

MANNKIND CORP
Form 8-K
February 10, 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): February 8, 2011

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

Delaware
(State or other jurisdiction of
incorporation or organization)

000-50865
(Commission File Number)

13-3607736
(IRS Employer
Identification No.)

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

91355
(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):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.02 Termination of a Material Definitive Agreement.

On November 16, 2007, we entered into a supply agreement (the "Supply Agreement") with N.V. Organon, now a subsidiary of Merck & Co., Inc. ("Organon"), pursuant to which Organon would manufacture and supply specified quantities of recombinant human insulin to us. Under the terms of the Supply Agreement, we may terminate the agreement upon 30 days' advance written notice to Organon if the U.S. Food & Drug Administration (the "FDA") fails to approve our insulin formulation, AFREZZA® (insulin human [rDNA origin]) Inhalation Powder. As previously reported by us, on January 18, 2011, we received a Complete Response letter from the FDA regarding the New Drug Application (the "NDA") for AFREZZA. In connection with this regulatory action, on February 8, 2011, we gave written notice to Organon to terminate the Supply Agreement, effective 30 days after such notice. Pursuant to the terms of the Supply Agreement, we will be required to pay Organon a termination fee if Organon is unable to sell certain quantities of insulin to other parties. While we cannot determine at this time the amount of the termination fee, if any, that we may have to pay to Organon, we estimate that the maximum amount of the termination fee is approximately \$22.7 million based on the current applicable exchange rate. A description of the terms and conditions of the Supply Agreement appears in our Current Report on Form 8-K filed on November 19, 2007 and is incorporated herein by reference.

Item 2.02 Results of Operations and Financial Condition.

On February 10, 2011, we issued a press release announcing our financial results for the quarter and year ended December 31, 2010. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 2.02 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On February 10, 2011, we announced that following receipt of the Complete Response letter from the FDA regarding the NDA for AFREZZA, we have implemented a restructuring to streamline our operations, reduce our operating expenses, extend our cash runway and focus our resources on securing the FDA's approval of the NDA for AFREZZA. In connection with the restructuring, we will reduce our total workforce by approximately 41 percent to 257 employees. The restructuring was approved by our Board of Directors on February 2, 2011, and affected employees were informed on February 10, 2011. We expect to complete the workforce reduction by mid-April of 2011. We estimate that we will record charges of approximately \$6.0 million for employee severance and other related termination benefits. Severance payments are expected to be paid in full by the end of the second quarter of 2011.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.* The following exhibit is furnished herewith:

- 99.1 Press release dated February 10, 2011, reporting our financial results for the quarter and year ended December 31, 2010.

Forward Looking Statements

This Current Report contains forward-looking statements, including statements related to the estimated maximum termination fee under the Supply Agreement, the benefits, including cost savings, and charges expected to result from the restructuring and the anticipated approval by the FDA of our NDA for AFREZZA, that involve risks and uncertainties. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar 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, the difficulty in estimating a termination fee based on the amount of future sales of insulin by Organon, the difficulty in forecasting actual costs and savings resulting from a restructuring, 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

Name: David Thomson, Ph.D., J.D.

Title: Corporate Vice President, General
Counsel and Secretary

Dated: February 10, 2011