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Will MannKind's Dream Come True?

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Diabetes was ranked as the seventh leading cause of death in the U.S. and contributed to a growing list of other serious ailments (National Institutes of Health, 2014). This disease was traditionally treated with a drug called insulin, which had to be injected through a needle. Many diabetics did not want to stick a needle in their body every day to maintain health and prevent early death. Alfred Mann worked inside several firms to develop state-of-the-art medical products that made the management of diabetes easier for patients (Medtronic MiniMed, Inc, 2014). As founder and CEO of his newest firm, MannKind Corporation, he developed an inhaled insulin to treat diabetes without the use of needles. The product was composed of an insulin powder called Afrezza, and an inhaler called Dreamboat. Before Afrezza-Dreamboat could be made available to patients, it would need to be approved by the U.S. Food and Drug Administration (FDA).

When MannKind filed their 2010 New Drug Application (NDA) with the FDA, they used their new inhaler, Dreamboat, instead of their established inhaler, Medtone (see Figures 1 and 2). The FDA had previously approved Medtone, but MannKind opted to use their latest technology, Dreamboat. This substitution proved to be a costly mistake. The FDA rejected the MannKind NDA, creating major fluctuations in the firm's stock price and warranting layoffs that reduced the firm's workforce by 41% (Davis, 2011). MannKind made several subsequent FDA filings to show Dreamboat was as safe as Medtone, but more regulatory delays were encountered. In a 2011 interview with Globes, Mann voiced his frustration with the FDA: "That is the regulatory environment that we operate in, which together with other factors that are burdening the U.S. economy and health system, are simply killing innovation." (Weinreb, 2011). With each FDA delay, Mann voiced his concern about external challenges such as the regulatory process. Mann and other stakeholders were also concerned about internal firm challenges and how company decisions might have delayed FDA approval (Davis, 2011; Macaluso, 2012; Zinn, 2013).

Pfizer, a large pharmaceutical firm, had developed inhaled insulin that was similar to MannKind's product. The product, called "Exubera", had been approved by the FDA in 2006. However, Exubera failed in the marketplace, costing Pfizer billions of dollars. As a result of the Exubera failure, two competitors cancelled similar product development programs (Macaluso, 2012). Hence, Mann's investment in the Afrezza-Dreamboat product was risky. Would MannKind's product be able to succeed where others had failed? The company submitted a new application to the FDA in October 2013. Mann remained bullish regarding anticipated FDA approval. He even predicted it would occur by April 2014 (Orelli, 2013). Although Mann was reflective about his past strategic decisions, he was known as an innovative and fearless leader in

the industry. Past competitors' product failures, FDA delays, and stakeholder uncertainty did not deter his optimism about final FDA approval (Orelli, 2013).

Industry speculation grew as the final 2014 FDA decision date approached. Many observers assessed Mann's past strategic decisions (Davis, 2011; Macaluso, 2012; Markey, 2013; Zinn, 2013). Mann attributed his strategic management success to the founding and funding of medical device companies; but drug development was a relatively new endeavor. If you were Alfred Mann, what strategic analysis models and frameworks would you use to analyze the effectiveness of past company decisions and improve the chances of receiving final FDA approval for Afrezza-Dreamboat?

Industry Background

According to industry classification, MannKind was involved in both the biotechnology (biotech) and pharmaceutical (pharma) industries (NAICS Association, 2012; MannKind Corporation, 2013). Trends in both industries were used to view and analyze the characteristics of MannKind Corporation (Friedman, 2006; NAICS Association, 2012). Since current MannKind products and competitors existed more in the biotech industry, recent information was emphasized from this industry. Industry trends and challenges are provided in Appendix B (see Table 6)

Ten strategic planning models firms used to evaluate external and internal environments were listed in Table 7, Appendix B. Friedman (2006/2014) indicated that the two most commonly used external forces models for evaluating the influence of biotech markets were an abbreviated form of PESTLE called PEST and the Porter's Five Forces model. The Porter model measured the "attractiveness" and expected performance in an industry based on the threats of buyers, entry, rivalry, substitutes and suppliers (Porter, 1985; Porter, 2008). While more than 1,000 biotech firms operated in North America, only the top 1% generated a majority of the revenue (The Industry Handbook: Biotechnology, n.d.; NAICS Association, 2012). Drug development was a risky business, and profits were hard to achieve. Most firms were small, with only a few products in the pipeline. Hence, FDA approval of a firm's product was a critical performance measure. Unless a small firm had a blockbuster drug and enough funds to get it through final FDA approval and on to market, they tended not to survive (George, Zahra, Wheatley & Khan, 2001; Rothaermel & Deeds, 2004). Bringing a new drug to market could easily cost over $1 billion and require 15 years in the firm's pipeline. Thus, biotech firms were high cash burn operations and large amounts of money were invested before any financial returns were received.

Diabetes

Diabetes Mellitus was described as a worldwide epidemic affecting 25.8 million Americans (American Diabetes Association, 2011). This metabolic disease caused high abnormally high blood sugar in patients. There were two types of Diabetes Mellitus; both could be treated with insulin therapy (see Table 1).

Table 1: Comparison of Type 1 and Type 2 Diabetes Mellitus

Type 1	Type 2
5-10% of all cases	90-95% of all cases
Pancreas fails to produce enough insulin	Pancreas produces insulin, but the body does not metabolize it properly
More common in children and teenagers	More common in adults and the elderly
Impossible to prevent	Possible to prevent or delay by maintaining a healthy lifestyle

Source: Global Data, 2014

Insulin treatment made diabetes a manageable illness, but the process was demanding. Patients had to inject themselves with insulin on a regular basis. These injections were often painful and resulted in bleeding, irritation, and even scarring. Surveys conducted in 2012 found that at least 1/3 of patients did not take insulin as prescribed, and 20% of adult patients purposely skipped doses (Siminerio, Kulkarni & Meece, 2011). Only 29% of adults with diabetes in the U.S. used insulin therapy and while effective, injectable insulin was oddly under-utilized (Siminerio, et al., 2011). When left untreated, diabetes became a life-threatening condition. Patients with diabetes were at risk of developing permanent blindness. Diabetes increased the risk of stroke, high blood pressure, and coronary artery disease. In the U.S., costs of medical treatment for diabetes and its associated complications totaled over $100 billion annually (National Institutes of Health, 2014). A product like Afrezza-Dreamboat, which could help patients manage their disease without the use of needles, would likely be welcomed in the marketplace.

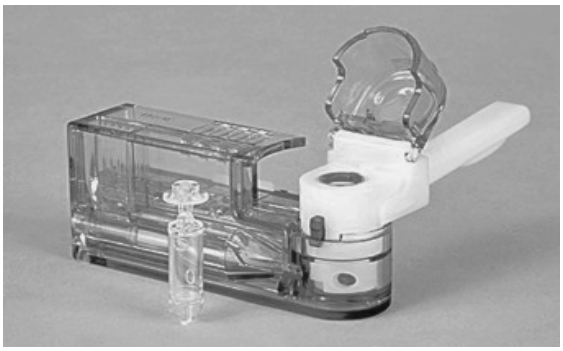
MannKind Products

MannKind aimed to improve diabetes management with Afrezza-Dreamboat, an inhaled insulin and delivery system product. The product was designed to lessen the frequency of needle injections for Type 1 diabetics and eliminate needle injections for Type 2 diabetics. When compared with injectable insulin, dry powder Afrezza was delivered to the bloodstream more quickly and it took less time to be cleared from the body. This more closely resembled insulin patterns in healthy individuals (Blohowiak, 2009).

MannKind's central focus was on Afrezza-Dreamboat, but the firm had other inhaled drugs and drug devices in the pipeline. The market for inhaled drug devices was on the rise and expected to reach $29.8 billion in 2016 (BCC Research, 2012). This was good news for MannKind; their patented inhalers had a wide range of medical uses (see Table 9, MannKind Corporation's Product Pipeline). In addition to diabetes, MannKind's inhalers could be used to deliver medicine for symptoms like pain and nausea. MannKind's pipeline report showed they had a drug/device technology platform under development called Technosphere Technology that had a wider range of usage, faster forecasted growth rate, and an even larger potential market than Afrezza-Dreamboat (see Tables 9 and 10).

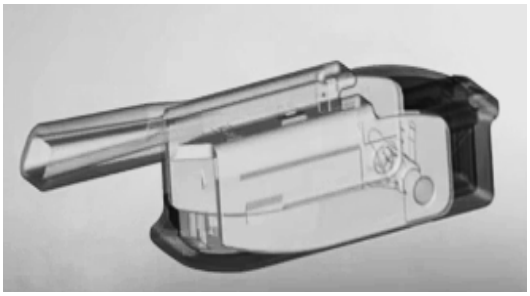
When MannKind applied for approval of Afrezza in 2010, it was rejected by the FDA (see Appendix C, Table 8). The firm's original clinical trials had used the Medtone inhaler, which was FDA-approved (see Figure 1). By the time MannKind was ready to apply for FDA approval of Afrezza, they had designed a new inhaler called Dreamboat (see Figure 2). Compared to Medtone, Dreamboat was smaller and more discreet. Its parts required less adjustment, so it was easier to use.

Figure 1: The Medtone Inhaler (not to scale)



Source: Leach, 2010

Figure 2: The Dreamboat Inhaler (not to scale)



Source: MannKind Corporation, 2013

Before filing for approval of Afrezza, MannKind asked the FDA for permission to use Dreamboat instead of Medtone. The FDA approved MannKind's request; however, the decision was later reversed. In January 2011, the FDA issued a complete response letter asking the company to conduct two more clinical trials (see Table 8). The trials were considered "non-inferiority", meaning that they were designed to test whether the new device, Dreamboat, was as safe and effective as Medtone (CurrentMedicine.tv, 2013). MannKind was concerned about more FDA delays and consulted an FDA advisory panel, which provided an expert opinion on whether the FDA should grant approval. While the FDA was not required to follow the suggestions of the advisory panels, it added extra credibility to the review process. On April 1, 2014, the FDA Advisory Committee voted 13-1 to approve MannKind's application for Afrezza-Dreamboat (MannKind Corporation, 2013).

Company Background

Table 8, Appendix C provides a snapshot of key events for the MannKind Corporation. To date, Alfred Mann had founded and funded 17 companies. Nine of these companies were acquired for a total of nearly $8 billion (AMF, 2011). In the mid-1960's, Mann helped develop one of the world's first commercial pacemakers. While founder and CEO of MiniMed Inc. in the 1980's, Mann used his existing pacemaker technology to develop revolutionary new devices for Type 1 diabetes (MannKind Corporation, 2013).

Mann formed MannKind Corporation in 1991 to focus on his long-time interest in healthcare. He also saw an opportunity to make a greater impact on diabetes. Mann invested $925 million into MannKind and purchased $77.2 million worth of stock (MannKind Corporation, 2013). The MannKind mission was to focus "on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes." Mann formed a team of experienced biotech industry veterans to help him accomplish these goals (see Table 2). Mann's heavy personal investment in the firm showed his faith and devotion to MannKind and Afrezza-Dreamboat in particular. By April 2014, Mann owned roughly 46% of MannKind (Zinn, 2013).

Management Background

Table 2: Executive Management, MannKind Corporation

Alfred E. Mann Founder, Chairman, and Chief Executive Officer Executive Board Since: 2001	Mr. Mann has been chairperson and CEO of the company since 2003. He founded and formerly served as Chairman and Chief Executive Officer of MiniMed, Inc., a publicly traded company focused on diabetes therapy and micro infusion drug delivery that was acquired by Medtronic, Inc. in August 2001. Mr. Mann also founded and, from 1972 through 1992, served as Chief Executive Officer of Pacesetter Systems, Inc. and its successor, Siemens Pacesetter, Inc. Mr. Mann founded and since 1993, served as Chairman and until January 2008, as Co-CEO of Advanced Bionics Corporation.
Hakan S. Edstrom Chief Operating Officer, Director, President Executive Board Since: 2001	Mr. Edstrom has been President, Chief Operating Officer, and Director of MannKind Corporation since April 2001. Mr. Edstrom was with Bausch & Lomb, Inc., a health care product company, from 1998 to 2001, advancing to the position of Senior Corporate Vice President and President of Bausch & Lomb, Inc. Americas Region.
Matthew J. Pfeffer Chief Financial Officer, Vice President Senior Management Since: 2008	Mr. Pfeffer has been Chief Financial Officer, Corporate Vice President of MannKind Corporation since April 2008. Mr. Pfeffer served as Chief Financial Officer and Senior Vice President of Finance and Administration of VaxGen, Inc. from 2006 until 2008. Mr. Pfeffer served on boards and advisory committees of the Biotechnology Industry Organization and the American Institute of Certified Public Accountants.
Juergen A. Martens Chief Technical Officer, Vice President Technical Operations Senior Management Since: 2005	Juergen A. Martens, PhD, has been Corporate Vice President of Operations and Chief Technology Officer since 2005. From 2000 to 2005, he was employed by Nektar Therapeutics, Inc., as Vice President of Pharmaceutical Technology Development.

Source: MannKind Corporation, 2013 and Thomas Reuters, 2014

Friedman (2006) indicated the growth of the biotech industry led to a shortage of top managers with executive experience. Yet, Mann managed to recruit and build a team of experienced industry savvy veterans with impressive backgrounds (see Table 2). Mann was a widely acclaimed billionaire, but he chose to work 70-hour weeks while taking only two vacations per year (Helfand, 2011). Industry observers wondered how many more miracles Mann had up his sleeve (Helfand, 2011; Macaluso, 2012; White, 2013).

Company Workforce and Structure

MannKind's corporate headquarters was located in Valencia, CA. The firm's manufacturing site in Danbury, Connecticut, was their largest facility (MannKind Corporation, 2013). In February of 2011, MannKind decided to let go 131 of the 270 employees working in the Danbury location (Davis, 2011). A total of 179 people were laid off that day. This was a 41% reduction of the firm's workforce. Matthew J. Pfeffer, MannKind's VP and CFO indicated that the layoffs were due to the FDA's rejection of Afrezza-Dreamboat (see Table 8, Appendix C). According to Pfeffer, the company had staffed up in anticipation of FDA approval. By 2013, MannKind had 245 total employees and the firm continued its operations. Yet, there was lingering uncertainty as to what would become of Afrezza-Dreamboat and the MannKind Corporation.

Financial Summary

There were mixed signals coming from internal and external sources about the long-term sustainability of MannKind. The company admitted that, due to FDA delays, MannKind had yet to generate any product revenue. There was external speculation that MannKind's largest internal threat was lack of funds (White, 2013). Company financial reports showed that by Q4 of 2013 the firm had a small amount of licensing revenue but burned millions of dollars in cash each month (Markey, 2013; Appendix F). Alfred Mann, founder and CEO of MannKind

Corporation, had invested nearly $1 billion of his own capital into the company (Zinn, 2013). The CEO had helped the firm to convert company debt to his personal equity position in the past (Pfeifer, 2012). However, company explanations of the 2013 Deerfield debt obligation suggested there were limits to Mann's willingness to continue funding the firm with his personal resources (Pfeifer, 2014). The Deerfield debt obligation was tied to convertible notes based on MannKind reaching internal R&D checkpoints and future revenue collected from Afrezza-Dreamboat once it was FDA-approved and marketed. A recent detailed financial report by an industry observer from Griffin Securities concluded that MannKind had ample funds. He even speculated that MannKind could become profitable in the year 2015 (Markey, 2013).

Key Financial Indicators

Five years of standard financial reports for MannKind are provided in Appendix F. These reports helped to evaluate the company's past strategic performance. They also shed light on current and future performance. Several tables with key MannKind financial indicators are also provided. Table 3 provides traditional MannKind indicators. Table 4 provides comparisons of MannKind indicators with the biotech industry. Analysis of the firm's financial reports was used to interpret past performance (Wheelen & Hunger, 2006; Barney, 2010). Common financial indicators such as profits, earning per share, and return on investment had helped most firms to assess their chances of survival. Traditional metrics, such as current ratio and free cash flow, were other interesting indicators (Rothaermel & Deeds, 2004; Friedman, 2006; Friedman, 2014; The Industry Handbook: Biotechnology, n.d.).

As previously stated, biotech firms had usually been high cash burn organizations. Traditional integrating financial tools, such as the DuPont Formula and Altman Z score, provided a more complete financial picture of a company's solvency (Barney, 2010; Liesz & Maranville, 2011; Altman, 2013). No matter how sophisticated the tools, financial indicators of firm performance were only the starting place for strategic evaluation (Kaplan & Norton, 1996; Wheelen & Hunger, 2006; Hitt et al., 2009; David, 2009; Rothaermel, 2015). It was noted that more complex arrangements of stakeholders for firms made traditional and integrative financial indicators of company performance less conclusive as measures of performance and strategic success (Kaplan & Norton, 1996; Wheelen & Hunger, 2006; David, 2009; Rothaermel, 2015).

Table 3: Key Financial Indicators

($ Values in 000s)	2009	2010	2011	2012	2013
Current Assets	37,666	73,954	5,821	66,810	76,275
Current Liabilities	28,853	18,134	25,360	144,775	127,794
Working Capital	8,813	55,820	(19,539)	(77,965)	(51,519)
Total Assets	247,397	277,256	199,553	251,314	258,646
Total Liabilities	306,618	462,788	513,205	361,993	289,359
Revenue (Non-Product)	0	93	50	35	0
Loss from Operations	(209,778)	(152,498)	(140,539)	(146,960)	(169,401)
Cash and Cash Equivalents	30,019	66,061	2,681	61,840	70,790
Current Ratio (Absolute)	1.31	4.08	0.23	0.46	0.6
Market Value of Equity	961,110	1,027,000	345,420	567,750	1,643,000

Source: SEC, 2012 (see Appendix F)

Table 4: MannKind Corporation and Biotech Industry – 5 Year Averages

($ Values in 000s)	Unit/Currency	MannKind Corporation 5 Year Average	Biotechnology Industry 5 Year Average
Capital Spending Growth Rate	USD	(37)	7
EBITD	USD	(408,135)	(77)
Net Profitability Margin	%	(512,542)	(99)
Operating Margin	%	(460,211)	(93)
Return on Assets	%	(73)	(4)
Return on Investment	%	(97)	(6)

Source: Thomas Reuters, 2014 (see Appendix F)

As shown in Table 3, MannKind's working capital was positive in 2009 and 2010, and became negative starting in 2011. Working capital was the difference between current assets and current liabilities. The current ratio was equal to current assets divided by current liabilities. A ratio greater than 1 indicated that a company was in good financial health and was capable of paying its debts. Table 3 shows MannKind's current ratio was greater than 1.0 in 2009, peaked in 2010, and then dropped below 1.0 starting in 2011. Another useful exercise was to benchmark company metrics to industry averages (George et al., 2001; Rothaermel & Deeds, 2004; Friedman, 2006; Friedman, 2014; The Industry Handbook: Biotechnology, n.d.). Table 4 benchmarks MannKind to the biotech industry as a whole. MannKind's 5-year margins for profitability, operations, returns on assets and investments were negative, which was also true for the biotech industry.

The Biotech Industry Background section mentioned that firms usually had multiple stakeholders and the business arrangements of most biotech firms became more complex as they moved through the product life cycle (Friedman, 2006; Friedman, 2014; The Industry Handbook: Biotechnology, n.d.). Thus, financial indicators that reflected the interests of multiple stakeholders or that were unique for a specific industry were preferred. The Balanced Scorecard (BSC) approach measured the complex arrangements in firm performance and was composed of financial, customer, internal business perspectives, and innovation and learning components. The BSC improved strategic formulation and evaluation. Rothaermel (2015) pointed out both the advantages and shortcomings of BCS for strategic implementation and formulation and suggested a three-component stakeholder Triple Bottom Line (TB) approach as an improvement. The TB approach measured sustainability and included internal and external stakeholders that focused on components such as economic, social and environmental goals (Rothaermel, 2015).

Internal Company View

CFO Matthew Pfeffer indicated that by Q4 of 2013, the firm continued to burn millions of dollars in cash each month and, due to FDA delays in approving Afrezza-Dreamboat, MannKind had yet to generate any revenue. Despite this fact, he went on record stating that the firm was in good financial standing:

> We're about as flush with cash today as we have been in any recent memory, which is a good thing. The last reported cash balance we had was 28.5 million, but that was back in June [2013]. The very next day we announced the Deerfield deal. (CurrentMedicine.tv, 2013)

Pfeffer described the debt financing with Deerfield; they had received two tranches of $40

million so far, and would be receiving a third $40 million tranche in December 2013. Pfeffer added that the company had given out one-year warrants for a total of 350 million shares and that those were due to expire. Mann also stated that he had "provided some financing." Therefore, Pfeffer concluded that the company was in "a pretty healthy cash position, at the moment" (CurrentMedicine.tv, 2013).

External Observers' View

External views were less positive, but encouraging. Many analysts believed that when there was strong internal ownership - 15% or greater - management was likely to act in the best interest of the company (NASDAQ, 2013). However, the Deerfield debt financing agreement could be interpreted in different ways. It may have signaled that the cash burn rate was unsustainable. On the other hand, it could have meant that the company was positioning itself for financing future business arrangements (Patel, 2013). The report by Griffin Securities in 2013 indicated that MannKind had a strong balance sheet and went on to state that MannKind had ready funds to support operations. They concluded that MannKind was on the road to profitability by 2015:

> The balance sheet included $62 million of cash as of December 31st [2013], not including $120 million available on a line of credit from MannKind's CEO Alfred Mann. This capital should cover the corporate needs for now, based on an estimated cash burn rate of $10 million - $12 million per month. Exercise of warrants that will expire in October could provide an additional $92 million (Markey, 2013).

Company stakeholders were expected to learn more about the future of MannKind Corporation very soon, which was largely dependent upon Afrezza's success.

Major Challenges

MannKind received positive news on April 1, 2014 concerning recommended FDA approval of the Afrezza-Dreamboat product application. The FDA advisory committee voted 13-1 to recommend that the FDA approve Afrezza. Mann stated:

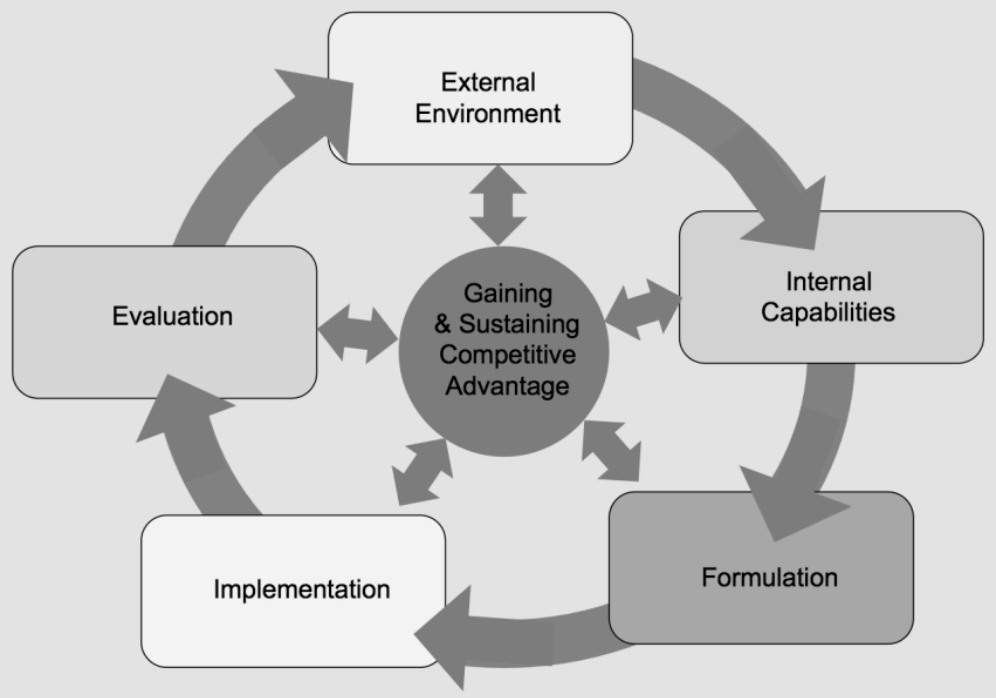
> We are pleased with the Advisory Committee's approval recommendation in support of Afrezza, and we appreciate the thoroughness of their review. We look forward to working with the FDA as they complete their evaluation of Afrezza. Diabetes is a major health problem in the United States, and we are committed to bring Afrezza to the many patients who might benefit from this novel product. (MannKind Corporation, 2013).

The advisory committee's recommendation did not ensure the FDA would approve Afrezza, but it was certainly a positive sign (see MannKind Products section). The final FDA decision date was set for April 15, 2014. Due to a checkered history of FDA approvals, partial approvals and delays, many stakeholders were anxious (Rho, 2013). The value of company stock for firms with a new drug application was usually tied to the FDA decision. Approval or rejection of a product could be a transformative company event. This was especially true when a long and expensive clinical testing process was involved. The MannKind Corporation was no exception. Early in April 2014, the company's stock price rose nearly 80% in anticipation of FDA approval (Thomas Reuters, 2014). Potential business partners in the U.S. and Europe were rumored to be

gearing up to market Afrezza-Dreamboat (Blohowiak, 2009). However, Mann knew that financial performance, though important, was only one metric used to evaluate company sustainability.

Although Alfred Mann was optimistic about the final April 15, 2014 FDA decision, there had been many challenges along the way. Would a more systematic strategic assessment of MannKind's internal and external challenges have prevented FDA regulatory delays? Would a generic strategic framework like the one pictured in Figure 3 below had helped the CEO and you to make this assessment regarding MannKind's key events, challenges and past strategic decisions? Which strategic planning models from Table 7, Appendix B and components of the generic strategic framework in Figure 3 would be most useful to this assessment?

Figure 3: Generic Strategic Management Framework



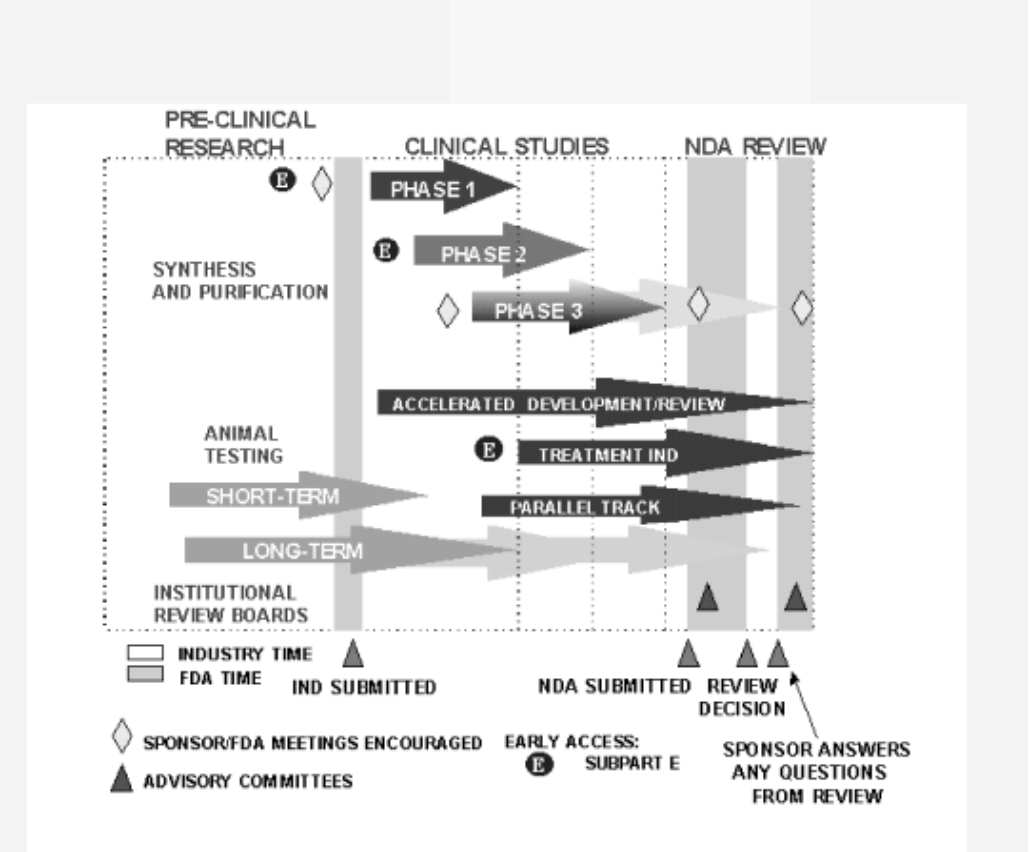
Source: Authors Notes, used with permission of Professor Keith Perry (2014)

Appendix A

Technical Note: Drug development and regulatory approval process

From discovery to marketing, the drug development process took an average of 15 years and cost more than $1 billion (U.S. Food and Drug Administration, 2004). Figure 4 provides a visual representation of what was involved in bringing a new drug to market in the U.S. As the process moved from left to the right, it became exponentially more costly.

Figure 4: Bringing a new drug to market, from pre-clinical research to NDA review.



Source: U.S. Food and Drug Administration, 2012

In the drug discovery phase, the company performed research and development activities to discover drug candidates. Of thousands of drugs being tested in the lab, only a handful were selected and used in animal studies. Once the drugs were shown to be safe and effective in animals, an Investigational New Drug (IND) application was submitted to the FDA asking for permission to perform drug testing in humans. Drug testing in humans, also known as clinical trials, tended to be a very long and expensive process. As shown in Table 5, clinical trials generally occurred in three phases. The process only advanced to the next phase if the drug demonstrated safety and effectiveness in its current phase.

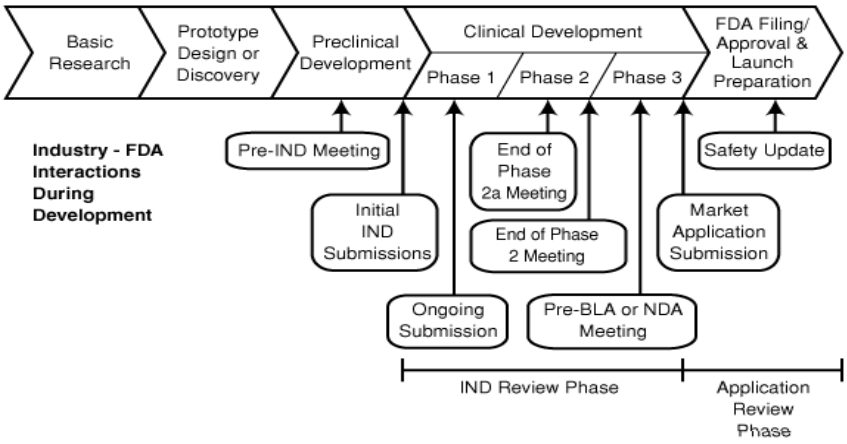
Table 5: Clinical Trial Process

Clinical Trial Phases			
Stage	**Average No. of Patients**	**Average Length of Time**	**Average Cost**
Phase I	20-80	1-2 years	$2.25 million
Phase II	100-200	2 years	$10.5 million
Phase III	1,000-3,000	2½ years	$150 million

Source: Pipeline Project, 2012

As the cost and scale of clinical trials increased, there was a corresponding decrease in overall probability of success. Most drugs did not make it to phase III; those that did still needed to have very compelling data in order to be approved by the FDA. If the clinical studies showed that the drug was better than conventional methods without causing too many side effects, then the company would file a New Drug Application (NDA). The FDA performed a review process, sometimes lasting 2 years or more, before a decision was made. FDA involvement in clinical trials and drug approval ensured that patients were protected and not subjected to any unnecessary harm; therefore, FDA oversight was minimal during the pre-clinical phases of drug development. The scope of FDA involvement in drug discovery is illustrated in Figure 5.

Figure 5: The scope of FDA involvement in the drug development process.



Source: U.S. Food and Drug Administration, 2004

Once the company submitted the IND to the FDA, there was a 30-day grace period before clinical testing could begin. The FDA would use this time to decide whether the study design was safe and reasonable (FDA, 2004). Key meetings with the FDA occurred when phase II clinical trials ended and before the NDA was submitted. The FDA continuously monitored the clinical trial process, and if necessary could halt studies that it deemed to be unsafe.

Appendix B

Table 6: Industry Trends and Challenges

Decade	Major Trends	Challenges
2010	Companies outsourced their capabilities, which had long been internalized, to Emerging Markets. This caused a shift in the source of industry growth; a trend that was expected to continue. Thus, it was essential for companies to take into account the needs of consumers in Emerging Markets, and enhance diversity of their workforce. The use of social media was also increasing the power of organized patient groups, so it was important for companies to establish a presence in the global social network.	The skyrocketing cost of R&D was being poorly managed, and the vast majority of marketed drugs failed to generate enough revenue for stakeholders to see any return on investment. Emerging Markets were becoming the major drivers of drug development, resulting in low growth and stagnation for the U.S. drug companies. Overall perception of the industry was negative; the public tended to believe that drug companies put profits first.
2000	Hybrid business models emerged to capitalize on the stability of the tools and service sales while selling the traditional product development. At the same time, a shift in scale, automation and information-based research occurred.	The high technology bubble caused the biotech industry to shrink and firms to look for new markets to capitalize on with products that did not require large R&D investment. The shift in scale of operations, automation and information-based research required a different type of employee and management in order to compete in an unstable, global environment; these resources were scarce. There was controversy over stem cell research.
1990	Platform and tools-based biotech firms emerged that sought to commercialize drugs, targets, services and technologies separately to create enhanced growth and new revenue streams. The outsourcing trend in most U.S. industries was taking hold in biotech.	The financial and product development risks increased when each components was viewed on a commodity rather than value added basis. There was controversy over cloning and obsolescence as well as many ethical concerns were not addressed.
1980	Biotech firms tried to counter the long internal development and FDA approval cycles for a growing list of product innovations by licensing rights to larger partners primarily in the pharmaceutical sector and used their traditional marketing channels.	Pharma industry sentiment softened because some biotech firms were viewed as competitors and, where partnerships existed, many pharma firms used internal funds to booster their own slowing growth rates. Controversy over patents for GMOs decided by U.S. Supreme Court.
1970	Since public sentiment was favorable and external financing was available, many companies attempted to achieve a competitive advantage and market independence by vertical integration.	The large number of firms that attempted to use this 1970s business model diluted the available financing and management pool for high cash burn operations. Certain DNA experiments ceased.

Source: Adopted from Friedman (2006, 2014); PhRMA (2014); Industry Handbook: Biotechnology(n.d)

Table 7: Popular Strategic Planning Models

Strategic Planning Models	Classification or Type of Model
1. Stakeholder Analysis	Balancing of Forces
2. Seven S	Balancing of Forces
3. Five Forces	Balancing of Forces
4. SWOT	Balancing of Forces and Portfolio
5. Product-Mission Matrix	Portfolio
6. Boston Consulting Group	Portfolio
7 GE product Screen	Portfolio, Balancing and Life Cycle
8. Red/Blue Ocean	Portfolio
9. Product-Market Evolution Matrix	Portfolio and Life Cycle
10.Techology Adoption	Life Cycle

Source: Author's Notes Regarding Top Ten Strategic Planning Models

Appendix C

Table 8: MannKind Corporation – Events Timeline

2014	Regulatory Approvals	The FDA advisory panel voted 13-1 April 1, 2014 to recommend that the FDA approve Afrezza.
2013	Regulatory Filings	MannKind re-filed FDA application in October.
2013	Clinical Trials	MannKind announced positive results of Afrezza phase III clinical trials.
2013	Contracts and Agreements	MannKind entered into debt financing with Deerfield Management Company, L.P. Company explained July deal was designed to support regulatory process and commercial activities.
2012	Clinical Trials	MannKind completed patient recruitment for Afrezza phase III clinical trials.
2011	Regulatory Approvals	The FDA issued a complete response letter rejecting MannKind's NDA for Afrezza and requesting additional safety and efficacy data. After the FDA rejection, MannKind reduced its workforce by 41 % and CFO, Pfeffer, attributed the downsizing directly to this FDA action.
2010	Regulatory Filings	After rejection, MannKind re-filed NDA application with FDA in July.
2009	Mergers and Acquisitions	In June 2009, MannKind acquired Pfizer's remaining insulin assets.
2009	Regulatory Filings	In May 2009, the FDA accepted Mannkind's NDA for Afrezza, an ultra rapid-acting insulin.
2009	Contracts and Agreements	In March 2009, MannKind agreed to purchase Pfizer's manufacturing plant.
2008	Contracts and Agreements and Product Development	MannKind and Pfizer entered into a collaboration agreement in which Pfizer's Exubera product patients were transferred to MannKind's Technosphere Inhaled Insulin.
2008	Contracts and Agreements and Product Development	MannKind announced collaborative research agreement with the Leukemia and Lymphoma Society in May 2008 to develop blood cancer drugs for start of oncology product strategy.
2006	Clinical Trials	Patient enrollment was completed for a phase III safety study of Technosphere Inhaled Insulin for patients with diabetes.
2004	Initial Public Offering	In August 2004, MannKind completed an IPO of its common stock for $14.00/share.
2001	Contracts and Agreements and Product Development	One of Alfred Mann's firms, MiniMed, which designed insulin pumps was acquired by Medtronic August 2001. Medtronic decided not to continue insulin/diabetes programs. Mann purchased Pharmaceutical Discovery.
1997	Product Development	Pharmaceutical Discovery demonstrated inhaled insulin product to Mann.
1991	Establishment	Mannkind Corporation was founded.

Source: MannKind Corporation, 2013

Appendix D

Table 9: MannKind Corporation's Product Pipeline

Product Name	**Drug or Device**	**Therapeutic Area**	**Indication**	**Development Phase**
Afrezza Inhaled Insulin	Drug	Endocrinology	Diabetes Mellitus, Types 1 and 2	Phase III Clinical Trial (Complete)
Dreamboat Inhaler (for Afrezza)	Device	Endocrinology	Diabetes Mellitus, Types 1 and 2	Phase III Non-Inferiority Study (Complete)
Medtone Inhaler (for Afrezza)	Device	Endocrinology	Diabetes Mellitus, Types 1 and 2	FDA Approved
Technosphere Technology	Drug/Device Combination	Applicable to Many	Applicable to Many	Development Phase
MKC253 Inhaled Insulin	Drug	Endocrinology	Diabetes Mellitus, Type 1	Early Clinical
MKC1106-PP	Drug	Oncology	Solid Tumors	Phase I Clinical (Complete)
MKC1106-MT	Drug	Oncology	Advanced Melanoma	Phase II Clinical
MKC1106-NS	Drug	Oncology	Blood Cancer	Pre-Clinical
MKC204	Drug	Oncology	Blood Cancer	Pre-Clinical

Source: U.S. Securities and Exchange Commission, 2012

Appendix E

Table 10: List of MannKind Products with Forecasted Growth Rates and Global Market Size Classifications

Product Name	Niche	Compound Annual Growth Rate (CAGR) %	Size of 2017 Global Market ($B)	Market (Existing or New)
Afrezza Inhalable Insulin	Inhaled Insulin	Unknown	Unknown	Existing
Dreamboat Inhaler (for Afrezza)	Dry Power Inhalers	12.3	13.4	New
MedTone Inhaler (for Afrezza)	Dry Powder Inhalers	12.3	13.4	Existing
Technosphere Technology	Pulmonary Drug Devices	15.7	29.8	New
MKC253 Inhalable Insulin	Inhaled Insulin	Unknown	Unknown	New
MKC1106-PP MKC1106-MT MKC1106-NS MKC204	Cancer Drugs	7	100.5	Existing

Source: BCC Research, 2012; Trefis, 2014

Appendix F

MannKind Corporation financial data, 10-K reports and key financial ratios.

MannKind Corporation

(A Development Stage Company)

Condensed Consolidated Balance Sheet

(Unaudited)

(in thousands)

	December 31, 2009
Assets	
Current assets:	
Cash and cash equivalents	$ 30,019
Marketable securities	2,475
State research and development credit exchange receivable -- current	1,500
Prepaid expenses and other current assets	3,672
Total current assets	37,666
Property and equipment -- net	208,229
State research and development credit exchange receivable -- net of current portion	918
Other assets	584
Total	$ 247,397
Liabilities and Stockholders' Equity	
Current liabilities	$ 28,853
Senior convertible notes	112,765
Note payable to principal stockholder	165,000
Stockholders' equity (deficit)	(59,221)
Total	$ 247,397

Note: The original 2009 MannKind Balance Sheet was enlarged and edited for better alignment

Consolidated Statements Of Operations (USD $) In Thousands, except Per Share data, unless otherwise specified	12 Months Ended			275 Months Ended
	Dec. 31, 2013	Dec. 31, 2012	Dec. 31, 2011	Dec. 31, 2013
Revenue		$ 35	$ 50	$ 3,166
Operating expenses:				
Research and development	109,719	101,522	99,959	1,577,292
General and administrative	59,682	45,473	40,630	485,386
In-process research and development costs				19,726
Goodwill impairment				151,428
Total operating expenses	169,401	146,995	140,589	2,233,832
Loss from operations	(169,401)	(146,960)	(140,539)	(2,230,666)
Other income (expense)	(635)	(1,191)	1,541	(2,902)
Interest expense on note payable to principal stockholder	(6,309)	(10,491)	(10,883)	(45,134)
Interest expense on notes	(15,153)	(11,139)	(10,941)	(55,086)
Interest income	8	7	18	37,004
Loss before benefit for income taxes	(191,490)	(169,774)	(160,804)	(2,296,784)
Income tax benefit		408		382
Net loss	(191,490)	(169,366)	(160,804)	(2,296,402)
Deemed dividend related to beneficial conversion feature of convertible preferred stock				(22,260)
Accretion on redeemable preferred stock				(952)
Net loss applicable to common stockholders	$ (191,490)	$ (169,366)	$ (160,804)	$ (2,319,614)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.64)	$ (0.94)	$ (1.32)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	299,591	180,855	121,817	

Consolidated Statements of Operations (USD $) In Thousands, except Per Share data, unless otherwise specified	12 Months Ended			251 Months Ended
	Dec. 31, 2011	Dec. 31, 2010	Dec. 31, 2009	Dec. 31, 2011
Consolidated Statements of Operations [Abstract]				
Revenue	$ 50	$ 93		$ 3,131
Operating expenses:				
Research and development	99,959	112,279	156,331	1,366,051
General and administrative	40,630	40,312	53,447	380,231
In-process research and development				19,726
Goodwill impairment				151,428
Total operating expenses	140,589	152,591	209,778	1,917,436
Loss from operations	(140,539)	(152,498)	(209,778)	(1,914,305)
Other income (expense)	1,541	(725)	51	(1,076)
Interest expense on note payable to related party	(10,883)	(10,249)	(5,679)	(28,334)
Interest expense on senior convertible notes	(10,941)	(7,128)	(4,768)	(28,794)
Interest income	18	40	70	36,989
Loss before provision for income taxes	(160,804)	(170,560)	(220,104)	(1,935,520)
Income taxes				(26)
Net loss	(160,804)	(170,560)	(220,104)	(1,935,546)
Deemed dividend related to beneficial conversion feature of convertible preferred stock				(22,260)
Accretion on redeemable preferred stock				(952)
Net loss applicable to common stockholders	$ (160,804)	$ (170,560)	$ (220,104)	$ (1,958,758)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.32)	$ (1.50)	$ (2.07)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	121,817	113,672	106,534	

Consolidated Balance Sheets (USD $) In Thousands, unless otherwise specified	Dec. 31, 2013	Dec. 31, 2012
Current assets:		
Cash and cash equivalents	$ 70,790	$ 61,840
State research and development credit exchange receivable - current		450
Prepaid expenses and other current assets	5,485	4,520
Total current assets	76,275	66,810
Property and equipment - net	176,557	183,961
State research and development credit exchange receivable - net of current portion	298	313
Other assets	5,516	230
Total	258,646	251,314
Current liabilities:		
Accounts payable	3,860	4,555
Accrued expenses and other current liabilities	21,634	25,777
Facility financing obligation	102,300	
Senior convertible notes		114,443
Total current liabilities	127,794	144,775
Senior convertible notes	98,439	97,583
Note payable to principal stockholder	49,521	119,635
Other liabilities	13,605	
Total liabilities	289,359	361,993
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2012 and 2013		
Common stock, $0.01 par value - 550,000,000 shares authorized at December 31, 2012 and 2013, respectively; 286,035,082 and 369,391,972 shares issued and outstanding at December 31, 2012 and 2013, respectively	3,697	2,860
Additional paid-in capital	2,261,996	1,991,379
Accumulated other comprehensive income (loss)	(4)	(6)
Deficit accumulated during the development stage	(2,296,402)	(2,104,912)
Total stockholders' deficit	(30,713)	(110,679)
Total	$ 258,646	$ 251,314

Consolidated Balance Sheets (USD $) In Thousands, unless otherwise specified	Dec. 31, 2011	Dec. 31, 2010
Current assets:		
Cash and cash equivalents	$ 2,681	$ 66,061
Marketable securities	515	4,370
State research and development credit exchange receivable - current	0	674
Prepaid expenses and other current assets	2,625	2,849
Total current assets	5,821	73,954
Property and equipment - net	193,029	202,356
State research and development credit exchange receivable - net of current portion	473	629
Other assets	230	317
Total	199,553	277,256
Current liabilities:		
Accounts payable	4,624	3,294
Accrued expenses and other current liabilities	20,736	14,840
Total current liabilities	25,360	18,134
Senior convertible notes	210,642	209,335
Note payable to related party	277,203	235,319
Total liabilities	513,205	462,788
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2010 and 2011		
Common stock, $0.01 par value -200,000,000 and 250,000,000 shares authorized at December 31, 2010 and 2011, respectively; 127,793,178 and 131,522,945 shares issued and outstanding at December 31, 2010 and 2011, respectively	1,315	1,278
Additional paid-in capital	1,620,535	1,587,858
Accumulated other comprehensive income (loss)	44	74
Deficit accumulated during the development stage	(1,935,546)	(1,774,742)
Total stockholders' deficit	(313,652)	(185,532)
Total	$ 199,553	$ 277,256

MANAGEMENT EFFECTIVENESS

	Company	Industry	Sector
Return on Assets (TTM)	-92.13	-2.83	6.29
Return on Assets - 5 Yr. Avg.	-73.22	-3.57	14.14
Return on Investment (TTM)	-309.23	-2.20	19.42
Return on Investment - 5 Yr. Avg.	-97.23	-5.51	19.01
Return on Equity (TTM)	--	-7.11	20.28
Return on Equity - 5 Yr. Avg.	--	-13.30	19.59

GROWTH RATES

	Company	Industry	Sector
Sales (MRQ) vs Qtr. 1 Yr. Ago	--	1,947.84	30.25
Sales (TTM) vs TTM 1 Yr. Ago	-100.00	19.77	16.70
Sales - 5 Yr. Growth Rate	--	24.45	12.14
EPS (MRQ) vs Qtr. 1 Yr. Ago	3.49	-342.76	11.76
EPS (TTM) vs TTM 1 Yr. Ago	23.21	--	--
EPS - 5 Yr. Growth Rate	--	10.52	14.43
Capital Spending - 5 Yr. Growth Rate	-37.30	6.55	22.00

PROFITABILITY RATIOS

	Company	Industry	Sector
Gross Margin (TTM)	--	30.87	52.93
Gross Margin - 5 Yr. Avg.	--	45.80	53.25
EBITD Margin (TTM)	--	--	--
EBITD - 5 Yr. Avg	-408,135.41	-76.91	19.08
Operating Margin (TTM)	--	-317.74	10.96
Operating Margin - 5 Yr. Avg.	-460,211.31	-93.17	15.03
Pre-Tax Margin (TTM)	--	-365.06	10.91
Pre-Tax Margin - 5 Yr. Avg.	-512,770.81	-96.27	15.25
Net Profit Margin (TTM)	--	-364.73	7.10
Net Profit Margin - 5 Yr. Avg.	-512,541.59	-98.81	10.98
Effective Tax Rate (TTM)	--	31.09	24.47
Effective Tax Rate - 5 Yr. Avg.	--	16.94	29.05

Source**:** SEC, 2012; Thomas Reuters, 2014; MannKind Corporation, 2013

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