



MANKIND CORPORATION (NASDAQGM: MNKD)

- New safety and efficacy data lend additional support for approval of Afrezza®.
- The FDA and Mannkind will meet in June to discuss the Afrezza NDA.
- Clinical data to be presented at medical conferences in the coming months.
- Expenses remain under control; the Company prepares for a financing.
- Partnering moves to the forefront for Afrezza and oncology therapies.
- We reiterate our BUY recommendation and retain our target price of \$26 per share.

Mannkind Corporation (NasdaqGM: MNKD) is a clinical-stage pharmaceutical company with a novel inhalable drug delivery technology and a platform for developing cancer vaccines. The first inhalable drug that should debut is insulin under the brand name Afrezza®. Clinical trials involving more than 5,300 individuals have demonstrated this formulation’s ability to control postprandial glucose levels in a manner akin to that achieved by a normal person’s pancreas. Data have shown that there is a lower risk of hypoglycemia with Afrezza than with other short-acting insulins and that it is not associated with weight gain as are today’s therapies.

Mannkind will meet with the FDA in June to discuss how to resolve issues in the complete response letter that was received in March. Key questions dealt with the inhaler included in the NDA and Afrezza’s clinical utility, but the letter did not ask for a new trial. The Company aims to address questions about the inhaler by filing for approval of an improved version, the Dreamboat, and it has assembled more clinical data in support of Afrezza’s approval.

Partnering discussions are heating up, as the Company intends to gain an experienced marketer(s) for a global rollout of Afrezza. The FDA meeting in June may yield the information potential partners need to enter into an

Share Price (5/3/10)	\$7.23
52-Week Price Low / High	\$4.00-\$12.30
Mkt. Capitalization (issued)	\$820.2 million
Shares Outstanding (issued)	113.45 million
12-month Target Price	\$26.00
Website	www.mannkindcorp.com



agreement. Meanwhile, Mannkind is seeking collaborators for its oncology program that includes three therapeutic vaccines.

The FDA meeting should set the tone for the remainder of the year, as a constructive outcome would likely set the path to commercialization. Mannkind plans to report clinical data at scientific meetings this year that should educate physicians on Afrezza’s use. And a registration statement has been filed to help finance manufacturing scale-up. Thus, Afrezza’s launch is approaching. We are reiterating our BUY recommendation and our \$26 per share price target on Mannkind stock.

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NEW AFREZZA PROVIDES PRELUDE TO FDA MEETING

The latest data issued on this inhalable insulin affirmed earlier findings regarding the drug's safety and efficacy. The timing couldn't be better – the Company is scheduled to meet with the FDA in June to discuss the complete response letter received on March 12th.

Follow-up safety data showed that Afrezza is comparable to standard diabetes treatments in lung function tests. Specifically, 649 adults who participated in one of four clinical trials were monitored for lung function at one and three months after they had returned to standard care. During the trials, the type 1 and 2 patients taking Afrezza exhibited a small, non-progressive decline in forced expiratory volume and in carbon monoxide diffusing capacity. Regardless of how long the patients had taken Afrezza, their forced expiratory volume at three months post-trial was not significantly different than that of control subjects who received only standard therapy. In other words, the slight decline in lung function that accompanies Afrezza therapy is not permanent – lung function returns to normal upon cessation of the treatment.

The efficacy of Afrezza was affirmed in a 2-year study of 538 type 1 diabetic individuals who had not been adequately controlled by subcutaneous insulin. The results from the multisite, prospective study showed that Afrezza reduced HbA_{1c} levels as well as standard therapy did. Just as important, Afrezza patients lost weight, while standard diabetes care was associated with weight gain. Also, the Afrezza group experienced fewer and milder hypoglycemic events (61.8 cases and 2.36 severe cases per 100 subject-months, respectively) than the control arm (66.1 cases and 3.76 severe cases per 100 subject months).

An additional clinical trial, labeled study 117, was also completed recently to bolster the data available on the use of Afrezza by type 1 diabetic patients. The four-month trial, which compared Afrezza against a rapid-acting analog, both in combination with a long-acting insulin, was intended to demonstrate non-inferiority with respect to HbA_{1c} levels. Preliminary results indicate that the endpoint was comfortably met.

Combined, the aforementioned data should help the Company define the clinical utility of Afrezza and thereby satisfy a request by the FDA for a description of how the drug should be used after commercialization. This is a key point that will be discussed during the June meeting. The other important item on the agenda will probably be the Dreamboat inhaler. Mannkind intends to submit a supplemental NDA so that the regulators will consider this device, rather than the Medtone D that was included in the March 2009 filing. Since the Medtone D has raised questions at the FDA, the new filing should eliminate those queries. More important, bioequivalence data has been obtained on the new, simpler Dreamboat model, which compared it to the Medtone C used in the clinical trials. The Company intends to ship the Dreamboat so that patients will use a new inhaler every two weeks.

Meanwhile, Mannkind plans to present more clinical data, notably at the American Diabetes Association annual meeting in June (25th – 29th). And in September (20th – 24th) is the European Association for the Study of Diabetes meeting where the Company made several presentations last year.

EXPENSES DECLINE & A REGISTRATION STATEMENT IS FILED

First-quarter results reflected the changes that have occurred in the past 12 months. R&D spending dropped by 29%, to \$30.5 million, as the Afrezza clinical program has slowed since the NDA was filed in March 2009. General and administrative costs also declined, by 32% to \$10.1 million, because of a reduction in the workforce in 2009 and the elimination of one-time expenses related to last year's negotiation with Pfizer, which resulted in an acquisition of bulk insulin with a retail value of \$10 billion. The quarter closed with a loss of \$44.7 million, down 25% from last year's \$59.4 million of red ink. Future quarters should reflect similarly reduced expense levels.

The Company maintained its cash position near \$30 million by borrowing \$40 million on the line of credit extended by its Chairman & CEO Alfred Mann. This left \$145 million still available on the loan agreement. More recently, Mannkind prepared to raise additional funds via a debt and/or equity financing for up to \$200 million. We believe this is a prudent step, since even though a partnering deal could generate a

sizable upfront payment. The registration statement provides extra flexibility and may be used to build inventory in anticipation of FDA approval.

PARTNERING EFFORTS EXPAND

On its April 30th conference call, Mannkind revealed that it is seeking partners for its oncology program, which consists of three therapeutic vaccines at this juncture. The lead candidate is a promising melanoma treatment that stimulates the patient's own immune system to attack the malignant cells. As such, it constitutes a new, systemic approach to the disease.

Meanwhile, the Company is negotiating to secure experienced marketing support for Afrezza. We believe the upcoming meeting with the FDA will answer many, if not all, of the questions that need to be addressed before an agreement is inked. Then, too, the timing is about right – for Mannkind to launch Afrezza in early 2011 as planned, it will need to sign a partner within the next four or five months.

INVESTMENT CONSIDERATIONS

Mannkind shares have been subject to short-selling over the years as some investors felt the Company would not obtain FDA approval or gain the experienced partner that it has sought. This has resulted in periods of high volatility. The next 12 months should play an important role in determining the corporate future, and much hinges on the June meeting with the FDA. The outcome to that meeting should determine whether the Dreamboat inhaler and the vast amount of clinical data on Afrezza are adequate to satisfy the agency. Moreover, a favorable exchange probably will facilitate negotiations with potential marketing partners. We note that one important hurdle was recently cleared, and that was the FDA's completion of a manufacturing plant inspection in France. (The plant, which is owned by Merck, will supply insulin to Mannkind.) That said, the Company does have ample other opportunities to pursue, because of its inhalation technology, which may be used with other drugs, and its oncology program.

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.

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PRICE CHART



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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.

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