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Will Mannkind's Dream Come True?

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Synopsis
The CEO and major stockholder of MannKind, Inc., convinced his firm to develop an inhalable insulin, Afrezza and inhaler, Dreamboat to treat diabetes. The unapproved Dreamboat inhaler with Afrezza instead of the approved Medtone inhaler was used when MannKind filed their application in 2010 with the U.S. Food and Drug Administration (FDA). MannKind used its latest inhaler technology and the inhaler substitution delayed the approval process because FDA wanted proof Dreamboat was as safe as Medtone. The delay triggered external and internal challenges such as stock price fluctuations, stockholder suits and layoffs. MannKind filed another FDA application in 2013 focusing on safety of the inhaler substitution. FDA delays caused the CEO to wonder about the success of his strategic framework. As the CEO awaited FDA approval in April 2014, he reflected on his dream to develop a product that tackled diabetes in spite of his frustration with the FDA process.

Learning Outcomes
The outcomes of this case are:

1. Identify the differences between external and internal analysis and determine which strategic approach would assist organizations to analyze the appropriateness of the firm's decisions aimed at FDA product approval and marketplace success.
2. Assess the effectiveness of company product strategies in the pre-approval FDA stage to achieve company goals.
3. Evaluate the role financial analysis plays in the determination of a firm's ability to achieve final FDA approval and firm sustainability.

Application
This case is appropriate for upper-level undergraduate biotechnology and related life science management courses, graduate courses in strategy, entrepreneurship, marketing and biotechnology management as well as workshops for life science industry professionals.

Key Words
Strategic management, entrepreneurship, product marketing and biotechnology management.

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