MANHATTAN PHARMACEUTICALS INC
Form 8-K
October 03, 2007

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

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 3, 2007

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

Delaware	**001-32639**	**36-3898269**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

810 Seventh Avenue, 4th Floor
New York, New York 10019
(Address of principal executive offices) (Zip Code)

(212) 582-3950
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

Manhattan Pharmaceuticals Presents Pipeline Update

Manhattan Pharmaceuticals, Inc. is giving an update on its product pipeline today at 4:30 PM through a presentation at the American Stock Exchange, 14th Floor Boardroom, 86 Trinity Place, New York, New York 10006. The presentation will be simultaneously webcast, which can be accessed on the internet by using the link **http://www.wsw.com/webcast/cc/mha4**

Pipeline Update

Topical PTH (1-34) for Psoriasis - A corporate investigational new drug (IND) application for the improved formulation of topical PTH (1-34) was accepted by the U.S. Food and Drug Administration (FDA) in September 2007. Clinical trial material has been manufactured and clinical sites have been identified and secured. Central internal review board approval has been received. Pending local clinical site review board approvals, the company intends to initiate a Phase 2a multi-center, randomized, double-blind, vehicle-controlled, parallel group clinical trial in the fourth quarter of 2007.

The study will involve 54 subjects in a 1:1:1 randomization, two doses of topical PTH (1-34) compared to vehicle for an eight week treatment period. The vehicle is the topical PTH (1-34) product without the active ingredient, PTH (1-34).

Altoderm™ for Atopic Dermatitis - Analysis of the preliminary data from the initial 12 week, blinded portion of this European Phase 3 randomized, double-blind, vehicle controlled clinical trial being conducted by Thornton & Ross Limited has been completed. In this study the vehicle was the Altoderm product without the active ingredient, cromolyn sodium.

Data indicate that Altoderm was safe and well tolerated. Altoderm treated subjects experienced a 33.1% improvement in SCORAD from baseline. (*See below for an explanation of SCORAD.*) This efficacy is consistent with findings from the first European Phase 3 study of Altoderm. While this improvement from baseline was dramatic in the Altoderm treated subjects, the vehicle only treated subjects experienced a similar improvement, and therefore, the study did not achieve statistical significance. Preliminary results of the open label extension of this study show that the subjects treated with the vehicle only in the blinded portion of the study demonstrated further marked improvement in SCORAD when switched to Altoderm. Manhattan Pharmaceuticals believes these outcomes were due to the vehicle being very effective on its own, as evidenced by the 20% improvement in SCORAD demonstrated in the prior Phase 3 study, and a much less rigorous study design where subjects were unrestricted in their use of concomitant therapies such as topical steroids and immunomodulators.

A meta-analysis of both studies shows Altoderm treated subjects experienced a statistically significant improvement in pruritus, the itch associated with atopic dermatitis, versus vehicle only treated subjects.

The extensive data obtained from these studies will be submitted in support of Altoderm to both European and US regulatory agencies.

Given the promising clinical data obtained from the prior European Phase 3 study, and the symptom improvements reported in the ongoing European Phase 3 study, both Manhattan Pharmaceuticals and Thornton & Ross Limited believe there is significant potential for Altoderm and will continue development of this product candidate. Manhattan Pharmaceuticals is requesting a pre-IND meeting with the FDA and is finalizing a pre-IND package in anticipation of that meeting. The company also expects Altoderm clinical studies to be required in the U.S. with the first of these studies commencing as early as the second quarter 2008.

Hedrin™ for Head Lice - Hedrin is currently marketed as a device in Western Europe and as a pharmaceutical in the UK. In Europe Hedrin has achieved significant sales (in excess of $40 million) and market share (greater than or equal to 40%) in certain countries. Manhattan Pharmaceuticals is pursuing a Premarket Approval (PMA) application development pathway for Hedrin as a medical device, and is currently preparing to meet with the FDA's Center for Devices and Radiological Health in the first quarter of 2008. Pending the outcome of these regulatory discussions, the company expects to initiate clinical activities in 2008. Manhattan Pharmaceuticals expects to be required to complete at least one clinical trial with this product candidate.

Altolyn™ for Mastocytosis - Manhattan Pharmaceuticals is working with Thornton and Ross Limited and the current U.K. manufacturer of Altolyn to develop a GMP compliant manufacturing process. Pending finalization of this process the company will request a pre-IND meeting and prepare a pre-IND package. The company believes that Altolyn may be a candidate for an accelerated 505(b)2 regulatory pathway or orphan drug designation in the indication of mastocytosis. Early U.K. clinical experience also suggests that Altolyn may have potential for patients with food allergy and gastrointestinal functional disorders, and the company intends to pursue these as additional indications.

More about SCORAD
SCORAD is an evaluation tool developed by the European Task Force on Atopic Dermatitis to objectively assess the severity of the condition, and is used extensively in Europe and in the United Kingdom (UK).

Safe Harbor Statement
The statements made in this presentation that are not historical are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. In particular, we make forward-looking statements about future events and financial performance, including statements about the following:

- Ø Our product development efforts
- Ø Anticipated operating losses and capital
- Ø Anticipated regulatory filing dates and clinical trial initiation dates
- Ø Our estimates regarding our capital requirements and our needs for additional financing
- Ø Our estimates for future revenues and profitability
- Ø Our selection and licensing of product candidates
- Ø Our ability to attract partners and other collaborators with acceptable development, regulatory, commercialization expertise
- Ø The benefits to be derived from corporate collaborations, license agreements and other collaborative efforts, including those relating to the development and commercialization of our product candidates
- Ø Sources of revenues and anticipated revenues, including contributions from corporation collaborations, license agreements and other collaborative efforts for the development and commercialization of our product candidates, and the continued viability and duration of those agreements and efforts

A number of important factors could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements. Such factors include, but are not limited to, the following: our lack of significant revenues and profitability; our need for additional capital; the results of clinical trials of our product candidates; our ability to successfully commercialize our technologies; our ability to obtain various regulatory approvals; the illiquidity and volatility of our common stock, and the other "Risk Factors" identified in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006.

Item 9.01. Financial Statements and Exhibits

(d) *Exhibits.*

Exhibit No.	Description
99.1	Power Point Slides dated October 3, 2007

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MANHATTAN PHARMACEUTICALS, INC.

Date: October 3, 2007

By: /s/ Michael G. McGuinness

Michael G. McGuinness
Chief Financial Officer

EXHIBIT INDEX

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