Edgar Filing: MANNKIND CORP - Form 8-K

MANNKIND CORP Form 8-K October 16, 2013

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 14, 2013

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

000-50865 (Commission

13-3607736 (IRS Employer

incorporation or organization)

File Number)

Identification No.)

Edgar Filing: MANNKIND CORP - Form 8-K

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):

- " 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))

Edgar Filing: MANNKIND CORP - Form 8-K

Item 8.01 Other Events.

On October 14, 2013, we announced the resubmission on October 13, 2013 of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of AFREZZA® (insulin human [rDNA origin]) Inhalation Powder with an indication to improve glycemic control in adults with type 1 or type 2 diabetes. The resubmission is based on the entire data set from the extensive AFREZZA clinical development program and particularly the positive results from two recent Phase 3 trials, one in patients with type 1 diabetes (study 171) and one in patients with type 2 diabetes (study 175).

On October 14, 2013 we issued a press release announcing the resubmission of the NDA to the FDA, a copy of which 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 October 14, 2013, reporting MannKind s resubmission of the NDA to the FDA seeking approval of AFREZZA.

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: October 14, 2013