MANHATTAN PHARMACEUTICALS INC
Form S-3
May 09, 2007

As filed with the Securities and Exchange Commission on May 9, 2007
Registration No. 333-_____

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

FORM S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Manhattan Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**36-3898269**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

Manhattan Pharmaceuticals, Inc.
810 Seventh Avenue, 4th Floor
New York, NY 10019
Telephone: (212) 582-3950
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mr. Michael G. McGuinness
Chief Financial Officer
Manhattan Pharmaceuticals, Inc.
810 Seventh Avenue, 4th Floor
New York, NY 10019
Telephone: (212) 582-3950
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Christopher J. Melsha, Esq.
Maslon Edelman Borman & Brand, LLP
90 South 7th Street, Suite 3300
Minneapolis, Minnesota 55402
Telephone: (612) 672-8200

Approximate date of commencement of proposed sale to the public:

From time to time after the effective date of this Registration Statement, as determined by the stockholders.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ý

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, par value $0.001 per share	14,259,674	$ 0.90	$ 12,833,706.60	$ 393.99

(1) Includes 4,074,172 shares of common stock issuable upon exercise of outstanding warrants.

(2) Estimated in accordance with Rule 457(c) of the Securities Act of 1933, as amended, solely for the purpose of computing the amount of the registration fee, based on the average of the high and low sales prices of the Registrant's Common Stock on the American Stock Exchange on May 4, 2007.

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

The information in this prospectus is not complete and may be changed. The stockholders identified in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated May 9, 2007

PROSPECTUS

14,259,674 Shares of Common Stock

Manhattan Pharmaceuticals, Inc.

This prospectus relates to shares of our common stock (including shares of common stock issuable upon exercise of outstanding warrants) that will be sold by the selling stockholders named in this prospectus. The selling stockholders acquired these shares from us in a private placement completed on March 30, 2007. We will not receive any of the proceeds from the sale of those shares.

Our common stock is traded on the American Stock Exchange under the symbol "MHA." On _____ __, 2007, the last reported sales price for our common stock on the American Stock Exchange was $____ per share.

See "Risk Factors" beginning on page 8 of this Prospectus for factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is _____ __, 2007.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as anticipate, estimate, plan, project, continuing, ongoing, expect, management believes, we believe, we intend and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed in this prospectus or incorporated by reference.

Because the factors discussed in this prospectus or incorporated by reference could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate to, among other factors: the development of our drug candidates; the regulatory approval of our drug candidates; our use of clinical research centers and other contractors; our ability to find collaborative partners for research, development and commercialization of potential products; acceptance of our products by doctors, patients or payors; our ability to market any of our products; our history of operating losses; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our product candidates; the effect of potential strategic transactions on our business; our ability to obtain adequate financing; and the volatility of our stock price. These and other risks are detailed in this prospectus under the discussion entitled “Risk Factors,” as well as in our reports filed from time to time under the Securities Act and/or the Exchange Act. You are encouraged to read these filings as they are made.

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

PROSPECTUS SUMMARY

The Securities and Exchange Commission, or SEC, allows us to "incorporate by reference" certain information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will update automatically, supplement and/or supersede this information. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should read the detailed information regarding our company, our common stock and our financial statements and notes to those statements appearing elsewhere in this prospectus or incorporated herein by reference. References in this prospectus to "our company," "we," "our," and "us" refer to Manhattan Pharmaceuticals, Inc.

Manhattan Pharmaceuticals, Inc.

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. In addition to the development of our current products, we are actively working to expand our product candidate pipeline.

Our Product Candidates

We currently have five product candidates in development:

- ***Oral Oleoyl-estrone*.** We hold an exclusive, worldwide license to develop and commercialize oral Oleoyl-estrone, or OE, pursuant to a 2002 license agreement with Oleoylestrone Developments, SL, or OED, a Spanish corporation. We are currently conducting two Phase 2a clinical studies of Oleoyl-estrone, one in common obese subjects and one in morbidly obese subjects.

Extensive preclinical studies of OE have shown evidence of weight loss, sustained weight loss after dosing stops, and reduced food intake. These studies have also shown evidence of beneficial changes in blood glucose and cholesterol levels. This work is supported by dozens of peer-reviewed journal publications over the past ten years. Results of the Phase 1 clinical studies with OE, reported in October 2005, showed OE was clinically well tolerated at all dose levels. The Phase 1 data in humans points to similar beneficial effects of OE as shown in preclinical studies including weight loss, sustained weight loss and beneficial changes in blood glucose and cholesterol. Clinical laboratory findings included dose-dependent elevations in estrone and estradiol levels, as well as reductions in testosterone levels; all had returned to baseline by the first follow-up visit, 8 days after dosing stopped.

In March 2006, we commenced a Phase 2a clinical study evaluating oral Oleoyl-estrone in obese adult subjects with a body mass index, or BMI, of 27-38.9. This randomized, double-blind, placebo-controlled, parallel group study is designed to evaluate the safety and preliminary efficacy of oral Oleoyl-estrone in 100 common obese male and female subjects. Enrollment in this study was completed in February 2007. We expect the last patient to complete the study in mid-June 2007, and we plan to complete data analysis in mid-July 2007.

In the fourth quarter of 2006, we also commenced a Phase 2a clinical study evaluating oral Oleoyl-estrone in 24 morbidly obese male subjects (BMI 40-55). F. Xavier Pi-Sunyer, MD, of St. Luke's-Roosevelt Hospital Center,

University Hospital of Columbia University College of Physicians and Surgeons is serving as Principal Investigator. The study is expected to conclude mid-year 2007.

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

Due to the high response rate seen in patients in the initial trial with PTH (1-34), we believe that it may have an important clinical advantage over current topical psoriasis treatments. A physician IND Phase 2a trial involving PTH (1-34) was initiated in December 2005 under the auspices of Boston University. In April 2006, we reported a delay in this Phase 2a clinical study of topical PTH (1-34) due to a formulation issue. We believe we have identified and resolved this issue. An improved formulation has been produced and several patent applications are being prepared. We expect to initiate clinical activities during 2007.

- ***Altoderm.*** We recently entered into a license agreement with Thornton & Ross LTD, or T&R, pursuant to which we acquired exclusive North American rights to a dermatology product candidate called Altoderm. Altoderm is a novel, proprietary formulation of topical cromolyn sodium and is designed to enhance the absorption of cromolyn sodium in order to treat atopic dermatitis, or "eczema." This product candidate is currently being tested in a Phase 3 clinical trial in the United Kingdom. In a previously completed randomized, double-blind, placebo-controlled, parallel-group, Phase 3 clinical study in the United Kingdom the compound was administered for 12 weeks to 114 child subjects with moderately severe atopic dermatitis. In the study results, published in the British Journal of Dermatology in February 2005, Altoderm demonstrated a statistically significant reduction in symptoms. During the study, subjects were permitted to continue with their existing treatment, in most cases this consisted of emollients and topical steroids. A positive secondary outcome of the study was a reduction in the use of topical steroids for the Altoderm-treated subjects. See "—Recent Developments - Altoderm License Agreement."

- ***Altolyn.*** In addition to the Altoderm license agreement, we entered into a separate license agreement with T&R pursuant to which we acquired exclusive North American rights to develop and commercialize Altolyn. Altolyn is a proprietary, site specific, tablet formulation of oral cromolyn sodium for the treatment of mastocytosis. This novel formulation is designed to provide optimal availability by preferentially releasing the drug in the upper part of the small intestine, the purported site of action. In addition to mastocytosis early clinical experience in the UK suggests promising activity in patients with various allergic disorders, including inflammatory bowel conditions. Oral cromolyn sodium is the active ingredient in Gastrocrom® an oral liquid solution that is currently FDA approved for the treatment of mastocytosis. See "—Recent Developments - Altolyn License Agreement."

- ***Propofol Lingual Spray.*** We are developing propofol lingual spray, which we in-licensed from NovaDel Pharma, Inc. for light to medium sedation, on a Section 505(b)(2) bioequivalence regulatory pathway toward approval by the U.S. Food and Drug Administration (FDA). In January 2005, the FDA accepted our IND for propofol lingual spray, allowing us to commence clinical trials. The FDA has indicated to us in discussions that we may proceed to a pivotal Phase III trial of propofol lingual spray following completion of Phase I trials. We continue to pursue a revised product presentation to meet the market opportunity and are working with several external experts to achieve these goals.

None of our product candidates have been approved by the FDA or any other regulatory body. Further, we have not received any commercial revenues to date and, until we receive the necessary regulatory approvals, we will not have

any commercial revenues.

Corporate Information

We were incorporated in Delaware in 1993 under the name "Atlantic Pharmaceuticals, Inc." and, in March 2000, we changed our name to "Atlantic Technology Ventures, Inc." In 2003, we completed a "reverse acquisition" of privately held "Manhattan Research Development, Inc." In connection with this transaction, we also changed our name to "Manhattan Pharmaceuticals, Inc." From an accounting perspective, the accounting acquirer is considered to be Manhattan Research Development, Inc. and accordingly, the historical financial statements are those of Manhattan Research Development, Inc.

During 2005, we merged with Tarpan Therapeutics, Inc. Tarpan was a privately held New York based biopharmaceutical company developing dermatological therapeutics. Through the merger, we acquired Tarpan's primary product candidate, topical PTH (1-34) for the treatment of psoriasis.

Our executive offices are located at 810 Seventh Avenue, 4th floor, New York, NY 10019 USA. Our telephone number is (212) 582-3950 and our internet address is www.manhattanpharma.com.

Altoderm™ and Altolyn™ are the trademarks for our topical cromolyn sodium and for our oral cromolyn sodium product candidates, both of which trademarks we license from T&R, from which we have licensed all of our rights to Altoderm and Altolyn. T&R has applied for registration for the Altoderm and Altolyn trademarks. All other trademarks and tradenames mentioned in this prospectus are the property of their respective owners.

Recent Developments

Private Placement

On March 30, 2007, we issued and sold in a private placement transaction an aggregate of 10,185,502 shares of our common stock. Of the total amount of shares issued, 10,129,947 were sold at a per share price of $0.84, and an additional 55,555 shares were sold to an entity affiliated with Neil Herskowitz, a director of Manhattan, at a per share price of $0.90, the closing sale price of our common stock on March 29, 2007. In addition to the shares of common stock, we also issued to the investors 5-year warrants to purchase an aggregate of 3,564,897 shares of our common stock at an exercise price of $1.00 per share. The warrants are exercisable during the period commencing September 30, 2007 and ending March 30, 2012. Accordingly, we received net proceeds of $7.9 million from the sale of these shares and warrants. We engaged Paramount BioCapital, Inc., as our placement agent in connection with the private placement. In consideration for its services, we paid aggregate cash commissions to the placement agent of approximately $600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares at an exercise price of $1.00 per share.

The shares being offered by this prospectus are comprised of the 10,185,502 common shares and the 3,564,897 shares issuable upon exercise of the warrants issued to investors in the offering, as well as 509,275 shares issuable upon exercise of the placement agent warrants.

Altoderm License Agreement

On April 3, 2007, we entered into an exclusive license agreement for "Altoderm" with Thornton & Ross, LTD, or T&R. We acquired an exclusive license in North America for certain patent rights and other intellectual property related to Altoderm, a proprietary topical formulation of cromolyn sodium used to treat atopic dermatitis, or "eczema". In consideration for the license, we issued T&R 125,000 shares of our common stock upon execution of the agreement and made a cash payment to T&R of $475,000. Under the agreement, we will make certain milestone payments of cash and common stock to T&R of $5,765,000 and 857,000 shares of our common stock upon the achievement of various clinical and regulatory milestones. We also agreed to pay royalties on net sales of products using the licensed

patent rights of 10% to 20%, depending on the level of net annual sales, and subject to an annual minimum royalty payment of $1,000,000 in each year following the first commercial sale of Altoderm. Also, we may sublicense the patent rights, and proceeds resulting from such sublicenses will be shared with T&R.

Under the agreement with T&R, we are responsible for maintaining the licensed patent rights at our own expense. T&R must notify us of any improvements to the licensed product and assist us in filing and maintaining such improvements with the applicable governmental bodies. We have the first right to initiate, at our sole expense, legal proceedings against any infringers or potential infringers of the licensed patent rights. T&R may, in certain circumstances and at its own expense, initiate legal proceedings against any infringers or potential infringers of the licensed patent rights. The parties may elect to share equally in the expenses incurred during, and proceeds received from, enforcement actions brought by the other party.

The license agreement, unless earlier terminated, will expire upon the expiration of the last to expire patent right covering a licensed product in North America, which is currently May 2019. T&R has the right, following 90 days' notice and opportunity to cure, to terminate the license agreement sooner in the event we commit a breach of the agreement. We may terminate, in our sole discretion, the license agreement at any time, upon 30 days' notice. Additionally, T&R may terminate the agreement if we declare bankruptcy or are declared bankrupt, if we are placed in the hands of a receiver or trustee for the benefit of creditors, or if we, or our sublicensee, fails to take affirmative actions towards the development of the licensed product. Upon termination of the license agreement, all rights to the licensed patents shall revert to T&R; however, we have the right to continue to sell all remaining licensed products in our inventory.

Altolyn License Agreement

On April 3, 2007, we entered into an exclusive license agreement for "Altolyn" with T&R. We acquired an exclusive license in North America for certain patent rights and other intellectual property related to Altolyn, a proprietary oral tablet formulation of cromolyn sodium for the treatment of mastocytosis, food allergies, and irritable bowel syndrome. In consideration for the license, we made a cash payment to T&R of $475,000. Under the agreement, we will have to make cash milestone payments to T&R of $5,765,000 upon the achievement of various clinical and regulatory milestones. We also agreed to pay royalties on net sales of products using the licensed patent rights of 10% to 20%, depending on the level of net annual sales, and subject to an annual minimum royalty payment of $1,000,000 in each year following the first commercial sale of Altolyn. Also, we may sublicense the patent rights, and proceeds resulting from such sublicenses will be shared with T&R.

Under the agreement with T&R, we are responsible for maintaining the licensed patent rights at our own expense. T&R must notify us of any improvements to the licensed product and assist us in filing and maintaining such improvements with the applicable governmental bodies. We have the first right to initiate, at our sole expense, legal proceedings against any infringers or potential infringers of the licensed patent rights. T&R may, in certain circumstances and at its own expense, initiate legal proceedings against any infringers or potential infringers of the licensed patent rights. The parties may elect to share equally in the expenses incurred during, and proceeds received from, enforcement actions brought by the other party.

The license agreement, unless earlier terminated, will expire upon the expiration of the last to expire patent right covering a licensed product in North America, which is currently November 2019. T&R has the right, following 90 days' notice and opportunity to cure, to terminate the license agreement sooner in the event we commit a breach of the agreement. We may terminate, in our sole discretion, the license agreement at any time, upon 30 days' notice. Additionally, T&R may terminate the agreement if we declare bankruptcy or are declared bankrupt, if we are placed in the hands of a receiver or trustee for the benefit of creditors, or if we, or our sublicensee, fails to take affirmative actions towards the development of the licensed product. Upon termination of the license agreement, all rights to the licensed patents shall revert to T&R; however, we have the right to continue to sell all remaining licensed products in our inventory.

The Offering

The selling stockholders identified on pages 17-20 of this prospectus are offering on a resale basis an aggregate of 14,259,674 shares of our common stock, of which 4,074,172 shares are issuable upon exercise of outstanding warrants.

Shares of common stock offered	10,185,502 shares
Shares of common stock issuable upon exercise of warrants offered	4,074,172 shares
Common stock outstanding before this offering (1)	70,470,419 shares
Common stock outstanding following this offering (2)	74,544,591 shares
Common stock American Stock Exchange Symbol	MHA

(1) Based on the number of shares outstanding as of May 2, 2007, not including approximately 18,734,166 shares issuable upon exercise of various warrants and options to purchase common stock as well as restricted stock grants.

(2) Assumes the issuance of all shares offered hereby that are issuable upon the exercise of warrants.

RISK FACTORS

Investment in our shares involves a degree of risk. You should consider the following discussion of risks as well as other information in this prospectus and the incorporated documents before purchasing any shares. The risks described below are not the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition, or results of operations could be materially adversely affected. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

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 and we expect to continue to have negative cash flow from our operations for at least the next several years. As of December 31, 2006, we had $3,029,118 of cash and cash equivalents. In connection with our March 2007 private placement of common stock and warrants, we received net proceeds of approximately $7.9 million. Even though we were successful in raising funds in March 2007 we will still have to raise substantial additional funds to complete the development of our drug candidates and to bring them to market. Beyond the capital requirements mentioned above, our future capital requirements will depend on numerous factors, including:

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

Additional financing may not be available on acceptable terms, if at all. If adequate funds are not available, we will be required to delay, scale back or eliminate one or more of our drug development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. We have incurred losses in every period since our inception on August 6, 2001. For the year ended December 31, 2006 and for the period from August 6, 2001 (inception) through December 31, 2006, we incurred net losses of $9,695,123, and $41,787,174, respectively. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future

as we:

- continue to undertake pre-clinical development and clinical trials for our product candidates;

- seek regulatory approvals for our product candidates;
- in-license new products;
- 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 our operations have been limited to organizing and staffing, and acquiring, developing and securing our proprietary technology and undertaking pre-clinical trials of principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

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

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must first submit to the FDA an Investigational New Drug Application, or an IND, which will set forth our plans for clinical testing of our product candidates. In January 2005, the FDA accepted INDs for both our Oleoyl-estrone and Propofol LS product candidates. We have not yet filed a corporate IND for PTH(1-34), Altoderm or Altolyn. In May and July 2005, we completed Phase 1a and Phase 1b trials in Basel, Switzerland to evaluate the safety and tolerability as well as preliminary signs of efficacy of defined doses of orally administered Oleoyl-estrone in obese adults, in accordance with relevant regulatory guidelines. Because Propofol has already been approved by the FDA for intravenous use, the FDA has informed us that we may utilize a rapid development strategy that will enable us to go directly to a Pivotal Phase 3 trial following completion of Phase 1 trials. We are unable to estimate the size and timing of all the Phase 2 and Phase 3 programs for Oleoyl-estrone at this time and, accordingly, cannot estimate the time when development of that product candidate will be completed.

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

- delay commercialization of, and our ability to derive product revenues from, our product candidates;

- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We have not yet made any determination as to which foreign jurisdictions we may seek approval and have not undertaken any steps to obtain approvals in any foreign jurisdiction.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials.

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans or effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.