



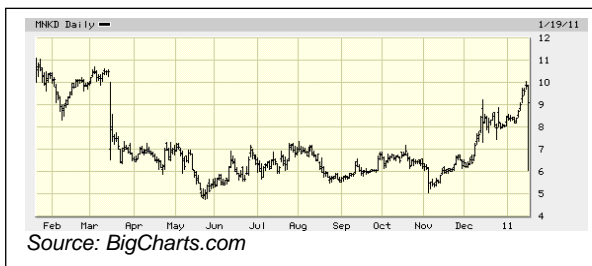
MANKIND CORPORATION (NASDAQGM: MNKD)

- The FDA hands mankind another setback in demanding new clinical data on Afrezza.
- Mannkind plans to respond with data from two recently started clinical trials.
- Approval of Afrezza is pushed into 2012, by our estimates.
- We have lowered our rating to HOLD and put our 12-month target price under review.

Mannkind Corporation (NasdaqGM: MNKD) has been awaiting approval of its inhalable insulin after submitting data on more than 5,300 patients who have used its drug for as much as five years. Nonetheless, the Company was dealt a setback when the FDA issued a Complete Response Letter, demanding two relatively short clinical trials to demonstrate the utility of its next-generation inhaler. Despite the reams of data submitted on the safety and efficacy of Afrezza with the Medtone inhaler, bioequivalence data comparing that device to the next-generation model, and a device design so simple that a toddler could use it, the regulators decided that they now require clinical data on type 1 and type 2 diabetic patients using the new device. Moreover, at least one of the two trials must compare the earlier model with the newer one. The goals are to demonstrate the safety and non-inferiority of Afrezza delivered via the new inhaler compared to the Medtone device.

While Mannkind recently initiated two clinical trials involving its next-generation inhaler, there is some uncertainty over how the studies will have to be modified to satisfy the FDA. The Company intends to continue to enroll patients so that the time to complete the studies will be minimized. But a meeting with the regulatory agency to review their demands is probably 60 days or so away. After allowing time for enrollment to be completed, patients stabilized, 12 weeks of data collected, data analyzed and

Share Price (1/19/11) close:	\$9.11
after-hours trading range:	\$5-\$5.25
52-Week Price Low / High	\$4.76 - \$11.08
Mkt. Capitalization (issued)	\$1.14 billion
Shares Outstanding (issued)	124.8 million
12-month Target Price	Under review
Website	www.mannkindcorp.com



submissions prepared, we figure Mannkind may have its next PDUFA date in the spring of 2012. This will need to be revised, though, as more details about the clinical trials become available.

The FDA's demands will likely require the Company to seek external financing to sustain its operations into next year, as its current cash on hand is budgeted to last through the third quarter.

Given the need for additional information on Afrezza's clinical trials, we have cut our rating on MNKD stock to HOLD and put our 12-month price target under review. Mannkind will provide an update on its quarterly conference call in early February.

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THE FDA'S NEW DEMANDS

The U.S. regulatory agency has been under fire at times for being too lenient, resulting in product quality issues of late for instance, and too unpredictable, causing consternation among patients, companies, and investors. Mannkind's Complete Response Letter is the latest example of the latter behavior. The device section, which participated in the review, apparently decided that standard bioequivalence data was insufficient to approve the drug/device combination.

Two new trials will be required to satisfy the FDA. The numbers of patients in the studies haven't been determined, but the end-points will include HbA1c levels and pulmonary function. One trial will enroll type 1 diabetic patients, while the other will involve individuals with type 2 diabetes. Thus, the results should establish the safety and efficacy of Afrezza administered with the next-generation inhaler for the two primary diabetic populations. And by comparing pulmonary function of patients using the two types of devices, the trial(s) will ascertain whether administration of a smaller quantity of powdered drug with the more efficient, newer inhaler impacts pulmonary function less than a larger quantity via the older inhaler. (In Mannkind's clinical trials conducted to date, patients experienced a minor and temporary reduction in pulmonary function.) The effect on pulmonary function, if any, can be detected very soon after initiation of therapy and it persists unchanged until drug treatment is discontinued. Accordingly, the trials will collect data for 12 weeks largely to assess efficacy, as measured via HbA1c levels. (Unfortunately, HbA1c, or glycated hemoglobin, is the FDA's standard, even though it has been determined to be a flawed index of glucose control.)

A rough assessment of the time required to enroll the patients, conduct the trials, analyze the data, and prepare the reports for the FDA suggests that Mannkind will submit the requested data late this year. This means that with a normal 6-month review, the FDA will have until the spring of 2012 to issue its next decision. Note, however, that this timetable is our approximation and that it will have to be adjusted for the numbers of patients, number of clinical centers participating in the trials, and the resources that the Company applies to preparing the documentation for submission.

INVESTOR CONSIDERATIONS

The delay in commercialization of Afrezza will probably prompt Mannkind to raise money. In the first nine months of 2010, operations consumed \$110 million of cash, and the Company closed the September quarter with \$98 million of cash and \$461 million of debt (\$209 million in convertible notes) on its balance sheet. In addition, it had access to \$98 million available under a loan arrangement with Chairman Alfred Mann. Different financing options have not been discussed publicly thus far.

On the day the Company issued a press release outlining the FDA's demands in the Complete Response Letter, the price of MNKD shares plummeted to \$6.05 before rebounding strongly to more than \$9. This volatility has been noted with other stocks, including Dendreon (NasdaqGS: DNDN) shortly before a regulatory decision was rendered. Subsequently, trading of MNKD stock was halted as the Company prepared for its news announcement. In after-hours trading, the shares were priced in the \$5.00 - \$5.25 range.

We have cut our rating on MNKD stock to HOLD and placed our 12-month target price under review to reflect the uncertainty over the timeline of the clinical trials required by the FDA. Mannkind intends to provide additional information during its quarterly conference call in early February, and we will update our rating and target price at that time. Note that we have NOT changed our view of the importance of Afrezza to humanity, as we continue to believe that its unique pharmacokinetic profile sets it apart as a treatment for post-prandial glucose control.

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. 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

ANALYST(S) CERTIFICATION: The analyst(s) responsible for covering the securities in this report certify that the views expressed in this research report accurately reflect their personal views about Mannkind Corporation (the “Company”) and its securities. The analyst(s) responsible for covering the securities in this report certify that no part of their compensation was, is, or will be directly or indirectly related to the specific recommendation or view contained in this research report.

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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; **1/20/11** – Updating Coverage: share price \$9.11; rating: Hold; 12-month price target: under review.

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