MANNKIND CORP
Form 8-K/A
August 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 14, 2013

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):

¨ 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))

This Current Report on Form 8-K/A is being filed by MannKind Corporation, a Delaware corporation (the Company), solely to clarify certain information under Item 8.01 of the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2013 (the Original Report) and to re-file Exhibit 99.1 thereto. The Original Report and the press release filed as Exhibit 99.1 to the Original Report stated that the event rate of severe hypoglycemia in Study 171 was 8.05 events per subject-month in the AFREZZA-Gen2 group and 14.45 events per subject-month in the insulin aspart group. In clarification, the event rate of severe hypoglycemia in Study 171 was 8.05 events per 100 subject-months in the AFREZZA-Gen2 group and 14.45 events per 100 subject-months in the insulin aspart group.

On August 14, 2013 the Company issued a press release correcting and replacing the previously issued press release announcing the results of Study 171. A copy of the corrected press release is attached as Exhibit 99.1 to this current report.

In accordance with Rule 12b-15 of the Securities Exchange Act of 1934, as amended, the complete text of Item 8.01 (as amended) follows.

Item 8.01 Other Events.

On August 14, 2013, we announced positive preliminary results from our two recently-completed Phase 3 clinical studies of AFREZZA® (insulin human [rDNA origin]) Inhalation Powder. The two studies were conducted based upon our discussions with the U.S. Food and Drug Administration (FDA) following our receipt of a Complete Response letter in January 2011. In the Complete Response letter, the FDA requested that we conduct two clinical studies with our next generation (Gen2) inhaler (also known as Dreamboat); one in patients with type 1 diabetes and one in patients with type 2 diabetes, with at least one of the studies including a treatment group using our first generation inhaler (also known as MedTone) in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices.

Study 171

Study 171 was an open-label study involving 518 patients with type 1 diabetes on basal/bolus insulin therapy who were studied at sites in the United States, Russia, Ukraine and Brazil. After a four-week run-in period to optimize their basal insulin, patients entered a 24-week treatment period in which they were randomized in one of three ways:

Continuing on subcutaneous insulin aspart in combination with a basal insulin (170 patients);

Switching to AFREZZA administered using the Gen2 inhaler in combination with their basal insulin (174 patients); or

Switching to AFREZZA administered using the MedTone inhaler in combination with their basal insulin (174 patients).

The treatment period consisted of 12 weeks of prandial insulin optimization with continued basal titration followed by a 12-week period during which subjects maintained stable doses of insulin (prandial and basal). There was also a follow-up visit four weeks after completion of the treatment period.

Over the 24-week treatment period of this study, A1c levels decreased comparably in the AFREZZA-Gen2 group (-0.21%) and the insulin aspart group (-0.40%). The 95% confidence interval (0.02% to 0.36%) of the between-group difference did not exceed the predetermined threshold of 0.40%, thereby establishing non-inferiority between AFREZZA-Gen2 and insulin aspart, which was the primary endpoint of the study.

There was a significant difference in fasting blood glucose (FBG) levels in the AFREZZA-Gen2 group compared to the insulin aspart group in Study 171. In the AFREZZA-Gen2 group, mean FBG levels decreased by 25.3 mg/dL by the end of the treatment period whereas the insulin aspart group experienced an increase of 10.2 mg/dL in FBG levels over the same period ($p=0.0027$). After the four-week follow-up period, during which all patients received insulin aspart and a basal insulin, there was no longer any difference in FBG levels between the treatment groups, demonstrating that this effect on FBG levels was attributable to AFREZZA therapy.

Significantly less total hypoglycemia was observed in the AFREZZA-Gen2 group (9.80 events per subject-month) compared to the insulin aspart group (13.97 events per subject-month; $p<0.0001$). The event rate of severe hypoglycemia was also lower in the AFREZZA-Gen2 group (8.05 events per 100 subject-months) than in the insulin aspart group (14.45 events per 100 subject-months); however, this difference was not statistically significant ($p=0.1022$).

The proportion of subjects achieving A1c target levels £7.0% or £6.5% at the end of the 24-week treatment period was less in the AFREZZA-Gen2 group than in the insulin aspart group; however, among patients who achieved A1c levels £7.0% and £6.5% at the end of the 24-week treatment period, the event rates for overall hypoglycemia (mild, moderate and severe) were all significantly lower in the AFREZZA-Gen2 group than in the insulin aspart group.

There was also a significant difference in weight outcomes in Study 171. Patients in the AFREZZA-Gen2 group lost an average of 0.39 kg over the treatment period compared to an average gain of 0.93 kg in the insulin aspart group (p=0.0102).

The main safety objective of Study 171 was to compare changes in FEV1 (forced expiratory volume in one second) from randomization to week 24 between the AFREZZA-Gen2 and AFREZZA-MedTone groups. Over this period, there was an insignificant difference of 0.01 L in mean change in FEV1 between the two AFREZZA groups (p=0.5364). Over the same 24-week treatment period, the decrease in FEV1 seen in the AFREZZA-Gen2 group was slightly greater than that seen in the aspart group (0.03 L). After cessation of the treatment period, FEV1 values in both AFREZZA groups increased, so that by the follow-up visit at week 28 there were virtually no differences in FEV1 among the three treatment groups.

In general, treatment with AFREZZA was well-tolerated over 24 weeks by subjects with type 1 diabetes. The incidence of serious adverse events related to study drug was similar in the AFREZZA-Gen2 (2.3%), AFREZZA-MedTone (2.9%) and insulin aspart (1.8%) groups. There were no serious cardiovascular events reported in this study. The most common drug-related adverse event was cough, reported by 30.5% of AFREZZA-Gen2 patients, 20.8% of AFREZZA-MedTone patients and 0% of insulin aspart patients. Cough was predominantly dry, intermittent, and usually occurred within 10 minutes of inhalation. The incidence of cough was highest during the first week of the treatment period and diminished quickly thereafter. The discontinuation rate due to cough was low (AFREZZA-Gen2: 5.7%; AFREZZA-MedTone: 2.9%; insulin aspart: 0%).

On August 14, 2013 we issued a press release announcing the results of Study 171, a copy of which is attached as Exhibit 99.1 to this current report.

Study 175

Study 175 was a double-blind, placebo-controlled study involving 353 patients with type 2 diabetes whose disease was inadequately controlled on metformin with or without a second or third oral medication. Patients were studied at sites in the United States, Russia, Ukraine and Brazil. After a six-week run-in period during which all patients received dietary counseling and initiated blood glucose monitoring while continuing their oral medications, patients entered a 24-week treatment period in which they were randomized to one of two groups where, in addition to their oral medication, they received either:

AFREZZA Inhalation Powder, administered using the Gen2 inhaler (177 patients); or

Technosphere Inhalation Powder (placebo), administered using the Gen2 inhaler (176 patients).

The treatment period consisted of 12 weeks of prandial insulin titration followed by 12 weeks of relatively stable dosing. Subjects could not adjust or alter the doses of their oral medications during the study without discussion between the principal investigator and the medical monitor. There was also a safety follow-up visit four weeks after completion of the treatment period, during which all subjects returned to oral therapy only.

The primary endpoint of the study was the mean change in A1c levels from baseline to week 24 between the two groups. Over the 24-week treatment period, mean A1c levels decreased by 0.82% in the AFREZZA group compared to a decrease of 0.42% in the comparator oral-therapy group. The between-group difference in change in mean A1c levels was statistically significant (p<0.0001), thereby establishing the superiority of AFREZZA over the comparator oral-therapy treatment.

A significantly greater percentage of patients in the AFREZZA group reached specified A1c target levels than in the comparator oral-therapy group. After 24 weeks of treatment, 37.7% of patients in the AFREZZA group achieved A1c levels below 7.0% compared to only 19.0% of patients in the comparator oral-therapy group (p=0.0005), and 15.9% of patients in the AFREZZA group achieved A1c levels below 6.5% compared to only 4.2% of the patients receiving only oral therapy (p=0.0021).

During the treatment period, postprandial glucose excursions were reduced in the AFREZZA group compared to those in the comparator oral-therapy group. By week 24, mean blood glucose levels did not exceed 170.2 mg/dL postprandially in the AFREZZA group whereas mean blood glucose levels reached as high as 194.7 mg/dL postprandially in the comparator oral-therapy group.

Over the treatment period, mean fasting blood glucose levels decreased moderately in the AFREZZA group by 11.2 mg/dL compared to a decrease of 3.8 mg/dL in the comparator oral-therapy group. This difference was not statistically significant (p=0.1698).

Patients in the AFREZZA group gained an average of 0.49 kg over the treatment period compared to an average loss of 1.13 kg by patients in the comparator oral-therapy group (p<0.0001).

As expected, the incidence of mild and moderate hypoglycemia was higher in the AFREZZA group (67.2% of patients) compared to the comparator oral-therapy group (30.1% of patients; p<0.0001). However, there was not a significant difference in the incidence of severe hypoglycemia, which was reported in nine (5.1%) AFREZZA patients compared to three (1.7%) oral-therapy patients (p=0.0943).

In general, treatment with AFREZZA was well-tolerated over 24 weeks by subjects with type 2 diabetes. The incidence of serious adverse events was lower in the AFREZZA group (2.8%) compared to the comparator oral-therapy group (5.1%). The incidence of serious cardiovascular events was low overall and balanced between the groups (AFREZZA: 2 events; oral therapy: 3 events). Similarly, the incidence of adverse events resulting in discontinuation was low overall and balanced between the treatment groups (AFREZZA: 4.0%; oral therapy: 5.1%). The most common adverse event was cough, occurring with comparable incidence in both the AFREZZA (23.7%) group and the oral therapy (19.9%) group (who were also taking a placebo powder). Cough was predominantly dry, intermittent, and usually occurred within 10 minutes of inhalation. The incidence of cough in both treatment groups was highest during the first week of the treatment period and diminished thereafter.

On August 14, 2013 we issued a press release announcing the results of Study 175, a copy of which is attached as Exhibit 99.2 to this current report.

The results of both Study 171 and Study 175 contained in this current report are preliminary and subject to additional analysis.

We anticipate that the results of Study 171 and Study 175 will form the basis of an amendment to our new drug application for AFREZZA, which we expect to submit to the FDA early in the fourth quarter of 2013.

Item 9.01 Financial Statements and Exhibits.

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

99.1 Press Release of MannKind Corporation dated August 14, 2013, reporting MannKind s results from a Phase 3 clinical study of AFREZZA in patients with type 1 diabetes (as corrected).

99.2 Press Release of MannKind Corporation dated August 14, 2013, reporting MannKind s results from a Phase 3 clinical study of AFREZZA in patients with type 2 diabetes (incorporated by reference to MannKind s current report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2013).

Forward-Looking Statements

This current report contains forward-looking statements, including statements related to the results of clinical studies and our expected preparation and timing of regulatory submissions, that involve risks and uncertainties. Words such as believes , anticipates , plans , expects , intend , 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 obtaining regulatory feedback or completing and analyzing the results of clinical studies, completion of further statistical analysis of the results of Study 171 and Study 175, whether the data from Study 171 and Study 175 will satisfy all requirements of the FDA and will be sufficient to support approval of an amended new drug application for AFREZZA, the timing of regulatory review and decisions, 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, 2012, periodic reports on Form 10-Q and current reports on 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 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: August 14, 2013