MANHATTAN PHARMACEUTICALS INC
Form S-3/A
April 06, 2006

As filed with the Securities and Exchange Commission April 6, 2006 **Registration No. 333-131814**

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

AMENDMENT NO. 1
FORM S-3/A
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 jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

810 Seventh Avenue, 4th Floor
New York, NY 10019
(Address and telephone number of registrant's principal executive offices and principal place of business)

Mr. Nicholas J. Rossettos	**Copies to:**
Chief Financial Officer	Christopher J. Melsha, Esq.
Manhattan Pharmaceuticals, Inc.	Maslon Edelman Borman & Brand, LLP
810 Seventh Avenue, 4th Floor	90 South 7th Street, Suite 3300
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(Name, address and telephone number of agent for service)	

Approximate date of proposed sale to the public: From time to time after the effective date of this Registration Statement, as shall be determined by the selling stockholders identified herein.

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

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: x

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. o

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. o

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. o

If this Form is a post-effective amendment to a registration statement filed 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. o

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 which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

****Pursuant to Rule 429, the prospectus included in this Registration Statement on Form S-3 also relates to 25,627,684 shares of common stock previously registered under the Registrant's registration statement on Form SB-2, File No. 333-128542, for which a registration fee was previously paid. Accordingly, as provided by Rule 429(b), this Registration Statement on Form S-3 is also intended to be deemed a post-effective amendment to the Registrant's Form SB-2, File No. 333-128542.**

EXPLANATORY NOTE NOT FORMING PART OF PROSPECTUS

This Registration Statement on Form S-3 relates to the resale of an aggregate of 810,810 shares of the Registrant's common stock issued to a third party vendor of the Registrant, including 135,135 shares issuable upon exercise of a warrant. Additionally, the prospectus included in this Form S-3 also relates to an aggregate of 25,627,684 shares of the Registrant's common stock that were previously registered on the Registrant's Registration Statement on Form SB-2, File No. 333-128542, filed with the Commission on September 23, 2005. In accordance with the provisions of Rule 429 under the Securities Act of 1933, the prospectus included in such Form SB-2 is being combined with the prospectus included in this Form S-3. Accordingly, the selling stockholder table included in the prospectus in this Form S-3 includes all of the selling stockholders identified in the Registrant's Form SB-2 (File 333-128542).

A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Subject to completion, dated April 5, 2006

OFFERING PROSPECTUS

Manhattan Pharmaceuticals, Inc.

26,438,473 Shares

Common Stock

The selling stockholders identified on pages 14-19 of this prospectus are offering on a resale basis a total of 26,438,473 shares of our common stock, including 3,114,092 shares issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is listed on the American Stock Exchange under the symbol “MHA.” On , 2006, the last sale price for our common stock as reported on the American Stock Exchange was $.

The securities offered by this prospectus involve a high degree of risk.
See “Risk Factors” beginning on page 5.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined that this prospectus is truthful or complete. A representation to the contrary is a criminal offense.

The date of this Prospectus is , 2006.

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PROSPECTUS SUMMARY

This summary provides a brief overview of the key aspects of this offering. Because it is only a summary, it does not contain all of the detailed information contained elsewhere in this prospectus or in the documents incorporated by reference into this prospectus or included as exhibits to the registration statement that contains this prospectus. Accordingly, you are urged to carefully review this prospectus (including all documents incorporated by reference into this prospectus) in its entirety.

Our Company

We are engaged in the business of developing and commercializing early-stage technologies, particularly biomedical and pharmaceutical technologies. We aim to acquire proprietary rights to these technologies, by license or acquisition of an ownership interest, fund their research and development and eventually bring the technologies to market. We currently are researching and developing three biomedical technologies: oleoyl-estrone, an orally administered hormone which we believe can be used to treat obesity; PTH (1-34), atopical treatment for psoriasis; and lingual spray propofol, a proprietary lingual spray technology to deliver propofol for pre-procedural sedation prior to diagnostic, therapeutic or endoscopic procedure. None of the product candidates have been approved by the United States Federal Drug Administration or any other regulatory body. Further, we have not received any commercial revenues to date and, until we receive the necessary approvals from the FDA or a similar foreign regulatory authority, we will not have any commercial revenues.

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

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

The Phase Ib study was a seven day repeat dose study involving 24 obese volunteers in four cohorts of 6 patients each who received either placebo or Oleoyl-estrone in doses ranging from 10 mg to 150 mg once daily for seven consecutive days. The results indicated that Oleoyl-estrone was generally well-tolerated at all doses and no serious adverse events were reported. There were also no clinically significant changes in the physical exams, vital signs, ECGs, coagulation and liver function tests. The study demonstrated evidence of greater weight loss among the treated groups compared with the placebo group as well as evidence of reduction in desire to eat, hunger levels, fasting glucose and LDL cholesterol. Important clinical laboratories findings included reversible, dose-dependent elevations in estrone and estradiol levels, as well as reductions in testosterone levels. We plan to initiate a follow on Phase IIa study using low doses of Oleoyl-estrone in the first half of 2006. In preparation for beginning the phase IIa clinical trial, the clinical study protocol is currently in the regulatory review cycle in Switzerland, having received local ethics commitee review and approval. The trial will begin immediately following receipt of final regulatory approval from Swissmedic, the Swiss Medical Authority.

- ***PTH(1-34)***, which we acquired as a result of our April 2005 acquisition of Tarpan Therapeutics, Inc., is being developed as a topical treatment for psoriasis. In early 2001, a Phase I and II clinical trial of PTH(1-34) was

completed at Boston University Medical Center. The study evaluated safety and efficacy of the drug as a topical treatment for psoriasis. This double-blinded, controlled trial in 15 patients indicated that PTH(1-34) was a potentially safe and effective treatment for plaque psoriasis. After 8 weeks of treatment, application of PTH(1-34) appeared to result in at least a partial clearing of the treated lesion in 85 percent of the patients and complete clearing in 60 percent of the patients. None of the patients appeared to experience any significant adverse effects. Due to the high response rate seen in patients in this trial, we believe that PTH(1-43) may have an important clinical advantage over current topical psoriasis treatments. A follow-on physician IND Phase IIa trial involving PTH(1-34) was initiated in December 2005 under the auspices of Boston University. Patient recruitment is ongoing; dosing has not yet begun.

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

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

Our executive offices are located at 810 Seventh Avenue, 4th Floor, New York, New York, 10019 and our telephone number is (212) 582-3950. Our Internet site is www.manhattanpharma.com.

Risk Factors

For a discussion of some of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled "Risk Factors" beginning on page 5 of this prospectus.

The Offering

The selling stockholders identified on pages 15-20 of this prospectus are offering on a resale basis a total of 26,438,473 shares of our common stock, including 3,114,092 shares are issuable upon exercise of outstanding warrants and options, which were issued by us as follows:

- 11,917,680 outstanding common shares and 2,383,508 common shares issuable upon the exercise of the warrants issued to the investors in our August 2005 private placement;

- 595,449 common shares issuable upon the exercise of warrants issued to placement agents that provided services to us in connection with our August 2005 private placement;

- 10,731,026 shares of our common stock issued by us in connection with our acquisition of Tarpan Therapeutics, Inc. in April 2005; and

- 810,810 shares of our common stock, including 135,135 shares issuable upon the exercise of a warrant, which were issued by us to a third party vendor as payment for services rendered.

With the exception of the 810,810 shares offered by the third party vendor described above, the shares offered hereby were previously offered pursuant to our prospectus dated October 4, 2005, as supplemented to date, which prospectus was included in our previously filed registration statement on Form SB-2 (SEC No. 333-128542). This prospectus supersedes our October 4, 2005 prospectus (including all supplements thereto) in its entirety.

Common stock offered	26,438,473 shares
Common stock outstanding before the offering[(1)]	60,092,697 shares
Common stock outstanding after the offering[(2)]	63,206,789 shares
Common Stock American Stock Exchange symbol	MHA

(1) Based on the number of shares outstanding as of March 24, 2006, not including 12,915,242 shares issuable upon exercise of various warrants and options to purchase common stock.

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

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RISK FACTORS

An investment in our common stock is very risky. You may lose the entire amount of your investment. Prior to making an investment decision, you should carefully review this entire prospectus and consider the following risk factors:

Risks Relating 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 we receive approval from the FDA and other regulatory authorities for our product candidates. We have already spent substantial funds developing our potential products and business, however, and we expect to continue to have negative cash flow from our operations for at least the next several years. As of December 31, 2005, we had $9,826,336 of cash and cash equivalents and $1,007,818 of short-term investments. We will have to raise additional funds to complete the development of our drug candidates and to bring them to market, however. Beyond the capital requirements mentioned above, our future capital requirements will depend on numerous factors, including:

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

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

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For each of the fiscal years ended December 31, 2005, 2004, 2003 and 2002 and from August 6, 2001 (inception) through December 31, 2001, we realized net losses of $19,140,997, $5,896,031, $5,960,907, $1,037,320 and $56,796, respectively. Even if we succeed in developing and commercializing one or both of our current product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

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

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

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

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

- continuing to undertake pre-clinical and clinical development;
- 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 and clinical trials of principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

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

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must first submit to the FDA an Investigational New Drug Application, or an "IND," which will set forth our plans for clinical testing of our product candidates. In January 2005, the FDA accepted INDs for both our Oleoyl-estrone and Propofol LS product candidates. We have not yet filed a corporate IND for PTH(1-34). In May and July 2005, we completed Phase Ia and Phase Ib trials in Basel, Switzerland to evaluate the safety and tolerability as well as preliminary signs of efficacy of defined doses of orally administered oleoyl-estrone in obese adults, in accordance with relevant regulatory guidelines. Assuming formulation work is completed satisfactorily, we expect to conduct a Phase I clinical study for propofol lingual spray following formulation. Because propofol has already been approved by the FDA for intravenous use, the FDA has informed us that we may utilize a rapid development strategy that will enable us to go directly to a Pivotal Phase III trial following completion of our planned Phase I trials. Accordingly, we currently anticipate that development of propofol lingual spray may be completed as early as 2007. We are unable to estimate the size and timing of all the Phase II and Phase III programs for oleoyl-estrone at this time and, accordingly, cannot estimate the time when development of that product candidate will be completed.

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

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

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 candidates. Failure to obtain FDA approval 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 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 products 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.

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Our drug-development program will depend upon third-party researchers and other collaborators 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 have engaged third party independent investigators and collaborators, which may include universities and medical institutions, to conduct our pre-clinical and clinical trials for oleoyl-estrone, 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 will rely exclusively on third parties to formulate and manufacture our product candidates.

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

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