



**MANKIND CORPORATION (NASDAQGM: MNKD)**

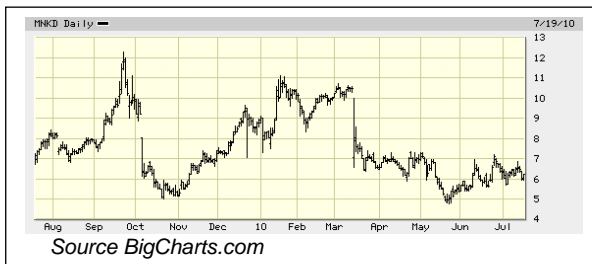
- FDA accepts amended NDA for Afrezza™ and sets PDUFA date of December 29<sup>th</sup>.
- Securing a global marketing partner is now a high priority.
- Receipt of the first commercial production line is expected in early August.
- Clinical trials are planned to support the marketing program.
- We reiterate our BUY recommendation and our target price of \$26 per share.

**Mannkind Corporation (NasdaqGM: MNKD)**

announced that the FDA has accepted its amended New Drug Application for its inhalable insulin Afrezza™ and set a PDUFA date of December 29<sup>th</sup>. The announcement is ironic for on this date in 1969 astronaut Neil Armstrong stated his immortal words, "That's one small step for man, one giant leap for mankind." Today's development is important, because it means the agency has accepted the bioequivalence data on the Dreamboat inhaler and that it is willing to review the latest clinical information. (This data must still be reviewed by the FDA.) Moreover, the PDUFA date set by the agency means that the amended NDA will not be treated as an entirely new submission, with a 10-month review process. Instead, the application will be treated as part of the original review, with a 6-month target date for a final decision.

Partnering is moving to a "high priority" status. Minutes of the Company's meeting with the FDA over the complete response letter received in March should provide potential partners with a good assessment of the agency's concerns and how well Mannkind has addressed them. In sum, the minutes and today's developments reduce the risks for potential partners. Note that as of last week, when we met with corporate executives, the minutes were expected to arrive imminently.

Share Price (7/19/10)	\$6.21
52-Week Price Low / High	\$4.26 - \$12.30
Mkt. Capitalization (issued)	\$704.6 million
Shares Outstanding (issued)	113.5 million
12-month Target Price	\$26.00
Website	<a href="http://www.mannkindcorp.com">www.mannkindcorp.com</a>



Meanwhile, Mannkind is preparing for Afrezza's commercial launch. A high-speed production line is scheduled to arrive in early August, and clinical trials are planned to provide extra documentation of the drug's therapeutic efficacy and its competitive advantages.

Overall, the favorable regulatory developments and prelaunch preparations put Afrezza's commercialization on schedule for the first half of 2011. Only a global partner and a possible financing are needed to complete the picture. We are maintaining our BUY recommendation and our \$26-a-share price target.

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## THE FDA DELIVERS GOOD NEWS

Since Mannkind filed its NDA with the agency on March 16, 2009, there has been speculation over how regulators would respond, with some individuals feeling the petition would be rejected and others believing strongly in the Company's work. The review did not go quite as smoothly as it might have. But that's partly because Mannkind chose to file the application with a device that it never intended to commercialize. Instead, the device was a position holder for the Dreamboat, a model that more efficiently delivers insulin into the lungs than the device used during the clinical trials. The Dreamboat is also less expensive to manufacture and it is simpler to use. But to include this device in the NDA and receive FDA approval as quickly as possible, the Company had to file the petition with the placeholder and then substitute the Dreamboat via an amendment, which is what happened, or to submit the Dreamboat separately if the original NDA had been approved.

The agency's acceptance of the amended NDA places the review on track for a late 2010 approval and Afrezza's launch in 2011 – on track with Mannkind's original schedule. This does not guarantee approval, since it must go through the review process. But it means that the Company's filing strategy has worked well so far, as the amended NDA has been assigned a normal 6-month review with a PDUFA date of December 29<sup>th</sup>. Had the agency decided that inclusion of the Dreamboat changed the NDA sufficiently, it could have treated the amended petition as a new application with a 10-month review schedule.

When will the agency render a decision is the next question. We figure the probabilities of approval in the three most likely time periods are as follows: fourth quarter of 2010, 60%; first quarter of 2011, 35%; second quarter of 2011, 5%.

## PARTNERING BECOMES A TOP PRIORITY

Mannkind entered into discussions with potential marketing partners last summer, but the talks ended when the companies sought information that would not be available until much later in the regulatory review. Now that the Company has discussed the complete response letter with the FDA, it should be able to provide interested parties with considerably more information. And the minutes of that meeting, which are expected to arrive in the near future, should suffice, since they will provide an insight into the FDA's assessment of the drug and Mannkind's responses to questions raised in the letter.

We believe several companies have shown an interest in Afrezza, but whether one might be considered in the lead is unknown. What we can say is that Mannkind probably would like to sign an agreement in the current (September) quarter with a global marketer. A deal at that time would provide the two companies with ample leeway to prepare the packaging, labels, and marketing materials; set the marketing strategy; and build the initial inventory for a launch in the first half of 2011. Other partnering agreements probably will be signed to ensure Afrezza's penetration of smaller, less commercially important regions that a global marketer would not reach.

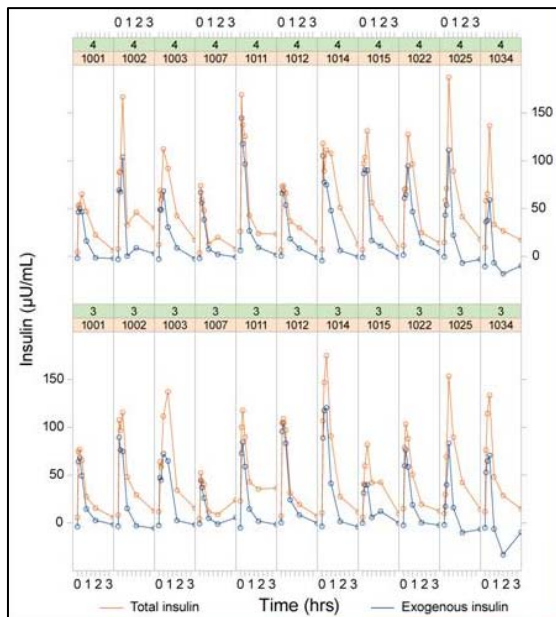
## PRELAUNCH PREPARATIONS SHOULD BEGIN SOON

**Financing:** Terms of the deal may determine whether Mannkind does an external financing in the near future. The Company filed a registration statement to raise up to \$200 million for working capital purposes and investments in manufacturing equipment. However, the marketing agreement may come with an upfront payment that precludes the need for external financing. We note that the Company's Chairman and CEO Alfred Mann has taken steps historically to prevent shareholder dilution.

**Production Capacity Expansion:** Mannkind expects to receive the first commercial-capacity production line in early August. That should give the Company sufficient time to have the line validated by the FDA for a commercial launch in early 2011. The equipment, which will have the capacity to produce 400 insulin cartridges per minute, will be installed in the Company's Danbury, Connecticut plant. That facility has sufficient space to produce 2 billion cartridges per year, or enough Afrezza for about 1 million diabetic patients. Expanding the plant's capacity will be achieved with another 400 cartridge-per-minute line,

followed by production lines capable of turning out 600 cartridges per minute. We believe the facility will be used to supply the domestic market primarily and that Mannkind will ship its specially formulated insulin in bulk to contract manufacturers in other markets for filling and finishing. Indeed, discussions have already begun with such companies in six countries for local production. This strategy makes sense, since it would minimize Mannkind's capital requirements and the cost of shipping Afrezza overseas.

**Future Clinical Trials:** Mannkind intends to conduct clinical trials in collaboration with its partner(s) to satisfy local regulatory requirements and to generate data that will be used for marketing purposes. One study in the latter category is of particular interest, in our opinion. The Company has already shown that patients need not carefully titrate Afrezza as they do other types of insulin, because it is unlikely to cause hypoglycemia. Indeed, clinical studies have demonstrated that patients do not even need to consume any food to avoid hypoglycemia with Afrezza. We attribute that trait to the drug's ability to mimic the pharmacokinetic profile of insulin released by the pancreas (see Figure 1) – something that no other insulin or insulin-analog is capable of duplicating.



**Figure 1.** Changes in total (orange) and exogenous (blue) insulin are plotted after administration of Afrezza and consumption of a standardized meal by 11 healthy volunteers. Note the strong temporal correlation between the initial appearance of exogenous insulin and total insulin levels. The difference between the total and exogenous insulin levels is endogenous insulin released by the pancreas, as measured indirectly by quantitation of a co-released peptide, C-peptide.

Afrezza's ability to mimic endogenous insulin release protects against hyperglycemia that often occurs with other insulins upon consumption of a meal, and it reduces the demands placed upon the pancreatic  $\beta$  cells that are still functioning in early-stage type 2 diabetic subjects. Moreover, the potential for developing hypoglycemia is reduced with Afrezza since the insulin that it delivers has been eliminated from circulation before glucose levels associated with a meal begin to decline. (The pancreas releases insulin at the start of a meal to halt glucose production by the liver and to prepare the body for glucose derived from the meal.)

Source: Marino, MT, et al. C-peptide correction method to determine exogenous insulin levels in PK studies using Afrezza (Technosphere Insulin). Presented at the American Diabetes Association meeting, June 2009.

The next clinical trial that we believe is most intriguing is one in which Afrezza will be used to control post-prandial glucose in diabetic patients who rely on an implanted drug pump to supply their basal insulin. This study is important, because Mannkind attributes the hypoglycemic events in its clinical trials to the basal insulins (e.g., sanofi-aventis' Lantus®). The new study should address the Company's hypothesis. Since insulin pumps provide very fine control of basal insulin levels, patients taking Afrezza should experience very few episodes of hypoglycemia. The trial should also yield other important information regarding the ability of Afrezza to control HbA<sub>1c</sub>, a marker of long-term glucose control. Studies conducted so far have found Afrezza to be non-inferior to other insulins used post-prandially. But Mannkind has evidence that its insulin holds glucose levels within a tighter range, and therefore believes that patients will achieve better control with its drug if fasting glucose levels are managed via an insulin pump. In the planned study, patients will have their fasting glucose levels optimized into a range of 90 – 110 mg/dl before commencing Afrezza therapy. This range is not regularly achieved by most patients today, because of the risk of hypoglycemia. We believe data in agreement with the Company's contentions would provide strong marketing support.

The data from this trial might even lay the groundwork for the use of Afrezza as early as possible by type 2 diabetics. Glucose is toxic to insulin-secreting pancreatic  $\beta$  cells, so better control during the early stages of the disease may slow disease progression by protecting the  $\beta$  cells. That would create a vastly larger market for the drug than we are currently projecting. As described in our Initiation Report on Mannkind, dated October 21, 2009, our financial analysis is based on Afrezza being used only by the 27% of diagnosed diabetic patients who are insulin dependent. Demonstrating a disease-modifying capability of Afrezza would thus expand the market by roughly four fold, to nearly 25 million individuals in the United States alone. (Mannkind is not seeking FDA approval of Afrezza by diabetic patients who smoke or suffer from chronic obstructive pulmonary disease.)

## INVESTMENT CONSIDERATIONS

We believe the next major event will be the signing of a global marketing partner, probably sometime in the July – September timeframe. Other, smaller deals may follow, but they are unlikely to have the same impact on the share price as the global partnering agreement will. (Note that as of June 30<sup>th</sup>, short positions equaled 26.7% of the MNKD float.) After that, speculation over the timing of the FDA's decision will likely influence the share price, followed by excitement over Afrezza's acceptance in the marketplace. By the second half of 2011, we look for the stock's value to be driven more by fundamentals than speculation, even though Mannkind has an attractive oncology program and the opportunity to enter into partnering agreements related to its Technosphere<sup>®</sup> inhalable drug delivery technology. Overall, we believe the risks associated with MNKD shares have diminished considerably with the FDA's acceptance of the amended NDA and the setting of the PDUFA date. Our target price remains unchanged at \$26.00 per share.

## INVESTMENT RISKS AND CONCERNS

For a complete description of risks and uncertainties related to Mannkind's business, see the "Risk Factors" section in Mannkind's SEC filings, which can be accessed directly from the SEC Edgar filings at [www.sec.gov](http://www.sec.gov). Potential risks include:

- ❑ **Stock risk and market risk:** There can be no assurance that an active and liquid trading will be sustained in Mannkind's stock, which could limit one's ability to buy or sell the Company's common stock at a desired price. Investors should also consider technical risks common to stock investments, such as float, risk of dilution, dependence upon key personnel, and the strength of competitors that may be larger and better capitalized.
- ❑ **New and rapidly changing field:** The pharmaceutical and biotechnology markets are rapidly evolving, and research and development are expected to continue at a rapid pace. Other companies are actively engaged in the development of therapies to directly or indirectly treat those disorders being pursued by Mannkind. These companies may have substantially greater research and development capabilities, as well as significantly greater marketing, financial, and human resources than Mannkind.
- ❑ **Products still in development phases:** Although the Company is preparing to commercialize its inhalable insulin, Afrezza, it intends to continue to develop drugs with its inhalation technology and to invest further in its oncology program. Successful commercialization of Afrezza and development of other products is uncertain. R&D costs and timelines can vary significantly for each product candidate and are difficult to accurately predict. In addition, products in development that appear to be promising may not reach commercialization for various reasons, including failure to achieve regulatory approvals, safety concerns, and/or the inability to be manufactured at a reasonable cost. And even once a drug has rolled out, there is no assurance that it will be accepted by consumers or the medical community.
- ❑ **Funding requirements:** It is difficult to predict the Company's future capital requirements. Mannkind may need additional financing to continue funding the research and development of its products and to expand its business. There is no guarantee that it can secure the desired future capital or, if sufficient capital is secured, that current shareholders will not suffer significant dilution.
- ❑ **Regulatory risk:** Various statutes and regulations govern or influence the manufacturing, safety, labeling, storage, recordkeeping and marketing of each product. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect Mannkind's business. There is no guarantee that the Company's products will be approved by the U.S. Food and Drug Administration (FDA) or international regulatory bodies for marketing in the U.S. or abroad.
- ❑ **Competitive risk:** The pharmaceutical industry is extremely competitive, mainly due to its large market potential. Many companies are developing products for the same therapeutic indications targeted by Mannkind. These companies may have substantially more resources than Mannkind and any potential partners, which could adversely affect the Company's position in the marketplace.

## DISCLOSURES

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## PRICE CHART



Source: BigCharts.com

**10/21/2009** – Initiating Coverage: share price: \$5.08; rating: BUY; 12-month price target: \$26.00 **2/4/10** – Updating Coverage: share price: \$9.41; rating: BUY; 12-month price target: \$26.00; **3/18/10** – Updating Coverage: share price: \$7.49; rating: BUY; 12-month price target: \$26.00; **5/4/10** – Updating Coverage: share price: \$6.95; rating: BUY; 12-month price target: \$26.00; **7/20/10** – Updating Coverage: share price \$6.21; rating: BUY; 12-month price target: \$26.00.

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