MANNKIND CORP
Form 8-K
January 31, 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): January 31, 2012

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))

Item 2.02 Results of Operations and Financial Condition.

Our cash, cash equivalents and marketable securities were approximately $3.2 million as of December 31, 2011. This financial result is preliminary, unaudited and subject to completion and may differ from what will be reflected in our audited condensed consolidated financial statements as of and for the year ended December 31, 2011.

As of December 31, 2011, 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 $277.2 million, and we had $45.0 million of available borrowings under the arrangement.

Item 7.01 Regulation FD Disclosure.

We are conducting a private offering under Rule 144A of the Securities Act of 1933, as amended, of up to $161 million of Convertible Senior Secured Notes due 2019, or the Secured Notes. The Secured Notes will be secured by a first priority lien on substantially all of our assets, excluding our insulin inventory supply and subject to other customary exclusions, and are anticipated to accrue interest at the rate of 7% per annum, payable biannually in arrears. The Secured Notes will mature in seven years from the date of issuance, but investors are expected to have a right to put the Secured Notes to the Company on February 15, 2015 at a price equal to 100% of the principal amount. The Secured Notes are anticipated to be convertible into shares of our common stock at an initial conversion price of $3.00 per share, subject to customary adjustments and full-ratchet anti-dilution protection for any issuances, other than certain excluded issuances, of (i) common stock at a price less than the conversion price of the notes or (ii) securities convertible into or exercisable for common stock having a conversion or exercise price less than the conversion price of the notes. We intend to use the net proceeds from the offering of the Secured Notes (1) to repay or repurchase certain of our outstanding Senior Convertible Notes due 2013 in privately negotiated transactions, and (2) for general corporate purposes, including research and development expenses, capital expenditures, working capital and general administrative expenses.

Item 8.01 Other Events.

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

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 approximately 366 million people have diabetes today; by 2030 this is expected to have risen to approximately 552 million**.**

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. Over the next eight months, we participated in a number of written and verbal exchanges with the FDA in order to clarify the agency s requirements for approval of AFREZZA, culminating in an in-person meeting in August 2011 in which we confirmed with the FDA the designs of the two requested studies.

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 device and our Dreamboat device. 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 basic design of this study (comparing different mealtime insulins in combination with a basal insulin regimen) is similar in design to a previous Phase 3 study that we conducted in patients with type 1 diabetes using our 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. We have previously compared AFREZZA to placebo powder in successful Phase 2 studies involving patients with type 2 diabetes using the MedTone inhaler.

Both studies are currently enrolling subjects. If enrollment continues at current levels, we expect to complete both of these studies by or near the end of 2012. We then would expect to submit the results to the FDA as an amendment to our NDA during the first half 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 be able to 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.

In addition to our Technosphere platform, we have evaluated an investigational cancer immunotherapy product, MKC1106-MT, in a Phase 2 clinical trial. We have also conducted preclinical studies of a drug candidate, MKC204, that may have the potential to treat certain malignancies and inflammatory diseases. Due to resource constraints, we have halted most of our internal development activities in our non-AFREZZA programs.

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. To date we have not reached an agreement regarding a collaboration with any of these companies. Although we have stated an objective to complete a partnership by mid-2012, there can be no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms, if at all.

Our Technosphere drug formulation technology, including AFREZZA, enjoys patent protection relating to the particles, their manufacture, and their use for pulmonary delivery of drugs. As of January [15], 2012, AFREZZA was protected by 312 issued patents, and we had over 300 pending applications in the United States and selected jurisdictions around the world.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2011, we have incurred a cumulative net loss of $1.9 billion and an accumulated stockholders deficit of $280.8 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities, convertible debt securities and borrowings under our related party loan. If we are unable to obtain additional funding in the future, there will be substantial doubt about our ability to continue as a going concern.

We do not expect to record sales of any product prior to regulatory approval and commercialization of AFREZZA. We currently do not have the required approvals to market any of our product candidates, and we may not receive such approvals. We may not be profitable even if we succeed in commercializing any of our product candidates. We expect to make substantial expenditures and to incur additional operating losses for at least the next several years as we:

- continue the clinical development of AFREZZA and new inhalation systems for the treatment of diabetes;
- seek regulatory approval to sell AFREZZA in the United States and other markets;
- seek development and commercialization collaborations for AFREZZA; and
- develop additional applications of our proprietary Technosphere formulation technology for the pulmonary delivery of other drugs.

Our business is subject to significant risks, including but not limited to the risks inherent in our ongoing clinical trials and the regulatory approval process, our potential inability to enter into sales and marketing collaborations or to commercialize AFREZZA in a timely manner, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

Legal Proceedings

On December 13, 2011, we announced that we reached a final resolution of the arbitration proceedings initiated by John Arditi, our former Senior Director GCP Regulatory Affairs. In connection with the resolution of the matter, Mr. Arditi withdrew his wrongful discharge and related claims against us. In return, we withdrew our claims against Mr. Arditi. Neither party paid any monetary consideration to the other party in connection with the resolution of the arbitration proceedings.

Beginning January 31, 2011, several complaints were filed in the U.S. District Court for the Central District of California against us and four of our officers Alfred E. Mann, Hakan S. Edstrom, Dr. Peter C. Richardson and Matthew J. Pfeffer on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and have been brought as purported shareholder class actions. In general, the complaints allege that the defendants violated federal securities laws by making materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking unspecified monetary damages and other relief. The complaints have been transferred to a single court and consolidated for all purposes. The court appointed a lead plaintiff and lead counsel and a consolidated complaint was filed on June 27, 2011. On August 12, 2011, we filed a motion to dismiss the complaint and a motion to strike the expert report attached to that complaint. On December 16, 2011, the Court denied both motions. We expect discovery to commence shortly, and will vigorously defend against the claims advanced.

In February 2011, shareholder derivative complaints were filed in the Superior Court of California for the County of Los Angeles and in the U.S. District Court for the Central District of California against all of our directors and certain of our officers. The complaints in the shareholder derivative actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that the defendants caused or allowed for the dissemination of materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock.The plaintiffs are seeking unspecified monetary damages and other relief, including reforms to our corporate governance and internal procedures. The Superior Court of California for the County of Los Angeles has consolidated the actions pending before it and the parties have stipulated to stay the litigation. Likewise, the U.S. District Court for the Central District of California has consolidated the actions pending before it. The U.S. District Court for the Central District of California has also appointed lead plaintiffs and lead counsel and a consolidated complaint was filed on August 12, 2011. We filed a motion to dismiss this complaint on September 26, 2011 and the parties subsequently stipulated to stay the litigation. That stay has expired, and the parties are now negotiating a briefing and hearing schedule on defendants motion to dismiss the consolidated derivative complaint. We will vigorously defend against the claims advanced.

Risk Factors

We will be required to raise additional capital to fund our operations, and our inability to do so could raise doubt about our ability to continue as a going concern.

Based upon our current expectations, we believe that our existing capital resources, including the available borrowings under our loan arrangement with The Mann Group, as amended on January 16, 2012, as well as the anticipated net proceeds of our proposed public offering of common stock, will enable us to continue planned operations into the third quarter of 2012. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. In any event, we plan to raise additional funds, whether through the sale of equity or debt securities (including our proposed private placement to The Mann Group and proposed private note offering and related exchange transactions), the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, or an increase in the borrowings available under the loan arrangement with our related party, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. However, it may be difficult for us to raise additional funds through these planned measures. As of September 30, 2011, we had a stockholders deficit of $280.8 million which may raise concerns about our solvency and affect our ability to raise additional capital. The amount of additional funds we need will depend on a number of factors, including:

- rate of progress and costs of our clinical trials and research and development activities, including costs of procuring clinical materials and operating our manufacturing facilities;
- our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions we are able to establish;
- actions taken by the FDA and other regulatory authorities affecting our products and competitive products;
- our degree of success in commercializing AFREZZA, assuming receipt of required regulatory approvals;
- the emergence of competing technologies and products and other adverse market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal expenses, including those expenses associated with the securities class actions and derivative lawsuits filed against us and certain of our executive officers and directors and any settlement or damages payments associated with litigation;
- the costs of discontinuing projects and technologies; and
- the costs of decommissioning existing facilities, if we undertake such activities.

We have raised capital in the past primarily through the sale of equity and debt securities. We may in the future pursue the sale of additional equity and/or debt securities (including our proposed financing transactions described above), or the establishment of other funding facilities. There can be no assurances, however, that we will be able to raise additional capital on acceptable terms, or at all. Issuances of additional debt or equity securities or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock could impact the rights of the holders of our common stock and may dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer

assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably.

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets and confidentiality agreements. We own a number of domestic and international patents, have a number of domestic and international patent applications pending and have licenses to additional patents. We cannot assure you that our patents and licenses will successfully preclude others from using our technologies, and we could incur substantial costs in seeking enforcement of our proprietary rights against infringement. Even if issued, the patents may not give us an advantage over competitors with alternative technologies. Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, although some patents providing protection for our AFREZZA inhalation powder expire in 2012, other patents providing similar protection will remain in force into 2020. In addition, patents providing protection for our inhaler and cartridges will remain in force into 2023, and we have been allowed method of treatment claims that can be maintained in force into 2029. As and when these different patents expire, AFREZZA could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations in the United States. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

Because we will not be able to generate operating cash flow unless and until AFREZZA is commercialized, which we expect will require us to reach an agreement with a commercialization partner, we cannot provide assurances that changed or unexpected circumstances, including, among other things, delays in obtaining regulatory approval and in identifying and reaching agreements with a commercialization partner, will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we may be required to raise additional capital in advance of our current expectations. There can be no assurances that we will be able to raise additional capital on acceptable terms, or at all. If planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financings or entering into a strategic business collaboration with a pharmaceutical or biotechnology company, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will be substantial doubt about our ability to make payment on outstanding debt or even continue as a going concern.

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, Ph.D., J.D.
Name: David Thomson, Ph.D., J.D.
Title: Corporate Vice President, General Counsel and Secretary

Dated: January 31, 2012