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Finding the Perfect Strategic Partner for an FDA Approved Drug

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Introduction

MannKind Corporation, stock symbol MNKD, burned $10 million in cash monthly to develop new insulin that could spare millions of people from the seventh largest cause of death but external funds were needed to avoid company demise (Markey, 2013). MNKD's losses mounted as it spent billions to develop the new drug (Afrezza) to help diabetics manage the dreaded disease and avoid having to stick themselves with needles (Seeking Alpha, 2014). Insulin usually had to be injected but Afrezza was fast acting dry powder and less intrusive since it could be inhaled. The Federal Drug Administration (FDA) approved it; but, Afrezza was not yet on the market, thus MNKD was unprofitable. The firm decided to find a partner that could bring Afrezza to market and provide needed funds. Pfizer, a large pharmaceutical (pharma) firm, had tried to market a similar product in 2006 and failed, costing the firm $3 billion (Macaluso, 2012). MNKD knew money and marketing were not the only things needed to make a drug successful. Management reviewed decision tools and processes that allowed them to select the best firm from a short list to market Afrezza and sustain their firm (Seeking Alpha, 2014).

Industry Background

Kale & Singh (2009) suggested industry characteristics were as important to strategic alliance success as key internal partner traits. Industry characteristics provided external opportunities and threats that allowed alliances to achieve success. The biotechnology industry was competitive and the top 1% created most of the revenue (The Industry Handbook: Biotechnology, n. d.). For biotechnology firms without profitable products, a major threat to long-term survival was lack of external financing (Rothaermel & Deeds, 2004). Thus, firms invested most of their resources in drug development and then partnered with pharma firms to market FDA approved drugs (Rothaermel & Deeds, 2004; The Industry Handbook: Biotechnology, n. d.). Strong strategic partners had internal traits such as a healthy network of Healthcare Professionals (HCPs) and involved seven other internal traits as shown on the short list of potential partners in Table 1.

Potential Strategic Business Partners

Several firms on the short list were capable of marketing Afrezza (see Table 1). Pfizer, Johnson & Johnson, Merck & Co. and Eli Lily & Co. were large, stable and diversified U. S. based firms. As point out, Pfizer failed with a similar product in the past and Eli Lily was the only one of the four that marketed the same type of insulin as Afrezza. The second largest pharma firm in the world, Switzerland based Novartis, had a weak reputation in the diabetes market. Swiss firm, Roche, was the third largest pharma company in the world; yet, failed to create a strong presence in the diabetes market. French based Sanofi ranked fifth in the world among big pharma and marketed the same type of insulin as Afrezza. UK based GlaxoSmithKline was the seventh largest pharma firm in the world but, similar to Novartis and Roche, they had not formed a strong presence in the diabetes market. UK firm, AstraZeneca, ranked tenth in big pharma, was a major player and successfully marketed many diabetes drugs. Danish pharma firm, Novo Nordisk, ranked nineteenth globally, had a vast diabetes pipeline and had a drug similar to Afrezza under development (Seeking Alpha, 2014). Kale & Singh (2009) placed all internal partnership traits into three categories (commitment, complementarity and compatibility) to analyze the scope and success of strategic interfirm relationships.

Table 1: Potential Partners for MannKind Strategic Alliance Formation (2013)

Company Name	Global Rank	US Rank	Revenue USD $M	No. of HCPs Paid	Gross Profit Margin	Diabetes Products Name/Description	Competing Products?	Complementary Products?
Johnson & Johnson	1	5	71,310	97,000	69%	LifeScan Ultra: Blood sugar meter Animas: Insulin pump	No	No
Novartis	2	6	56,670	64,500	69%	Starlix: Oral drug	No	No
Roche	3	2	52,310	NR	66%	Accu-Chek: Blood sugar meter	No	No
Pfizer	4	1	51,580	142,600	81%	Exubera: Inhaled insulin (discontinued); Ertugliflozin (Phase 3): Fast-acting oral	Yes, Ertugliflozin	No
Sanofi	5	9	52,300	NR	59%	Lantus: Long-lasting injectable insulin; Apidra: Fast-acting injectable insulin	No	Yes, Lantus, Apridra
Merck	6	3	44,000	81,300	62%	Januvia: Oral drug; Ertugliflozin (Phase 3): Fast-acting oral	Yes,Januvia, Ertugliflozin	No
GlaxoSmith Kline	7	7	43,900	85,100	68%	Avandia: Oral drug	No	No
AstraZeneca	10	11	25,700	111,200	77%	Oral: Onglyza, Symlin Komboglyze Farxiga; Injectable Exenatide: Inject, long-lasing	Yes, Exenatide	No
Eli Lilly & Co.	11	8	23,100	79,000	79%	Humalog: Fast-acting injectable	Yes, Humalog	Yes - Humulin
Novo Nordisk	19	13	15,400	NR	77%	Levemir: Long-lasting injectable	Yes, FIAsp	Yes - Levemir

Source: Seeking Alpha, 2014; Ornstein, Grochowski Jones & Sagara, 2014; Stock Analysis on Net, 2014

Company Background and Scope of Strategic Alliance Interfirm Relationships

Kale & Singh (2009) asserted the scope of interfirm relationships ranged from contractual to equity arrangements and determined strategic partnership success. MNKD was not yet profitable and stakeholders anxiously awaited a marketing partnership. Immediate financial distress moved many firms in this situation to focus on contractual deals that offered a sizeable upfront payment. Still, contractual arrangements such as large, up-front licensing fees tended to mean smaller future royalty payments (Pullan, N.D.). Since the CEO had substantial equity in MNKD and prior experience with partnerships, he was unlikely to settle for a licensing deal that failed to benefit himself and the firm long-term. Thus, he pondered whether all traits showed in Table 1 were equally crucial criteria for selecting strategic business partners (Seeking Alpha, 2014).

The Strategic Alliance Decision Challenge

Although arrangements that improved weak cash flow were important short-term MNKD needs, long-term sustainability was also important. The second most vital consideration for a strategic alliance deal was whether a firm had a strong presence in the diabetes market (Seeking Alpha, 2014). Most firms believed potential partners needed to have a proven ability to market diabetes products. Not far behind in terms of importance were established contacts with HCPs, a solid reputation, and expert diabetes knowledge (Seeking Alpha, 2014). Afrezza, along with new products by Eli Lily and Sanofi, was “fast-acting” insulin that worked quickly after use and lasted for a few hours (Seeking Alpha, 2014). In addition to knowledge about conventional diabetes treatment options, an ideal partner needed to be knowledgeable about fast-acting insulin. As a novel product, Afrezza required HCPs to become educated and trained about how it worked and how to use it – which was a potential barrier to market (Seeking Alpha, 2014). If this new type of inhaled insulin was not well received by HCPs, potential business partners would need to be very skilled in this area to avoid the risk it would miss patients who could reap the benefits.

The need for MNKD to find a partner was not as simple as finding a big pharma firm with an existing diabetes network, product platform and money to invest (Seeking Alpha, 2014). Although this trait or factor was not as important as previously mentioned company traits, direct competition with a partner’s existing or future diabetes product might entice a firm to become a partner for the sole purpose of making sure Afrezza never made it to market (Seeking Alpha, 2014). This scenario was a major threat to MNKD future royalty payments, which were desperately needed to continue operations. An ideal scenario was a firm with diabetes products that complemented Afrezza (Seeking Alpha, 2014). If Afrezza worked well for some patients but not others, a complementary product would work well for those patients who did not benefit from Afrezza. If you were CEO, what confidence for success did the short list create and what decision process and tool would you use to select the best strategic business partner in Table 1?

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