

MANNKIND CORP
Form 8-K
April 02, 2014

**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) **April 1, 2014**

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

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 filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ 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))
-

Item 8.01. Other Events.

On April 1, 2014, we announced that the U.S. Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee (EMDA) voted 13 to 1 to recommend that AFREZZA® (insulin human [rDNA origin]) Inhalation Powder be granted marketing approval by the FDA to improve glycemic control in adults with type 1 diabetes and voted 14 to 0 to recommend that AFREZZA be granted marketing approval by the FDA to improve glycemic control in adults with type 2 diabetes.

Although the EMDA provides recommendations to the FDA, the FDA makes the final decision with respect to approval of a drug. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of April 15, 2014 for its review of our New Drug Application (NDA) for AFREZZA®.

A copy of the press release is attached as Exhibit 99.1 to this current report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits. The following exhibits are filed herewith:

99.1 Press Release of MannKind Corporation dated April 1, 2014, announcing FDA Advisory Committee's recommendation to approve MannKind's Investigational Drug to Treat Diabetes

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

(Registrant)

April 1, 2014

(Date)

/s/ DAVID THOMSON, PH.D., J.D.

David Thomson, Ph.D., J.D.

Corporate Vice President, General Counsel and Secretary