# 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): August 26, 2013**

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

| **Delaware** | **000-50865** | **13-3607736** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(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 filing 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))

**Item 7.01 Regulation FD Disclosure.**

On August 26, 2013, MannKind Corporation posted Frequently Asked Questions about the Affinity 1 and Affinity 2 Trials on its corporate website www.mannkindcorp.com.

The information in this Current Report 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 Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

**Item 9.01 Financial Statements and Exhibits**

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

99.1 Frequently Asked Questions about the Affinity 1 and Affinity 2 Trials.

**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 26, 2013

**Frequently Asked Questions about the**
**Affinity 1 and Affinity 2 Trials[i]**
**(August 26, 2013)**

**1. Will the results of these trials be enough to satisfy the FDA based on their most recent Complete Response Letter?**

The recently completed Affinity trials were designed specifically to address the issues raised by the FDA in their complete response letters. In designing the Affinity trials we had multiple meetings with the agency to get their input and clarification on the protocols and endpoints of the trials. Based on those interactions and the trial results we believe that these studies have indeed met their primary endpoints and that the results will support approval of the product. However, we cannot at this time provide absolute assurance regarding the outcome of the FDA review and whether the agency will agree that the forthcoming NDA submission will be adequate for approval. There can never be certainty that the FDA would not still request that we conduct additional clinical studies. Although it is not relevant for purposes of predicting FDA action, Deerfield evaluated the two Affinity trials, including through an independent regulatory consultant with access to all the key data, and determined that the results met the primary efficacy endpoints and did not show any adverse safety issue that would reasonably be expected to prevent approval of AFREZZA®. Such validation was required for Deerfield to provide the second $40 million tranche of the $160 million financing.

**2. There have been reports circulating that you withheld data from the Affinity 1 trial, specifically surrounding efficacy of the MedTone inhaler. At least one purported analyst found this "suspicious" and even "unprecedented". Can you comment?**

Efficacy of the MedTone inhaler was never an endpoint of that study. MedTone was included in the Affinity 1 trial at the FDA's request in order to perform a head-to-head comparison of the pulmonary safety data for MedTone compared to the Gen2 device. Comparable pulmonary safety results would allow us to bridge the Gen2 device to the extensive safety data that we collected in our earlier clinical studies using the MedTone inhaler. As we reported in the conference call, the Gen2 and the MedTone groups in the Affinity 1 studies demonstrated a similar safety profile, thereby meeting this important secondary endpoint of the study.

It would be highly unusual to include data of a regulatory trial that is not a defined key component of a study in "top line" results, which by definition only focus on important elements. That was why we did not publish the efficacy data for the MedTone group. Even so, when asked about those results during the conference call, we replied that the performance of the MedTone and the Gen2 devices were comparable and we do not see any appreciable difference between the two. In fact, the actual difference in mean HbA1c between the two inhaler groups was only 0.08%, which was not significant. This measure for both inhaler groups was non-inferior to that for the injected insulin control arm. This was not surprising, given that we had previously shown that the two inhalers were bioequivalent. It is disheartening that anyone who holds themselves out to be an analyst would use subjective and alarmist language with respect to such a minor result, or if they were confused, would not at least contact us and ask about it before publishing misinformation of this kind.

**3. In the past, you have consistently shown a hypoglycemia advantage with Afrezza, yet you did not show an advantage in severe hypoglycemia in Affinity 1. Why do you think this is?**

In fact, the data showed a hypoglycemia advantage in every measure of hypoglycemia in the Affinity 1 trial. In 3 of the 4 included measures, this advantage was large and statistically significant. Importantly, we also showed an advantage in severe hypoglycemia, where we had 8.05 incidents per hundred subject-months in the Afrezza arm versus 14.45 incidents per hundred subject-months in the control arm. However, there were not sufficient incidents in this trial for the difference in this particular measure to reach statistical significance; to do so would have required a larger number of severe hypo events. We think the advantages we have shown in every measure of hypoglycemia in this and previous trials of insulin-dependent patients is a very important advantage of Afrezza.

**4. Likewise, in the past you have consistently shown a weight advantage with Afrezza, which you did again in Affinity 1, but in Affinity 2 there was a disadvantage. Why do you think this is?**

First, it should be noted that the average amount of weight gained by Afrezza users in the Affinity 2 trial was small (only about 1 pound), particularly relative to their average starting weight (about 198 pounds). Even though the weight gain in the Afrezza arm was very small, because the average weight in the control arm continued down, the absolute difference was larger, reaching statistical significance.

One of the challenges of doing a trial in early-stage type 2 diabetics is that their HbA1c levels can be influenced by a range of extraneous factors, particularly changes in lifestyle. In the Affinity 2 study, all the participants were given extensive training in how best to manage their diabetes, including counseling on nutrition, diet, exercise, and so forth. As a consequence, participants' HbA1c levels were declining throughout the run-in period, even before Afrezza was introduced. We also gave patients blood glucose monitors and required that they check their blood sugar levels several times per day and record the data in an electronic diary. We know from prior experience that with close monitoring patients tend to alter their behavior and behave more as they "should". The result of this can be seen in the Affinity 2 trial where both HbA1c levels and weight continued to drop in the control group following randomization. We know the placebo could not influence either of these measures, so it was the change in lifestyle that almost certainly led to those improvements. The Afrezza arm was also exposed to this training but there was one key difference. If a patient in the control arm were to decide to "cheat" a bit and have a carb laden meal, it would likely show up immediately in the blood sugar. It is hoped that seeing this would discourage patients from such practices in the future. By contrast, in the Afrezza arm a dose of insulin taken with the meal would much more likely keep the blood sugar excursions in check, allowing the patient to "get away" with such practices, or at least keep the effects from being so alarming. One could speculate as to what effect this potential feedback might have on weight over the course of the study.

**5. I am puzzled about the outcome of the Affinity 2 trial. I thought I remembered you saying earlier that you needed a 0.5% change in HbA1c to show superiority, yet you only showed 0.4%. Was the trial successful?**

Yes. The study met its primary endpoint of superiority at a highly significant level, with a P value of <0.0001. Demonstrating superiority is what was required in the study and that is what we showed. The FDA did not specify a particular margin that would be needed to show superiority. Instead, the success of such a trial is generally governed by the statistics.

Biostatisticians design studies around assumed levels of variability and needed confidence intervals to assess how large the study must be. To do this, they come up with powering assumptions designed to show a particular level of change with an assumed confidence interval. In our case, the Affinity 2 study was originally designed to show a 0.5% reduction with a one-sided alpha of 0.025%, with a high degree of confidence. The actual difference turned out to be 0.4%, with a remarkable P value of 0.0001, demonstrating extreme significance. It is clear that in Affinity 2 we demonstrated the superiority of Afrezza in an unequivocal fashion.

**6. I noticed that once again in your Affinity 1 trial you showed a significant improvement in fasting blood glucose levels. First, do you know why that is? And second, with that level of improvement, how is it that you did not show better HbA1c levels in the Afrezza arm, but only showed non-inferiority? Doesn't that mean you did a poorer job controlling glucose excursions at mealtime?**

First, we must admit that we are not certain as to what causes that lowering of fasting blood glucose that we have seen in such studies of Afrezza. Some experts have postulated that it is related to a reduction in insulin resistance or perhaps from reducing the level of pancreatic stress. It would be difficult to confirm what causes this effect on fasting glucose and we have not yet attempted to do so, although we have seen it consistently in all our earlier trials in type 1 and late type 2 diabetes.

In analyzing HbA1c results, it is important to remember that HbA1c is essentially a proxy for average blood glucose levels. Fasting levels can affect this, but so can many other things. As an example, frequent plunges in blood glucose levels, including those resulting in hypoglycemia, from any excess insulin remaining in the bloodstream following meal digestion, can have a dramatic effect on HbA1c. It would be hard to argue that this late plunge of glucose is a good thing, yet it does lower HbA1c levels. As such, HbA1c is an imperfect measure of the beneficial effect of a prandial insulin. However, this is the accepted measure of efficacy used today by the FDA.

As has been consistently shown in earlier trials we have shown in both these Affinity studies that Afrezza reduces both the prandial rise in blood sugar following a meal and also reduces the frequency and degree of hypoglycemia, smoothing out the curves, so to speak. But this does not necessarily result in better HbA1c results, which is why the Affinity 1 trial was designed to be a non-inferiority trial, not a superiority trial. Our primary objective with Affinity 1 was to produce data that would support approval of this product and get it on the market. We expect that in real like use the inherent advantages of Afrezza over other prandial insulins and also non-insulin anti-glycemic agents will quickly become apparent, making it a commercial success.

**7. I have been reading accounts on the message boards of the experiences of someone who claims to have been a participant in the Affinity 1 study. Is this guy for real? Don't your patients have to sign some form of confidentiality agreement?**

There have been considerable postings on the message boards, both touting the benefits of Afrezza and also panning this product and MannKind. We are aware of a number of actual patients who have indeed participated in our trials that have posted on the message boards — to our knowledge all very positive. The particular posting on August 16 was certainly by a patient in the Affinity 1 study. Patient confidentiality rules under the HIPAA rules generally prevent us from knowing the identity of patients in the trials. However, this particular patient and his doctor had contacted us seeking continuation of Afrezza therapy after the patient's trial participation was completed. We eventually learned from him that he had been posting messages of praise on the boards. Even had that not occurred, some of the posts demonstrated a degree of knowledge

about the mechanics of the trial from a patient's perspective and that convinced us he was genuine. His experience was real and was good. But there is nothing preventing someone from claiming to have been a patient and reporting good or bad experiences that may even be completely false. While we are sure many people who post on these boards are honest and sincere, we are equally certain that there are many who are neither, but who are only trying to advance some self-serving agenda.

Patients in the clinical trials are not required to remain silent and they do not sign confidentiality agreements on the theory that there is little that can be learned from the experiences of one patient. Only the clinicians are required to sign such agreements since they may have many patients in a trial and would be better able to predict that trial's success. Therefore the clinician must keep that knowledge confidential (even from MannKind, the sponsor, at least until the study is unblinded.)

**8. I noticed in SEC filings the week of August 19 that most of your key officers had sold some of their stock, at what seems like a very low price. Have they lost faith in the company or its prospects based on the results of these trials?**

The Form 4 filings with the SEC were not reporting sales of stock. There were no shares sold by any officers into the market during that week. What happened was that in recognition of their performance, the Board of Directors had granted all of our officers restricted stock, some of which vested that week. When this happens, it is considered compensation by the IRS, which requires the company to withhold taxes based on the market value of the stock on the date of vesting. But because no cash is being paid out, the company instead simply withholds some shares to "pay" the tax, which is then paid by the company. The surrender of those shares was what was being reported on the Form 4's. This can be seen in a footnote at the bottom of the Form 4. If you check, you will see similar filings at around this same time last year and years prior, for the same reason.

**Forward-Looking Statements**

This document contains forward-looking statements, including statements related to the results of clinical studies, 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 the company's 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 these studies, whether the data from these two studies will satisfy all requirements of the FDA and will be sufficient to support approval of the amended new drug application for AFREZZA, and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2012 and periodic reports on Form 10-Q and Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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[i] Includes Affinity 1 (also known as Study 171) and Affinity 2 (also known as Study 175), two Phase 3 clinical studies of AFREZZA® (insulin human [rDNA origin]) Inhalation Powder, an investigational, ultra rapid-acting mealtime insulin therapy administered using MannKind's next-generation (Gen2) inhaler (also known as the Dreamboat™ inhaler). Further information about these trials is included in MannKind's press releases and reports filed with the Securities and Exchange Commission.