MANNKIND CORP
Form 8-K
January 20, 2011

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): January 18, 2011

MannKind Corporation
(Exact name of registrant as specified in its charter)

Delaware	**000-50865**	**13-3607736**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

28903 North Avenue Paine Valencia, California	**91355**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(661) 775-5300**

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

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.

On January 18, 2011, we received a Complete Response letter from the U.S. Food & Drug Administration (the FDA) regarding the New Drug Application (the NDA) for AFREZZA® (insulin human [rDNA origin]) Inhalation Powder. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form.

The principal issue raised by the FDA concerned the usage of *in vitro* performance data and clinical pharmacology data to bridge our next-generation inhaler to the phase 3 trials conducted using our MedTone® inhaler. The FDA requested that we conduct two clinical trials with the next-generation inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one trial including a treatment group using the MedTone inhaler in order to obtain a head-to-head comparison of the data for the two devices. In the Complete Response letter, the FDA stated that after an adequate titration of study medication there should be at least twelve weeks of relatively stable insulin dosing at the end of the treatment period.

The FDA also requested additional information concerning the performance characteristics, usage, handling, shipment and storage of the next-generation device, an update of safety information related to AFREZZA as well as information on proposed user training and changes to the proposed labeling of the device, blister pack, foil wrap and cartons.

Prior to this regulatory action, we had begun a series of clinical trials of the next-generation inhaler in patients with type 1 and type 2 diabetes that are designed to focus on adequate titration of insulin dose and include at least twelve weeks of relatively stable dosing at the end of the treatment period. We plan to meet with the FDA as quickly as possible to be confident that these clinical trials, with appropriate modifications to incorporate a comparison to the MedTone inhaler, will suffice in addressing the FDA s relevant requests. There can be no assurance that we will be able to satisfy the FDA s requirements with these clinical trials. In light of these developments, we no longer expect that we will obtain approval of the NDA in time for a commercial launch of AFREZZA in 2011.

Forward Looking Statements

This Current Report contains forward-looking statements, including statements related to our clinical trials, future interactions with the FDA, our plans for the development and commercialization of AFREZZA and the regulatory status of AFREZZA, that involve risks and uncertainties. Words such as believes , anticipates , plans , expects , inte will , goal , potential and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon our current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, difficulties or delays in seeking or obtaining regulatory approval, our ability to manage our existing cash resources or raise additional cash resources, stock price volatility and other risks detailed in our filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2009 and periodic reports on Form 10-Q and Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Current Report. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation and expressly disclaim any duty to revise or update any forward-looking statements to reflect events or circumstances after the date of this Current Report.

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.

MANNKIND CORPORATION

By: /s/ David Thomson, Ph.D., J.D.
Name: David Thomson, Ph.D., J.D.
Title: Corporate Vice President, General Counsel and Secretary

Dated: January 20, 2011