance of shares	
	282,388
	—
	282,388
	85

Issuance of common stock for acquisition

—  
2,336,242  
2,336,242

Short-term investments received in connection with sale of license

—  
359,907  
359,907

See accompanying notes to consolidated financial statements.

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

Notes to Consolidated Financial Statements

December 31, 2004 and 2003

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

On February 21, 2003, the Company (formerly known as “Atlantic Technology Ventures, Inc.”) completed a reverse acquisition of privately held Manhattan Research Development, Inc. (formerly Manhattan Pharmaceuticals, Inc.), a Delaware corporation. The merger was effected pursuant to an Agreement and Plan of Merger dated December 17, 2002 (the “Merger Agreement”) by and among the Company, Manhattan Research and Manhattan Pharmaceuticals Acquisition Corp, the Company’s wholly owned subsidiary (“MPAC”). In accordance with the terms of the Merger Agreement, MPAC merged with and into Manhattan Research, with Manhattan Research remaining as the surviving corporation and a wholly owned subsidiary of the Company. Pursuant to the Merger Agreement, upon the effective time of the merger, the outstanding shares of common stock of Manhattan Research automatically converted into an aggregate of 18,689,917 shares of the Company’s common stock, which represented 80 percent of the Company’s outstanding voting stock after giving effect to the merger. All share and per share amounts have been adjusted for a 1-for-5 combination on September 25, 2003 (see Note 5). In addition, immediately prior to the merger Manhattan Research had outstanding options and warrants to purchase an aggregate of 172,856 shares of its common stock, which, in accordance with the terms of the merger, automatically converted into options and warrants to purchase an aggregate of 2,196,944 shares of the Company’s common stock. Since the stockholders of Manhattan Research received the majority of the voting shares of the Company, the merger was accounted for as a reverse acquisition whereby Manhattan Research was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer). Based on the five-day average price of the Company’s common stock of \$0.50 per share, the purchase price approximated \$2,336,000 (\$3,167,178 including net liabilities assumed) which represents 20 percent of the market value of the combined Company’s post-merger total outstanding shares of 23,362,396. In connection with the merger, the Company changed its name from “Atlantic Technology Ventures, Inc.” to “Manhattan Pharmaceuticals, Inc.” At the time of the merger, Manhattan Research recognized patents and licenses for substantially all of the purchase price. A purchase price allocation was completed in the third quarter of 2003 and did not result in changes to the initial estimate. As a result of acquiring Manhattan Research, the Company received new technologies.

A summary of the purchase price allocation is as follows:

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

Notes to Consolidated Financial Statements

December 31, 2004 and 2003

Common stock issued	\$ 2,336,241
Acquisition costs paid	32,808
Total purchase price	2,369,049
<hr/>	
Net liabilities assumed in acquisition	798,129
Excess purchase price (allocated to intangible assets)	\$ 3,167,178
Assets purchased:	
Prepaid expenses	\$ 38,307
Property and equipment	7,683
Deposits	19,938
	65,928
Liabilities assumed:	
Accounts payable	323,735
Accrued expenses	540,322
	864,057
Net liabilities assumed	\$ (798,129)



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

Notes to Consolidated Financial Statements

December 31, 2004 and 2003

The following unaudited pro forma financial information presents the combined results of operations of Manhattan Pharmaceuticals and Manhattan Research as if the acquisition had occurred as of January 1, 2003, after giving effect to certain adjustments, including the issuance of Manhattan Pharmaceuticals common stock as part of the purchase price. For the purpose of this pro forma presentation, both Manhattan Pharmaceuticals' and Manhattan Research's financial information is presented for the year ended December 31, 2003. The unaudited pro forma condensed consolidated financial information does not necessarily reflect the results of operations that would have occurred had Manhattan Pharmaceuticals and Manhattan Research been a single entity during such period.

	<b>Year ended December 31, 2003</b>
Revenues	\$ —
Net loss	(6,160,455)
Weighted-average shares of common stock outstanding: Basic and diluted	23,362,396
Basic and diluted net loss per common share	\$ (0.26)

On August 22, 2003, the Company sold all of its remaining rights to its CT-3 technology to Indevus Pharmaceuticals, Inc. ("Indevus"), the Company's licensee, for aggregate consideration of approximately \$559,000. The purchase price was paid through a combination of cash and shares of Indevus' common stock. On the same date, the Company settled its arbitration with Dr. Sumner Burstein, the inventor of the CT-3 technology, which includes a complete mutual release from all claims that either party had against the other. As a result of the sale of the Company's rights to the CT-3 technology to Indevus, the Company recorded a one-time charge of \$1,213,878 in 2003.

In addition, on August 8, 2003, Bausch & Lomb informed the Company that it had elected not to pursue its development of the Avantix technology, effective August 11, 2003. According to the terms of the Company's agreement with Bausch & Lomb, the Company may re-acquire the technology from Bausch & Lomb and sell or re-license the technology to a third party. The price to re-acquire the technology from Bausch & Lomb is 50% of the proceeds from a third party sale to a maximum of \$3,000,000. The Company has no further obligation under the agreement. As a result of Bausch & Lomb's decision not to develop the Avantix technology, the Company recorded a one-time charge of \$1,248,230 in 2003 for the impairment of the related intangible asset.

As a result of the events discussed in the two preceding paragraphs, as of December 31, 2003, all intangible assets were eliminated from the Company's consolidated financial statements and amortization of such intangible assets ceased.

As described above, the Company resulted from the February 21, 2003 reverse merger between Atlantic Technology Ventures, Inc., which was incorporated on May 18, 1993, and privately-held Manhattan Research Development, Inc., incorporated on August 6, 2001. The Company was incorporated in the State of Delaware. In connection with the

merger, the former stockholders of Manhattan Research received a number of shares of Atlantic's common stock so that following the merger they collectively owned 80 percent of the outstanding shares. Upon completion of the merger, Atlantic changed its name to Manhattan Pharmaceuticals, Inc. and thereafter adopted the business of Manhattan Research Development.

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

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

Notes to Consolidated Financial Statements

December 31, 2004 and 2003

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

***Liquidity***

The Company has reported a net loss of \$5,960,907 and negative cash flows from operating activities of \$3,451,525 for the year ended December 31, 2003 and a net loss of \$5,896,031 and negative cash flows from operating activities of \$5,690,445 for the year ended December 31, 2004. The net loss from date of inception, August 6, 2001 to December 31, 2004 amounts to \$12,951,054.

Management believes that the Company will continue to incur net losses and negative cash flows from operating activities through at least December 31, 2005. Based on the resources of the Company available at December 31, 2004, management believes that the Company will need additional equity or debt financing or will need to generate revenues during 2005 through licensing of its products or entering into strategic alliances to be able to sustain its operations through 2005 and that it will need additional financing thereafter until it can achieve profitability, if ever. These matters raise substantial doubt about the Company's ability to continue as a going concern.

The Company's continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances and its ability to realize the full potential of its technology in development. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long term. Through December 31, 2004, a significant portion of the Company's financing has been through private placements of common and preferred stock and debt financing. Until and unless the Company's operations generate significant revenues and cash flows from operating activities, the Company will attempt to continue to fund operations from cash on hand and through the sources of capital previously described.

***Basis of Presentation***

The consolidated financial statements have been prepared in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 7, "Accounting and Reporting by Development Stage Enterprises."

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

***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.

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***Research and Development***

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

***Income Taxes***

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

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

Basic net loss per common share is calculated by dividing net loss applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect because the Company incurred a net loss during each period presented. The amounts of potentially dilutive securities excluded from the calculation were 14,871,502 and 15,420,033 shares at December 31, 2004 and 2003, respectively.

***Stock-Based Compensation***

Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), provides for the use of a fair value based method of accounting for employee stock compensation. However, SFAS 123 also allows an entity to continue to measure compensation cost for stock options granted to employees using the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), which only requires charges to compensation expense for the excess, if any, of the fair value of the underlying stock at the date a stock option is granted (or at an appropriate subsequent measurement date) over the amount the employee must pay to acquire the stock, if such amounts differ materially from historical amounts. The Company has elected to continue to account for employee stock options using the intrinsic value method under APB 25. By making that election, it is required by SFAS 123 and SFAS 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" to provide pro forma disclosures of net income (loss) and earnings (loss) per share as if a fair value based method of accounting had been applied.



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Had compensation costs been determined in accordance with the fair value method prescribed by SFAS No. 123 for all options issued to employees and amortized over the vesting period, the Company's net loss applicable to common shares and net loss per common share (basic and diluted) for plan options would have been increased to the pro forma amounts indicated below.

	2004	2003
Net loss applicable to common shares, as reported	\$ (6,481,830)	\$ (6,379,089)
Deduct: Total stock-based employee compensation expense determined under fair value method		
)		(1,211,384)
)		(302,974)
Net loss applicable to common shares, pro forma		
\$		(7,693,214)
)		
\$		(6,682,063)
)		
Net loss applicable to common shares – basic		
As reported		
\$		(0.24)
)		
\$		(0.28)
)		
Pro forma		
)		(0.29)
)		(0.30)

The fair value of each option granted is estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions used for the grants in 2004 and 2003: dividend yield of 0%; expected volatility of 73% and 78% for 2004 and 82% for 2003; risk-free interest rate of 2.0% for 2004 and 3.2% for 2003; and expected lives of eight years for each year presented.

As a result of amendments to SFAS No. 123, the Company will be required to expense the fair value of employee

stock options over the vesting period, beginning January 1, 2006.

***Financial Instruments***

At December 31, 2004 and 2003, the fair values of cash and cash equivalents, short-term investments, accounts payable and accrued expenses approximate carrying values due to the short-term nature of these instruments.

***Short-term Investments***

Short-term investments are carried at market value since they are considered available-for-sale. The following is a summary of the Company's short-term investments:

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	<b>2003</b>	<b>Cost</b>	<b>Unrealized loss</b>	<b>Fair value</b>
	<b>Indevus Pharmaceuticals, Inc.</b>			
	common stock			
\$				359,907
\$				(7,760)
)				
\$				352,147

	<b>2004</b>	<b>Cost</b>	<b>Unrealized gain</b>	<b>Fair value</b>
	<b>Eaton Vance Floating Rate Fund</b>			
		\$ 4,500,979	\$ 13,237	\$ 4,514,216

Unrealized gain (and loss, if any) is excluded from operations and included in accumulated other comprehensive income (loss). The Company's comprehensive losses (net losses adjusted for changes in unrealized gains/losses on short-term investments) for 2004 and 2003 were \$5,875,034 and \$5,968,667, respectively.

**(4) Property and Equipment**

Property and equipment consists of the following at December 31:

	<b>2004</b>	<b>2003</b>
Property and equipment	\$ 165,394	\$ 27,054
Less accumulated depreciation	(46,377)	(19,033)
Net property and equipment	\$ 119,017	\$ 8,021

**(5) Stockholders' Equity**

***Common Stock***

On January 13, 2004, the Company completed a private placement of 3,368,637 shares of its common stock at a per share price of \$1.10. After deducting commissions and other expenses relating to the private placement, the Company received aggregate net proceeds of approximately \$3,362,000. In connection with the common stock private



placement and the Series A Convertible Preferred private placement, the Company issued to the placement agents a 5-year warrant to purchase 1,235,589 shares of common stock at a price of \$1.10 per share.

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On July 25, 2003, the Board of Directors adopted a resolution authorizing an amendment to the certificate of incorporation providing for a 1-for-5 combination of the Company's common stock. A resolution approving the 1-for-5 combination was thereafter consented to in writing by holders of a majority of the Company's outstanding common stock. The 1-for-5 combination became effective on September 25, 2003. Accordingly, all share and per share information in these consolidated financial statements has been restated to retroactively reflect the 1-for-5 combination.

The Company issued 10,167,740 shares of common stock to investors during December 2001 for subscriptions receivable of \$4,000 or \$0.0004 per share. During 2002, the Company received the \$4,000.

In August 2002, the Company entered into one-year agreements with four consultants and issued options to these consultants to purchase 101,678 shares of the Company's common stock at an exercise price of \$.0039 per share expiring in August 2007. The Company valued these options at \$60,589, using the minimum value method, and amortized the expense through August 2003. Therefore, the Company expensed \$22,721 in 2002 and \$37,868 in 2003. During 2002 and 2003 no options were exercised.

During 2002, the Company commenced a private placement and sold 239,450 shares of common stock at \$8 (\$0.63 post merger) per share and received proceeds of \$1,704,318, net of expenses of \$211,281. These shares converted into 3,043,332 shares of the Company's common stock when the Company completed the reverse acquisition of Manhattan Research as discussed in Note 1. In addition, each investor received warrants equal to 10% of the number of shares of common stock purchased and, accordingly, Manhattan Research issued warrants to purchase 23,945 shares of common stock in 2002 in connection with the private placement. Upon the merger, these converted into warrants to purchase approximately 304,000 shares of the Company's common stock. Each warrant had an exercise price of \$8 per share, which post merger converted to approximately \$0.63. These warrants expire in 2007.

During January and February 2003, the Company sold an additional 104,000 shares of common stock at \$8 (\$0.63, post merger) per share and warrants to purchase 10,400 shares of common stock exercisable at \$8 (\$0.63 post merger) through the private placement and received net proceeds of \$743,691. These shares converted into 1,321,806 shares of the Company's common stock when the Company completed its reverse acquisition of Manhattan Research. The warrants to purchase 10,400 shares of common stock converted into warrants to purchase 132,181 common shares of the Company.

In addition, in connection with the private placement, the Company issued to Joseph Stevens & Co., Inc., a NASD-member broker-dealer, warrants to purchase 130,511 shares of its common stock that are exercisable at \$8 (\$0.63 post merger) per share and expire in 2008. Upon the merger, these warrants converted into warrants to purchase 1,658,753 shares of common stock of the Company.

***Series A Preferred Stock***

On November 7, 2003, the Company completed a private placement of 1,000,000 shares of its newly-designated Series A Convertible Preferred Stock at a price of \$10 per share, resulting in gross proceeds to the Company of \$10,000,000 (net proceeds \$9,046,176). Each share of Series A Convertible Preferred Stock is convertible at the

holder's election into shares of the company's common stock at a conversion price of \$1.10 per share. The conversion price of the Series A Convertible Preferred Stock was less than the market value of the Company's common stock on November 7, 2003. Accordingly, the Company recorded a charge for the beneficial conversion feature associated with the convertible preferred stock of \$418,182. The Series A Convertible Preferred Stock has a payment-in-kind dividend of 5 percent.

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Maxim Group, LLC of New York, together with Paramount Capital, Inc., a related party, acted as the placement agents in connection with the private placement.

On all matters submitted for stockholder approval, each share of Series A stock is entitled to such number of votes as is equal to the number of common shares into which such preferred shares are then convertible. In addition, so long as at least 50 percent of the number of Series A shares originally issued are outstanding, the affirmative vote of at least two-thirds of all outstanding Series A shares voting separately as a class shall be necessary to permit, effect any one or more of the following:

- the amendment, alteration or repeal of any provision of our certificate of incorporation or bylaws so as to adversely affect the relative rights and preferences of the Series A stock;
- the declaration or payment of any dividend or distribution on any securities of the Company other than the Series A stock;
- the authorization, issuance or increase of any security ranking prior to or on parity with the Series A stock in connection with a dissolution, sale of all or substantially all of our assets or other "Liquidation Event," or with respect to the payment of any dividends or distributions;
  - the approval of any Liquidation Event; and
- the effect any amendment of our certificate of incorporation or bylaws that would materially adversely affect the rights of the Series A stock.

**(6) Stock Options**

***2003 Stock Option Plan***

In December 2003 the Company established the 2003 Stock Option Plan (the 2003 Plan), which provides for the granting of up to 5,400,000 options to officers, directors, employees and consultants for the purchase of stock. At December 31, 2004 and 2003, 5,400,000 shares were authorized for issuance. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally 3 years) and are issued at fair market value. The 2003 Plan expires on December 10, 2013 or when all options have been granted, whichever is sooner.

***1995 Stock Option Plan***

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In July 1995, the Company established the 1995 Stock Option Plan (the 1995 Plan), which provided for the granting of up to 130,000 options to officers, directors, employees and consultants for the purchase of stock. In July 1996, the 1995 Plan was amended to increase the total number of shares authorized for issuance by 60,000 shares to a total of 190,000 shares and beginning with the 1997 calendar year, by an amount equal to one percent (1%) of the shares of common stock outstanding on December 31 of the immediately preceding calendar year. At December 31, 2004 and 2003, 522,381 and 298,767 shares were authorized for issuance. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally 4 years) and are issued at fair market value. The 1995 Plan expires June 30, 2005.

A summary of the status of the Company's stock options as of December 31, 2004 and 2003 and changes during the years then ended is presented below:

	<b>2004</b>		<b>2003</b>
	<b>Weighted average exercise price</b>		<b>Weighted average exercise price</b>
<b>Shares</b>		<b>Shares</b>	
Outstanding at beginning of year			1,392,690
\$			1.68
			689,840
\$			5.00
Granted			1,672,000
			1.44
			876,490
			0.40
Exercised			(27,600)
)			101

	1.09
Cancelled	
)	(214,950
	6.57
)	(173,640
	8.43
Outstanding at end of year	
	2,822,140
\$	1.17
	1,392,690
\$	1.68
Options exercisable at year-end	
	1,282,292
	398,617
Weighted-average fair value of options granted during the year	
\$	0.91
\$	0.06

The following table summarizes the information about stock options outstanding at December 31, 2004:

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Exercise price	Number outstanding	Remaining contractual life (years)	Number of options exercisable
\$0.400	876,090	8.16	730,075
0.425	400	8.15	400
0.970	503,500	8.75	113,334
1.000	97,400	7.24	97,400
1.250	175,750	7.14	160,083
1.650	1,149,000	9.08	161,000
4.375	10,000	6.14	10,000
20.938	10,000	5.28	10,000
	2,822,140		1,282,292

**(7) Stock Warrants Relating to Atlantic Technology Ventures, Inc.**

As of December 31, 2004, the Company had a total of 348,901 warrants outstanding relating to Atlantic Technology Ventures, Inc. The prices of these warrants range from \$2.95 to approximately \$27. These warrants expire between 2005 and 2007.

**(8) Related-Party Transactions**

In 2004 and 2003 the Company entered into consulting agreements with certain members of its Board of Directors. These agreements required aggregate payments of \$10,417 per month. Consulting expense under these agreements was approximately \$173,000 and \$125,000 for the years ended December 31, 2004 and 2003, respectively. These agreements were terminated during 2004.

**Oleoylstrone Developments, SL**

Pursuant to the terms of a license agreement dated February 15, 2002 by and between Manhattan Research Development, Inc., the Company's wholly owned subsidiary, and Oleoylstrone Developments, SL ("OED"), the Company has an exclusive, worldwide license to U.S. and foreign patents and patent applications relating to certain technologies. Although the Company is not obligated to pay royalties to OED, the license agreement requires the Company to make certain performance-based milestone payments. See Note 10. OED currently owns approximately 16 percent of the Company's outstanding common stock. Additionally, Mr. Pons, a member of the Company's board of directors, is chief executive officer of OED.

**NovaDel Pharma Inc.**

As discussed in Note 10, pursuant to the terms of a license agreement dated April 4, 2003 by and between the Company and NovaDel Pharma Inc. (NovaDel), the Company has the rights to develop NovaDel's proprietary lingual spray technology to deliver propofol for preprocedural sedation. The license agreement with NovaDel requires the Company to make certain license and milestone payments, as well as pay royalties. During 2003, the Company paid

aggregate license fees of \$500,000 to NovaDel under the license agreement. In 2004, there were no similar payments made to NovaDel. Lindsay A. Rosenwald, who beneficially owns more than 10 percent of the Company's common stock, also beneficially owns in excess of 20 percent of the common stock of NovaDel and may therefore be deemed to be an affiliate of that company.

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**Paramount BioCapital, Inc.**

Two members of the Company's board of directors, Timothy McInerney and Michael Weiser, are also employees of Paramount BioCapital, Inc. or one of its affiliates. In addition, two members of the Company's board of directors, Joshua Kazam and David Tanen were employed by Paramount BioCapital through August 2004. The sole shareholder of Paramount BioCapital, Inc. (Paramount BioCapital) is Lindsay A. Rosenwald, M.D. Dr. Rosenwald beneficially owns more than 10 percent of the Company's common stock as of December 31, 2004. In November 2003, the Company paid to Paramount BioCapital approximately \$460,000 as commissions earned in consideration for placement agent services rendered in connection with the private placement of the Company's Series A Convertible Preferred Stock, which amount represented 7 percent of the shares sold by Paramount BioCapital in the offering. In addition, in January 2004, the Company paid approximately \$260,000 as commissions earned in consideration for placement agent services rendered by Paramount BioCapital in connection with a private placement of the Company's common stock, which amount represented 7 percent of the shares sold by Paramount BioCapital in the private placement. In connection with both private placements and as a result of their employment with Paramount BioCapital, Mr. Kazam, Mr. McInerney and Dr. Weiser were allocated 5-year placement agent warrants to purchase 60,174, 58,642 and 103,655 shares of the Company's common stock, respectively, at a price of \$1.10 per share.

**(9) Income Taxes**

There was no current or deferred tax expense for the years ended December 31, 2004 and 2003 because of the Company's operating losses.

The components of deferred tax assets as of December 31, 2004 and 2003 are as follows:

	2004	2003
Deferred tax assets:		
Tax loss carryforwards	\$ 4,175,000	\$ 1,889,000
Research and development credit	226,000	51,000
License and other costs	115,000	84,000
Gross deferred tax assets	4,516,000	2,024,000
Less valuation allowance	(4,516,000)	(2,024,000)
Net deferred tax assets	\$ —	\$ —

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The reasons for the difference between actual income tax benefit for the years ended December 31, 2004 and 2003 and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit are as follows:

	<b>2004</b>		<b>2003</b>
	<b>Amount</b>	<b>% of pretax loss</b>	<b>Amount</b>
			<b>% of pretax loss</b>
Income tax benefit at statutory rate			
\$			(2,005,000)
)			
			(34.0
%)			
\$			(2,027,000)
)			
			(34.0
%)			
State income taxes, net of Federal tax			
			(342,000)
)			
			(5.8
%)			
			(354,000)
)			
			(5.9
%)			
Change in valuation allowance			
			2,492,000
			42.3
%)			

	1,568,000
	26.3
% Credits generated in current year	
)	(175,000
	(3.0
%)	
)	(30,000
	(0.5
%) Impairment of intangible assets	
	—
	—
	424,000
	7.1
% Loss on sale of intangible assets	
	—
	—
	412,000
	6.9
% Other, net	
	30,000
	0.5
%	
	7,000
	0.1
% Income tax benefit	
	107

\$

—

%

—

\$

—

%

—

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2004 and 2003 was an increase of \$2,492,000 and \$1,568,000, respectively. The tax benefit assumed using the federal statutory tax rate of 34% has been reduced to an actual benefit of zero due principally to the aforementioned valuation allowance.

At December 31, 2004, the Company had potentially utilizable federal and state net operating loss tax carryforwards of approximately \$10,619,000. The net operating loss carryforwards expire in various amounts through 2024 for federal and state tax purposes. The Tax Reform Act of 1986 contains provisions, which limit the ability to utilize net operating loss carryforwards in the case of certain events including significant changes in ownership interests. As a result of the merger with Manhattan Research Development, Inc. in February 2003, the Company incurred a significant change in its ownership, limiting its ability to utilize net operating loss carryforwards to approximately \$100,000 annually. If the Company has taxable income in the future which exceeds this permissible annual net operating loss carryforward, the Company would incur a federal income tax liability even though net operating loss carryforwards would be available in future years. At December 31, 2004, the Company also had research and development credit carryforwards of approximately \$226,000 for federal tax purposes which expire in various amounts through 2024.

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**(10) License and Consulting Agreements**

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

Under the License Agreement, the Company agreed to pay to OED certain licensing fees which are being expensed as they are incurred. Through December 31, 2004, the Company paid \$175,000 in licensing fees which is included in 2002 research and development expense. In addition, pursuant to the License Agreement, the Company issued 1,000,000 shares of its common stock to OED. The Company valued these shares at their then estimated fair value of \$1,000.

In connection with the License Agreement, the Company has agreed to future 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").

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

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

applications with applicable regulatory authorities. Holders of a significant portion of the Company's common stock own a significant portion of the common stock of NovaDel.

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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 IND for lingual spray propofol is accepted for review by the FDA; \$1,000,000 following the date that the first European Marketing Application is accepted for review by any European Union country; \$2,000,000 following the date when the first filed NDA for lingual spray propofol is approved by the FDA; \$2,000,000 following the date when the first filed European Marketing Application for lingual spray propofol is accepted for review; \$1,000,000 following the date on which an application for commercial approval of lingual spray propofol is approved by the appropriate regulatory authority in each of Australia, Canada, Japan and South Africa; and \$50,000 following the date on which an application for commercial approval for lingual spray propofol is approved in any other country (other than the U.S. or a member of the European Union).

In addition, the Company is obligated to pay to NovaDel an annual royalty based on a fixed rate of net sales of licensed products, or if greater, the annual royalty is based on the Company's net profits from the sale of licensed products at a rate that is twice the net sales rate. In the event the Company sublicenses the licensed product to a third party, the Company is obligated to pay royalties based on a fixed rate of fees or royalties received from the sublicensee until such time as the Company recovers its out-of-pocket costs, and thereafter the royalty rate doubles. Because of the continuing development efforts required of NovaDel under the agreement, the royalty rates are substantially higher than customary for the industry. The Company is also required to pay an up-front fee in installments contingent on whether the Company receives certain amounts through financings, revenues or otherwise. Through December 31, 2003, the Company has paid and expensed \$500,000 of such up-front fee.

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

On August 22, 2003, the Company sold all of its remaining rights to its CT-3 technology to Indevus Pharmaceuticals, Inc. ("Indevus"), the Company's licensee, for aggregate consideration of approximately \$559,000. The purchase price was paid through a combination of cash and shares of Indevus' common stock. On the same date, the Company settled its arbitration with Dr. Sumner Burstein, the inventor of the CT-3 technology, which includes a complete mutual release from all claims that either party had against the other. As a result of the sale of the Company's rights to the CT-3 technology to Indevus, the Company recorded a one-time charge of \$1,213,878 in 2003.

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On August 8, 2003, Bausch & Lomb informed the Company that it had elected not to pursue its development of the Avantix technology effective August 11, 2003. According to the terms of Company's agreement with Bausch & Lomb, the Company may re-acquire the technology from Bausch & Lomb and sell or re-license the technology to a third party. The price to re-acquire the technology from Bausch & Lomb is 50 percent of the proceeds from a third party sale to a maximum of \$3 million. The Company has no further obligation under the agreement. As a result of Bausch & Lomb's decision not to develop the Avantix technology, the Company recorded a one-time charge of \$1,248,230 in 2003 for the impairment of the related intangible asset.

**(11) Commitments and Contingencies**

***Legal Proceedings***

The Company is currently not party to any claims or lawsuits.

***Employment Agreement***

The Company has an employment agreement with one employee for the payment of a base salary of \$175,000 as well as performance based bonuses. The agreement is for a term of two years and has a remaining obligation of \$350,000.

***Consulting Agreements***

The Company had month to month agreements with certain employees requiring aggregate monthly payments of \$20,834. These agreements were terminated during 2004.

***Leases***

Rent expense for the years ended December 31, 2004 and 2003 was \$112,176 and \$93,346, respectively.

Future minimum rental payments subsequent to December 31, 2004 under an operating lease for the Company's office facility are as follows:

Years Ending December 31,	Commitment
2005	\$ 141,600
2006	\$ 141,600
2007	\$ 141,600
2008	\$ 100,000



**MANHATTAN PHARMACEUTICALS, INC.**

(A Development Stage Company)

Notes to Consolidated Financial Statements

December 31, 2004 and 2003

**(12)**

**Subsequent Events**

On January 5, 2005, the Company announced it had signed a letter of intent to merge with Tarpan Therapeutics, Inc. ("Tarpan"), a privately-held, New York-based pharmaceutical company developing dermatological therapeutics, in an all stock transaction. Upon consummation of the transaction, Tarpan shareholders will own approximately 20% of the shares of Manhattan on a fully-diluted basis.

Pursuant to the merger, Douglas Abel, President and CEO of Tarpan will be appointed Chief Executive Officer of the Company, overseeing all operations and clinical development.

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**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>
2.1	Agreement and Plan of Merger among the Company, Manhattan Pharmaceuticals Acquisition Corp. and Manhattan Research Development, Inc. (formerly Manhattan Pharmaceuticals, Inc.) dated December 17, 2002 (incorporated by reference to Exhibit 2.1 from Form 8-K filed March 5, 2003).
3.1	Certificate of incorporation, as amended through September 25, 2003 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-QSB for the quarter ended September 30, 2003).
3.2	Bylaws, as amended to date (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
3.3	Certificate of Designations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (File No. 333-111897).
4.1	Form of unit certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.2	Specimen common stock certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.3	Form of redeemable warrant certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.4	Form of redeemable warrant agreement between the Registrant and Continental Stock Transfer & Trust Company (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.5	Form of underwriter's warrant certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.6	Form of underwriter's warrant agreement between the Registrant and Joseph Stevens & Company, L.P. (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.7	Form of bridge warrant (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
4.8	Warrant issued to John Prendergast to purchase 37,500 shares of Registrant's common stock (incorporated by reference from Exhibit 10.24 to the Registrant's Form 10-QSB for the quarter ended March 31, 1997).
4.9	Warrant No. 2 issued to Joseph Stevens & Company, Inc. to purchase 150,000 shares of Registrant's Common Stock exercisable January 4, 2001 (incorporated by reference to Exhibit 10.29 to the Registrant's Form 10-KSB for the year ended December 31, 1999).

- 4.10 Warrant No. 3 issued to Joseph Stevens & Company, Inc. to purchase 150,000 shares of Registrant's Common Stock exercisable January 4, 2002 (incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-KSB for the year ended December 31, 1999).
- 4.11 Form of stock purchase warrants issued on September 28, 2000 to BH Capital Investments, L.P., exercisable for shares of common stock of the Registrant (incorporated by reference to Exhibit 10.6 to the Registrant's Form 10-QSB for the quarter ended September 30, 2000).
- 4.12 Form of stock purchase warrants issued on September 28, 2000 to Excalibur Limited Partnership, exercisable for shares of common stock of the Registrant (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-QSB for the quarter ended September 30, 2000).
- 4.13 Warrant certificate issued March 8, 2001 by the Registrant to Dian Griesel (incorporated by reference to Exhibit 10.56 to the Registrant's Form 10-QSB for the quarter ended March 31, 2001).
- 4.14 Form of warrant issued by Manhattan Research Development, Inc., which automatically converted into warrants to purchase shares of the Registrant's common stock upon the merger transaction with such company (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
- 4.15 Form of warrant issued to placement agents in connection with the Registrant's November 2003 private placement of Series A Convertible Preferred Stock and the Registrant's January 2004 private placement (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (File No. 333-111897)).
- 4.16 Form of subscription agreement between Registrant and the selling stockholders (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No. 33-98478)).
- 10.1 1995 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-QSB for the quarter ended September 30, 1996).
- 10.2 Common stock purchase agreement dated March 16, 2001, between Registrant and Fusion Capital Fund II, LLC (incorporated by reference from Exhibit 10.55 of the Registrant's Form 10-QSB for the quarter ended March 31, 2001).
- 10.3 Third Amendment to Employment Agreement dated February 21, 2003 between the Registrant and Nicholas J. Rossettos (incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
- 10.4 Employment Agreement dated January 2, 2003, between Manhattan Research Development, Inc. and Leonard Firestone, as assigned to the Registrant effective as of February 21, 2003 (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
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10.5 Employment Agreement dated February 28, 2003, between the Registrant and Nicholas J. Rossettos (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).

10.6 License Agreement dated on or about February 28, 2002 between Manhattan Research Development, Inc. (f/k/a Manhattan Pharmaceuticals, Inc.) and Oleoyl-Estrone Developments SL (incorporated by reference to Exhibit 10.6 to the Registrant's Amendment No. 2 to Form 10-QSB/A for the quarter ended March 31, 2003 filed on March 12, 2004).

10.7 License Agreement dated April 4, 2003 between the Registrant and NovaDel Pharma, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to Form 10-QSB/A for the quarter ended June 30, 2003 filed on March 12, 2004).++

10.8 Employment Agreement dated January 2, 2004 between the Registrant and Leonard Firestone (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (No. 333-111897)).

10.9 2003 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed February 17, 2004).

23.1 Consent of J.H. Cohn LLP.

31.1 Certification of Principal Executive and Financial Officer.

32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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