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LONDON, UK (GlobalData), 7 June 2012 - The head of global research and development (R&D) for **Sanofi**, Elias Zerhouni, stated on May 31 that the company intends to expand its presence in the **diabetes market** space. Currently, Sanofi markets Lantus (injectable insulin glargine from rDNA origin), and will likely be filing for a new drug application (NDA) of its once-daily GLP-1 receptor agonist Lyxumia (lixisenatide) in the fourth quarter of 2012. Consistent with Dr. Zerhouni's statement, it was reported on May 25th that Sanofi made a first-round bid of over $25/share for **Amylin Pharmaceuticals**
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Amylin currently markets three diabetes drugs, two of which will directly compete with Lyxumia. Amylin's first product, Byetta (exenatide), which was the first GLP-1 receptor agonist to reach the market, is a twice daily injectable that had gross revenue of almost $518 million in 2011. Bydureon (exenatide weekly injection) is Amylin's updated and longer-acting version of exenatide and is anticipated by some analysts to reach peak sales of over $1 billion. However, Bydureon had a difficult two year extension of the approval process, where Amylin had to prove that the drug did not cause cardiac arrhythmias. On top of that, Amylin entered into litigation and eventually severed ties with its marketing and development partner Eli Lilly. This resulted in an upfront payment of $250 million plus up to $1.2 billion in sales royalties in order for Amylin to procure exclusive marketing rights for the diabetes drug. These excess costs will also be a factor for Sanofi, as they will inherit this agreement should they succeed in acquiring Amylin. The FDA is also requiring Phase IV studies to show that Bydureon does not cause heart attack or other cardiovascular complications, thyroid cancer, or pancreatitis.

A major concern for Sanofi in this deal is cannibalization of its GLP-1 product Lyxumia with Amylin's Byetta or Bydureon, or vice versa. However, Lyxumia is a fourth to market product that does not show any significant clinical improvement over currently marketed GLP-1 receptor agonists. Therefore, regardless of the results of the acquisition, Lyxumia will not likely affect the US market significantly.

An acquisition of Amylin Pharmaceuticals would make Sanofi a more diversified player in the diabetes space, giving them rights to 3 of the 4 marketed drugs in the GLP-1 receptor agonist class along with their industry leading insulin glargine product, Lantus. Sanofi would also gain rights to Amylin's $100 million a year product Symlin (pramlintide injection), for patients not responding to other diabetes medications. However, Sanofi's newly acquired GLP-1 receptor

agonist compounds would have to compete against Novo Nordisk's Victoza (ligaglutide injection), which is the clear market leader. Victoza is a once daily therapy, which is not as attractive as Bydureon's once weekly regimen; however clinical results performed by Amylin showed that Victoza can be more effective as a control for blood glucose levels. Therefore, Sanofi would have to market all three of its GLP-1 products against each other as well as against Victoza, making it difficult to overcome acquisition costs. Sanofi would definitely need to streamline Amylin's processes and realize significant cost synergies in order to make the acquisition successful.

Sanofi needs to be cautious through the Amylin acquisition process, due to stiff competition from players including Merck & Co., who have also already made a bid in excess of $25/share. Takeda and Bristol-Meyers Squibb are also expected to make bids for the company as well. This will cause the cost of the acquisition to increase due to the number of players making bids, and could result in a bidding war. Sanofi must ensure that they are getting a high enough return on investment (ROI) for Amylin, which could be difficult as bid prices increase. The company also has to make sure that they adequately and effectively integrate Amylin into their portfolio. There is also the potential for corporate culture clashes should the French pharmaceutical giant decide to keep the San Diego biotech's operations open. Managing these culture differences will be imperative for the acquisition to be successful.

However, Sanofi may not have a choice but to acquire Amylin for no other purpose than to gain rights to Bydureon. With patent expirations due for Sanofi's Multaq (drondarone) and Renvela (sevelamar) in summer 2012 ($879 million annually), Sanofi/Bristol-Meyer Squibb's co-marketed Avapro (irbesartan) and Plavix (clopridogrel) having already expired earlier in 2012 ($10.6 billion annually), Actonel (risedronate) set to expire in June of 2014 ($217 million annually) and Lantus (injectable insulin glargine from rDNA origin) going off patent in February of 2015 ($4.5 billion worldwide annual sales), Sanofi will be looking for other blockbuster drugs, like Bydureon, to fill the void these drugs are leaving. Amylin has the potential to at least partially fill that space, meaning that it may not matter that the biotech, with its high acquisition costs (greater than $4 billion plus integration costs), upwards of $1.2 billion in royalty payments to Eli Lilly, product portfolio redundancy, potential for corporate culture clash, and Bydureon's uncertain future, is not the most attractive acquisition target for Sanofi. Either way, Sanofi is looking at an unsure future company-wide as well as in the diabetes market, and will be likely to make multiple acquisitions for later-stage pipeline or marketed products.