

MANNKIND CORP
Form 8-K
October 17, 2012

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 17, 2012

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.)

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28903 North Avenue Paine

Valencia, California
(Address of principal executive offices)

Registrant's telephone number, including area code: (661) 775-5300

91355
(Zip Code)

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))

Item 2.02 Results of Operations and Financial Condition.

Our cash, cash equivalents and marketable securities were approximately \$2.1 million as of September 30, 2012. This financial result is preliminary, unaudited and subject to completion and may differ from what will be reflected in our condensed consolidated financial statements as of September 30, 2012.

As of September 30, 2012, the principal amount outstanding under our existing revolving loan arrangement provided by The Mann Group LLC, an entity controlled by our chief executive officer and principal stockholder, was \$223.1 million, and we had \$21.9 million of available borrowings under the arrangement. On October 5, 2012, we borrowed an additional \$1.5 million under this arrangement.

Item 7.01 Regulation FD Disclosure.

In connection with our recently announced proposed public offering of common stock and warrants to purchase common stock and proposed concurrent private placement to The Mann Group, we anticipate amending our revolving loan arrangement with The Mann Group to, among other things, extend the maturity date of the loan to January 1, 2014, extend the date through which we may borrow under the loan arrangement to September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one year London Interbank Offered Rate (LIBOR) on December 31, 2012 plus 5%, effective beginning on January 1, 2013.

Item 8.01 Other Events.

We are filing the following with the Securities and Exchange Commission for the purpose of updating certain aspects of our publicly disclosed description of our business.

Company Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead product candidate, AFREZZA (insulin human [rDNA origin]) inhalation powder, is an ultra rapid-acting insulin that is in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. Diabetes is a significant health concern. According to the Centers for Disease Control and Prevention, in the United States in 2011, approximately 25.8 million people had diabetes and if current trends continue, one in three adults in the United States are expected to have diabetes by 2050. The International Diabetes Federation has estimated that as of September 2011, approximately 366 million people had diabetes; by 2030 this number is expected to have risen to approximately 552 million people.

In March 2009, we submitted a new drug application, or NDA, for AFREZZA in which we sought approval of the product using our first-generation inhaler, known as MedTone. In March 2010, we received a Complete Response letter from the U.S. Food and Drug Administration, or FDA, that requested information and currently available clinical data to support the clinical utility of AFREZZA as well as information about the comparability of the commercial version of the MedTone inhaler to the earlier version of this device that was used in pivotal clinical trials. After meeting with the FDA in June 2010, we determined that the best way to address the agency's inhaler-related questions was to submit information regarding the bioequivalence of the MedTone inhaler and our next-generation inhaler, known as Dreamboat, which by that time had become our preferred device from a clinical and commercial perspective, given that it is smaller, easier to use and lower in cost than the MedTone inhaler. In June 2010, we submitted to the FDA the available bioequivalency data for the two devices along with additional evidence of efficacy of AFREZZA as part of our response to the 2010 Complete Response letter.

In January 2011, we received a second Complete Response letter in which the FDA requested that we conduct two clinical studies with the Dreamboat inhaler (one in patients with type 1 diabetes and one in patients with type 2 diabetes), with at least one trial including a treatment group using the MedTone inhaler in order to obtain a head-to-head comparison of the pulmonary safety data for the two devices.

The study in patients with type 1 diabetes, known as study 171, is an open-label study in which all patients are first optimized on their basal insulin regimen before being randomized to one of three arms: a control arm, in which patients utilize an injected insulin analog at mealtimes, or one of two AFREZZA arms, one each for our MedTone inhaler and our Dreamboat inhaler. After the mealtime insulin is titrated, there will be a 12-week observation period on relatively stable doses of the mealtime insulin to assess A1c levels. The primary endpoint is to show non-inferiority of the change in A1c levels in the Dreamboat group compared to the injected insulin analog group. The inclusion of two AFREZZA arms will permit us to perform a head-to-head comparison of the pulmonary safety data for the two devices, which we anticipate will provide a bridge to the extensive safety data that we collected in our earlier clinical studies of the MedTone inhaler.

The other requested study, known as study 175, is a placebo-controlled study in patients with type 2 diabetes who are inadequately controlled on metformin with or without a second or third oral medication. Patients are assigned to treatment with AFREZZA or placebo powder in a randomized fashion. There is a titration period followed by a 12-week observation period to assess A1c levels. The primary objective of this

study is to show superiority of the AFREZZA group over the placebo group in lowering A1c levels.

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We are conducting these studies at sites in the United States, Eastern Europe and South America. We finished recruiting patients into study 171 in late September 2012 and finished recruiting patients into study 175 in early October 2012, putting these studies on a schedule to be completed in the second quarter of 2013. Upon completion, we would expect to submit the results to the FDA as an amendment to our NDA during the third quarter of 2013. However, the data collected from these clinical trials may not reach statistical significance or otherwise be sufficient to support an amendment to our NDA, or FDA approval. Moreover, there can be no assurance that we will satisfy all of the FDA's requirements with these two clinical studies or that the FDA will ultimately find our proposed approach to these clinical studies acceptable. The FDA could also request that we conduct additional clinical studies beyond the currently planned studies in order to provide sufficient data for approval of AFREZZA.

AFREZZA utilizes our proprietary Technosphere formulation technology, which is based on a class of organic molecules that are designed to self-assemble into small particles onto which drug molecules can be loaded. With AFREZZA, we load recombinant human insulin onto the Technosphere particles; however, this technology is not limited to insulin delivery. We believe it represents a versatile drug delivery platform that may allow pulmonary administration of certain drugs that currently require administration by injection. Beyond convenience, we believe the key advantage of drugs inhaled as Technosphere formulations is that they have been shown to be absorbed very rapidly into the arterial circulation, essentially mimicking intra-arterial administration. Currently, we are actively working with several parties to assess the feasibility of formulating different active ingredients on Technosphere particles.

Forward-Looking Statements

This current report contains forward-looking statements, including statements related to our proposed financing activities and proposed amendment to our revolving loan arrangement with The Mann Group, involve risks and uncertainties. Words such as believe, anticipate, plan, expect, 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, risks associated with market conditions and the satisfaction of closing conditions related to our proposed public offering and/or concurrent private placement to The Mann Group, whether our proposed public offering and/or concurrent private placement to The Mann Group occurs, developments arising from future discussions with The Mann Group relating to our revolving loan arrangement, the progress, timing and results of clinical trials, difficulties or delays in seeking or obtaining regulatory approval, the manufacture of AFREZZA, competition from other pharmaceutical or biotechnology companies, our ability to enter into any collaborations or strategic partnerships, intellectual property matters, stock price volatility and other risks detailed in our filings with the SEC, including our quarterly report on Form 10-Q for the quarter ended June 30, 2012. 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 Company 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: October 17, 2012