Closer Look

MEMORANDUM

MannKind 2Q14 and Afrezza commercialization partnership with Sanofi - August 12, 2014

Executive Highlights

- Sanofi and MannKind jointly announced a worldwide exclusive licensing agreement for the development and commercialization of MannKind's inhaled insulin Afrezza. Total upfront and milestone payments to MannKind will total $925 million plus profit sharing.
- The companies plan to launch Afrezza in the US in 1Q15.
- Sanofi emphasized the inhaled delivery of Afrezza (i.e., no injections) and the drug's complementary fit within Sanofi's late-stage portfolio.

Just eight hours following the initial press release, MannKind CEO Al Mann led a call with Sanofi's Senior VP of Diabetes Mr. Pierre Chancel to discuss the companies' commercialization partnership for Afrezza. Along with sharing additional deal terms, the call provided valuable commentary on why Sanofi is an ideal partner to bring MannKind's Afrezza to market. We were particularly impressed to see Mr. Chancel on the line, who emphasized the inhaled delivery of Afrezza (i.e., no injections), its potential in type 2 diabetes (those afraid of injections and those on MDI), as well as how the drug complements Sanofi's existing portfolio (especially the basal insulin, Toujeo). Below, we include our top seven highlights from the call followed by Q&A from the call. We've also included the short financial update and Q&A shared in MannKind's 2Q14 call just hours later. In this report's appendix, you will find perspectives on Afrezza from the dQ&A patient, educator, and primary care panels; our key questions; and our most recent Closer Look coverage of Afrezza.

1. The worldwide, exclusive Afrezza commercialization partnership includes total upfront and milestone payments to MannKind that total $925 million plus profit sharing (65% Sanofi/35% MannKind). Sanofi is responsible for global commercial, regulatory, and development activities, and MannKind will manufacture Afrezza at its manufacturing facility in Danbury, CT. The companies plan to launch Afrezza in the US in the first quarter of 2015. They will split expenses, which is still a great deal for MannKind to carry.

2. Sanofi was positioned as an ideal commercial partner to bring Afrezza to market - the cited strengths included a leading global commercial infrastructure; Sanofi's complementary product portfolio; a proven track record of creating a new insulin category, Lantus; clinical, regulatory, and development expertise; and ability to drive manufacturing efficiencies and improve margins. We agree and believe only reduced focus by Sanofi could change the potential.

3. Sanofi's Senior VP of Diabetes Mr. Pierre Chancel emphasized the inhaled delivery of Afrezza (i.e., no injections) and how the drug complements the company's late-stage portfolio. In particular, he characterized Afrezza as a valuable addition to the new basal insulin, Toujeo. Notably, Sanofi has the right of first negotiation regarding MannKind's inhaled formulation of GLP-1.

4. Based on commentary from both Sanofi and MannKind, the focus of Afrezza commercialization efforts will likely be on type 2 patients failing orals (insulin naïve) and those currently on MDI. Sanofi will still market Afrezza to type 1 patients.

5. Initially, Sanofi and MannKind will focus on commercializing Afrezza in the US, though other geographies (especially the EU and Japan) are planned.

6. Despite several investor questions, there were no details on Afrezza's pricing or Sanofi's commercialization strategy.

7. MannKind's abbreviated 2Q14 call provided a short financial update on the company. Given the cash infusion from the Sanofi agreement, management did not appear concerned about cash or financial resources going forward. No financial runway was provided and no guidance was set regarding sales or profitability.

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Top Highlights

1. The partnership call shared additional deal terms above those disclosed in the initial press release - total upfront and milestone payments to MannKind will total $925 million **plus** profit sharing ("superior economics," in the words of MannKind management). The deal gives Sanofi worldwide exclusive licensing rights for the development and commercialization of Afrezza. The companies plan to launch Afrezza in the US in the first quarter of 2015.

- **Sanofi is responsible for global commercial, regulatory, and development activities.** The clinical development will encompass: (i) FDA-mandated post-approval studies (including a long-term safety study); (ii) label enhancement trials; (iii) market access studies; and (iv) regulatory approvals in other jurisdictions. It is a major win for MannKind that Sanofi will take these efforts on, given the cost of these trials and the level of expertise needed to do them properly. The MannKind 2Q14 call later in the day clarified that these trials are included in the profit/loss-sharing agreement, of which MannKind has a 35% share.
- **MannKind will manufacture Afrezza at its manufacturing facility in Danbury, CT.** The companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary. Sanofi will buy Afrezza from MannKind at cost (a transfer price equal to the cost of goods). For more than ten years, MannKind has sourced insulin from Amphastar, an agreement that was expanded on July 31 for another five years. Amphastar's insulin is references in the NDA for Afrezza. MannKind is working to qualify Sanofi's insulin as an additional source of insulin, but based on remarks in the 2Q14 call, that sounds like it will take some time (e.g., CMC work, clinical studies, bioequivalence data). Once Sanofi's insulin is qualified, it's expected to help drive down the costs of Afrezza in the future. As background, in the 4Q12 call, MannKind management said that its factory can support up to two million patients, and the expectation was to launch at ~25% capacity.
- **Sanofi and MannKind will share global profits and losses (65% for Sanofi and 35% for MannKind).** Net profit will be calculated on a quarterly basis. To help MannKind fund its 35% share in the case of losses, Sanofi will provide a loan facility of up to $175 million. If MannKind elects to use this loan facility, it will be prepaid out of the company's future share of profits. The profit-sharing agreement does expose MannKind to losses, though we don't imagine these will last for many quarters given Sanofi's commercial expertise and the potential of Afrezza. The lower bioavailability of Afrezza relative to injected insulin has caused many to question its profitability; we imagine Sanofi did plenty of diligence on the margin/pricing side of things, and once the product

reaches sufficient scale, we don't imagine it will be an issue (particularly once Sanofi's insulin is qualified by regulators as a supply source).

- **MannKind will receive an upfront payment of $150 million and potential milestone payments of up to $775 million.** The milestone payments are dependent upon the following regulatory, development targets, and sales thresholds. Management emphasized that the cash will provide "needed capital to fund future and new products" (e.g., drugs requiring rapid delivery; drugs for lung disease).

MannKind/Sanofi Deal Terms	
Profit/Loss Split	65% Sanofi / 35% MannKind
Milestone Payments	
Up-Front Manufacturing/Development Upon EU approval Upon Japan approval	$150 million $75 million $30 million $20 million
Sales threshold milestones beginning at $250 million (in aggregate)	$650 million
Total Potential milestone payments (excluding profit sharing)	**$925 million**

- **In the MannKind 2Q14 financial update later in the day, management clarified the rationale behind the deal terms** - apparently, the deal structure was a significant source of investor questions following the partnership announcement. First, the upfront milestone payments were intended to recognize MannKind's significant investment in the product to date. MannKind management did compare the profit-sharing agreement to a traditional royalty-based deal using internal sales projections for Afrezza (not disclosed) - to obtain equivalent economics to the profit-sharing agreement, mid-20% royalties would be needed ("highly favorable"). Another benefit of a profit sharing deal is it continues as long as the product is sold - it does not expire with IP. Last, the profit sharing agreement also gives incentives for both companies to maximize revenue and minimize costs. Collaboration on the manufacturing front is expected to drive the latter down significantly. The 65%/35% split was intended to reflect the relative contribution of company resources going forward. There are customary protections on both sides to prevent overspending, and an annual budget will jointly be set each year.

2. Most of prepared remarks focused on why Sanofi is an ideal commercial partner to bring Afrezza to market. MannKind management made a persuasive case, later augmented by commentary from Sanofi's Mr. Pierre Chancel (see #2 below). Said MannKind CFO Matthew Pfeffer in the 2Q14 call, "If I had to pick two highlights of this agreement in my mind - it's their [Sanofi's] ability to make the sales number larger than anybody else I can think of, but also to make the margin percentages larger than anybody else I can think of." The following strengths of Sanofi were mentioned in the two calls:

- **Leading global commercial infrastructure -** MannKind management highlighted Sanofi's large and experienced diabetes field sales organization, which includes market access teams, medical science liaisons, and diabetes educators. For competitive reasons, no specifics were shared on the size of Sanofi's sales force, management believes the company's commercial presence will maximize the opportunity to bring Afrezza to the most number of patients. We would note that Sanofi is particularly strong in primary care, where most type 2 patients are treated and where it made Lantus the product it is today ($2 billion per quarter).

- **Sanofi's complementary product portfolio -** A slide cited five distinct categories in Sanofi's product portfolio in the following order: (i) BGM (MyStarExtra, BGStar, IBGStar); (ii) digital (MyStarConnect, diabeo, GoMeals); (iii) drugs (Lantus, Apidra, Lyxumia, Toujeo, Lixilan); (iv) patient support (diabeo, StarBern, MyStarCare); and (v) drug delivery (AllStar, JuniorStar, ClikStar, SoloStar). We would note that Afrezza shores up a key weakness in Sanofi's portfolio, as the company does not have an ultra-rapid-acting insulin in development (Novo Nordisk is in phase 3 with an ultra-fast-acting insulin aspart), nor a strong rapid acting insulin (by our estimates, Apidra had an approximate ~5% share of the global fast-acting insulin market in 2013).
- **A proven track record of creating a new insulin category, Lantus ("the world's best-selling insulin brand").** We think this is perhaps the most key experience Sanofi brings to the table, especially given the novel aspects of Afrezza (new delivery route, new PK/PD). We wonder how much of the learnings from successfully commercializing Lantus can be transferred over to Afrezza. Lantus came to market in 2001, where the type 2 diabetes drug landscape was very different - there were no DPP-4 inhibitors, no GLP-1 agonists, and no SGLT-2 inhibitors. Afrezza will have to compete with all three glycemic-dependent drug classes, though we assume its use will be most focused on patients already using insulin.
- **Clinical, regulatory, and development expertise -** MannKind management highlighted Sanofi's experience in obtaining approval and selling insulin in ~120 countries worldwide. As part of the agreement, Sanofi will take on clinical development efforts in the aforementioned four areas: (i) FDA-mandated post-approval studies; (ii) label enhancement trials; (iii) market access studies; and (iv) regulatory approvals in other jurisdictions.
- **Ability to drive manufacturing efficiencies and improve margins -** Once MannKind secures approval to source insulin from Sanofi, significant margin and cost improvements are expected. Management did not give a time horizon, but comments generally made this sound like a one-year-plus process.

3. Sanofi's Senior VP of Diabetes Mr. Pierre Chancel emphasized the inhaled delivery of Afrezza (i.e., no injections) and how the drug complements Sanofi's late-stage portfolio. Said Mr. Chancel, "From Sanofi's perspective, Afrezza fits perfectly into our portfolio of diabetes solutions. Afrezza is [also] an insulin option that does not require injection. This will help a substantial number of patients." He highlighted Toujeo (U300 basal insulin), Lyxumia (lixisenatide), and lixisenatide/Lantus ("LixiLan") as assets that will complement Afrezza rather than compete with it. Sanofi's goal, emphasized Mr. Chancel, is to bring a portfolio of complementary solutions to patients with diabetes - he called Afrezza a "really nice upgrade and combination into the Sanofi portfolio."

- **Mr. Chancel spent the most time in Q&A discussing Toujeo,** noting that it is longer and flatter than insulin glargine and leads to 30% less hypoglycemia. He even shared his view that Toujeo's hypoglycemia benefits beat Novo Nordisk's insulin degludec in the first two to three months of use (the titration phase) - this period is particularly important, he said, as approximately one-third of patients drop-off treatment. Last, Toujeo comes in a U300 formulation, reducing injection volume. Mr. Chancel highlighted that the unique profile of Toujeo combined with Afrezza will be a "very nice combination" in the basal-bolus regimen. As a reminder, this insulin is currently under review in the EU and US and stands to be the first next-generation basal insulin to reach the market.
- **Regarding Lyxumia,** Mr. Chancel only said that it has launched in Europe in "some countries" (sales were a modest ~$8 million in 2Q14). He reminded callers that Sanofi is awaiting results from the ELIXA CVOT (expected in 1H15, per Sanofi's 2Q14 update). Mr. Chancel also said that development of LixiLan (a fixed-ratio combination of Lantus and Lyxumia) continues - as a reminder, two phase 3 trials, LixiLan-O (ClinicalTrials.gov Identifier: NCT02058147) and LixiLan-L (ClinicalTrials.gov Identifier: NCT02058160) are currently recruiting; both studies have completion dates in August 2015. He did not specifically tie Lyxumia or LixiLan to Afrezza.

- **"The fact that you can provide people living with diabetes an insulin that does not need to be injected is something that has real value," said Mr. Chancel.** According to the dQ&A diabetes educator panel (n=401), "needles or injecting" is the number one concern among type 2 patients when it comes to starting insulin (43%), far more than "disease is now more serious" (26%); "impact on lifestyle" (10%); "cost" (7%); and others. We believe Afrezza's inhaled delivery has the potential to improve the clinical inertia associated with starting insulin, and also to reduce the real hassles of taking insulin from a patient perspective (e.g., injecting outside the home, stigma, etc.). It will be interesting to see if Sanofi/MannKind conduct future studies to show improved adherence with Afrezza over injected insulin.
- **Notably, MannKind's subsequent 2Q14 call shared that Sanofi has the right of first negotiation regarding an inhaled formulation of GLP-1.** As a reminder, MannKind shared very early data on this compound at GTC Bio 2014 - a study in healthy volunteers found that GLP-1 levels peaked within five minutes, the resultant insulin secretion peaked within ten minutes (confirmed by C-peptide readings), and glucose lowering peaked at ~30 minutes post-inhalation. The effects were fairly short lasting, due to GLP-1's short plasma half-life. MannKind's Dr. Andrea Leone-Bay emphasized that GLP-1 inhalation produced many of the pharmacological effects of GLP-1 agonist administration (including better fasting and postprandial glycemic control), but with a much lower incidence of nausea and less of an effect on gastric motility, a likely effect of the quick-in, quick-out PK/PD profile. Management emphasized that all R&D outside of Afrezza is still at an early stage, so we don't expect to hear much on this any time soon. Still, the potential upside could be very high, and we wonder if an inhaled formulation of lixisenatide is possible.

4. Based on commentary from both Sanofi and MannKind, the focus of Afrezza commercialization efforts will likely be on type 2 patients failing orals (insulin naïve) and those currently on MDI - management did not say this explicitly, but these were the main patient populations alluded to in both calls and Q&A. Assuming pricing is relatively at parity with rapid-acting analogs, we expect reimbursement should not be a major problem in type 2. The dosing is less of an issue in type 2, the phase 3 data showed more clear cut benefits, and we believe the improvements in adherence and clinical inertia would be stronger in . As a reminder, Afrezza has a broad label - "A rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus" (i.e., type 1 and type 2 diabetes).

- **That said, Sanofi will indeed market Afrezza to type 1 patients** - Mr. Chancel emphasized in Q&A that marketing to type 1s and type 2s will require different strategies, and Sanofi will market the product to both populations. Given that a "puff" is equivalent to four units of injected rapid-acting insulin (this was a surprise at approval, since we had heard three units previously), we do not view Afrezza as a primary rapid-acting insulin for type 1 patients, although it was studied in phase 3 as such. We do think Afrezza would be valuable as a very rapid correction dose (a "hyperglycemia rescue"), but given that it would be supplementing usual care, we believe type 1 reimbursement will be more challenging (though the voices will be loud and we do think type 1 patients will ultimately be successful in acquiring it if they have good coverage and if the studies - official and unofficial - show good ability to lower glucose levels fast).

5. Initially, Sanofi and MannKind will focus on commercializing Afrezza in the US. Europe and Japan were the next options mentioned, but there was no specific timeline attached to these opportunities. MannKind did design the Afrezza phase 3 trials towards what would be required for approval in Europe, though some of the requirements do differ from the FDA - it was not clear if new trials would be needed to support EU registration. Commercialization in Japan - where fear of injections tends to be higher than in the US or EU - would definitely require additional clinical trials. MannKind management emphasized that Sanofi is "extraordinarily good" at getting insulin products approved and on the market, though it seemed that these registrations would be medium- to long-term priorities.

6. Despite several investor questions, there were no details on Afrezza's pricing or Sanofi's commercialization strategy. Commentary only hinted that in discussions with Sanofi, MannKind

management was "very pleased" with Sanofi's planned strategic approach. Mr. Chancel did not divulge details on pricing relative to other insulins, sales reps, detailing (e.g., endocrinologists vs. PCPs), or anything else related to commercialization.

7. MannKind's abbreviated 2Q14 call provided a short financial update on the company. Cash and cash equivalents were $41 million at June 30, a slight rise from $36 million in 1Q14. In 2Q14, MannKind received $16 million in proceeds from warrant and stock option exercises in addition to $20.0 million in Tranche B notes purchased by Deerfield. In 2Q14, operating expenses totaled $70 million, a significant rise from $42 million in 2Q13. The increase stemmed from a $31 million rise in non-cash stock compensation expense (the settlement terms for certain performance-based awards were modified requiring reclassification of these performance grants from equity awards to liability awards). Given the cash infusion from the Sanofi agreement, management did not appear concerned about cash or financial resources going forward. No financial runway was provided, and given the uncertainty around Afrezza's commercial ramp, no guidance was set regarding sales or profitability.

- **In addition to Sanofi, MannKind has additional financial resources at its disposal.** On July 18, $40.0 million in Tranche 4 notes were purchased by Deerfield under the provisions of the previous facility agreement upon FDA approval of Afrezza. Currently, up to $70 million of additional sales of Tranche B notes to Deerfield remain available, and there is also $30 million of available borrowings under the amended loan arrangement with Al Mann.

Questions and Answers - Partnership Call

Q: With respect to the commercialization effort by Sanofi, can you share any level of primary care detailing? What do you expect to be the dollar value of their sales and marketing on an annualized basis?

MannKind (Mr. Matthew Pfeffer and Mr. Hakan Edstrom): We certainly have discussed this with them and looked at in great detail. We are not in a position to reveal that for competitive reasons. We are very comfortable with all the efforts that have been put into the deal by Sanofi.

Q: Do you have any assurance that they will maintain that same level of detail effort going forward?

MannKind: Yes. Certainly when looking at the opportunity of what we can create together, we don't see internal competition. That's not an area of concern to us.

Sanofi (Mr. Pierre Chancel): Afrezza is not going to be in competition with the existing portfolio of Sanofi. It's a very nice combination and upgrade of our portfolio. First, it's for patients that are insulin naïve and not under control on orals that are struggling to start insulin because of injections. But it's also for those on MDI and using it on top of basal insulin. Even if you can decrease the number of injections by one or two, it's already a big win. A lot of patients would like to have a decrease in injections. There is no competition between the existing and future portfolio of Sanofi and Afrezza. It's going to be bring a nice portfolio of complementary solutions for patients with diabetes.

Q: So is the market opportunity for Afrezza in patients that are naïve to prandial insulin, or more as an alternative to those already on rapid-acting insulin?

Sanofi: The current label is broad. This is going to be a solution for people that are insulin naïve and those on MDI. The size of the different opportunities and the size of the total opportunity is something that we have contemplated and analyzed. The source of growth will come from both populations.

Q: Can you expand on the strategy to sell Afrezza in type 1 and type 2 diabetes? Is there a different strategy between the two types?

Sanofi: These patients are different - in type 1 or in type 2s on MDI, or in type 2s that are insulin naïve. We will not disclose the details of the strategy; you can understand that for very sensitive reasons. But we certainly will be focusing on going after these two populations.

Q: On the European submission, can you give us a better sense of timing now that the deal has been disclosed.

Sanofi: We'll really be focusing on the US first. There are elements and projects that could lead to registration in Europe and other geographies, such as Japan. Fear of injections in Japan, in general, is probably more so than in other geographies. But we will focus on the US first.

Q: Could you help us understand the strategic purpose of the supply agreement with Amphastar?

MannKind: People forget that you cannot just change insulin at will. You must go through the process with the FDA and do the clinical testing. Amphastar is the insulin that is approved in the product today. Anyone launching a product that they expect to be successful would be prudent to have a supply and would qualify other sources. We certainly expect to qualify other sources, including that manufactured by Sanofi in the future.

Q: It sounds like a terrific deal. Can you talk about the Sanofi R&D pipeline and the products that are coming to market in the next year or two related to diabetes? And how do you plan to book the milestone payments - all at once or amortized?

Sanofi: Among late-stage compounds, we have Toujeo, our investigational new basal insulin. It has the potential to become the next world standard. It's a U300 formulation and has a very interesting profile leading to a different PK/PD - it's longer and flatter. Toujeo is a very interesting product when compared to Lantus - it's better than Lantus. But it's also better than insulin degludec. Why? Because it leads to much less hypoglycemia, both nocturnal and at any time of day. It's an almost 30% decrease in hypoglycemia, which is very important. Also, one of the very interesting advantages of Toujeo is that during the titration phase, which usually lasts two to three months, you get even less hypoglycemia than degludec or Lantus. This is important because this is during the period of time where people are very sensitive to the new initiation of insulin. This is where you have one third drop off of treatment. This is a new tool that will help people start on basal insulin. It also leads to less weight gain or no weight gain, depending on the patient. With this unique profile, along with three times less volume than other basal insulins, will be a nice combination with Afrezza in the basal bolus regimen.

Also, we have Lyxumia (lixisenatide). It's registered in Europe and has launched in some EU countries. We are waiting results from ELIXA in the US. We are also awaiting the launch, combination LixiLan in the same injection device. These are the main assets in the late-stage pipeline.

MannKind: We think we have the answers to that question. But until we clear the deal, we're not sure how the accounting will work. We'll have the cash up front, but over what period of time it will be recognized on the P&L is yet to be determined.

Q: Should we still assume Afrezza will be priced at parity to injected rapid-acting analogs? Will development and commercial costs be split 65/35?

MannKind: We're not going to talk about pricing specifically. The only thing I can say, from MannKind's perspective, is that in our discussions with Sanofi, we have been very pleased with the strategic approach to Afrezza entering the market. As far as profit-sharing, yes, all of the costs in the collaboration will be pulled together and it will be a 65/35 split. However, in the near term, we have an arrangement with Sanofi - as we do this calculation on quarterly basis, to the extent that there are losses in quarter, and we will be responsible for covering 35% of those losses, we can elect at that time to apply it to this loan facility. You can almost think of it as a revolving line of credit. We can apply it to the balance if we wish to carry it forward, or we can pay it if we have the cash. So yes, it's a split on a quarterly basis of the profits and losses as you go along. Likely losses for a short time in the beginning, and hopefully profits very soon.

And one of the very beneficial effects of a profit share arrangement is that the profit share continues as long as the product is sold. It does not expire with IP. We see this as an expanding market and opportunity for a long time. That's where profit share is a very beneficial arrangement.

Q: Can you talk about the manufacturing side of the agreement? What part of the fixed costs at the Danbury facility are not covered? How will you account for the cost of the Danbury facility during the collaboration?

MannKind: Danbury is dedicated to manufacturing of Afrezza. All the costs of that manufacturing will be absorbed into the product and put on the balance sheet as inventory. Ultimately it will be sold and end up in COGS. We expect our financial statements to change fairly dramatically having embarked on this agreement. That's because much of what's been in R&D historically will suddenly come out and be moved into products. Some of the traditional things in accounting that are typically associated with a product might not be. For example, there is a certain amount of admin overhead that might not be. Also, anything not related to Afrezza is not included in this agreement - there are efforts to develop other potential applications of the product, but they are early at this point. You will see some minor spending in that area. But those would not be passed along to Sanofi or absorbed in COGS.

Q: What is the manufacturing status at Danbury? What about the regulatory discussions you've been having?

MannKind: We've previously mentioned we've expanded manufacturing capacity in Danbury, even as we speak. We've had one commercial line in operation for some time now, and we are in the final stages of putting two additional lines in places. That will bring us to about a quarter scale at Danbury from a design spec. So we'll have a good amount of capacity for manufacturing there. That work is nearing completion now. And we'll have to go through the normal process of validation lots and then we'll start manufacturing final product well in advance of a Q1 launch.

I'm not sure what you mean by the regulatory process. Responsibility for regulatory will now shift to Sanofi. They will ultimately be responsible for those discussions. The FDA has already approved the factory, as has Sanofi.

Q: Will you do additional trials for ex-US markets?

MannKind: We did design the US trials with a view to what might be required primarily in the European market. But we need to sit down and do a full evaluation of what might be required. Regulatory requirements are a little bit different, though we certainly believe we are well under way. We know that the Japanese market will require additional clinical trials. We now have a partner who is extraordinarily good at this. They have successfully gotten insulin products approved and on the market in 120 different countries. We're happy to pass that along to someone much better qualified than us to do it, and we'll be cheering them on.

Q: Is the calculation for profit split simply Afrezza revenue minus sales efforts? Or are there other costs?

MannKind: Pretty much - it's anything associated with the product. Admittedly, most of those costs will be Sanofi's in the future. On our side, there is manufacturing and some product development in some different areas we have not disclosed. The bulk of spending is on Sanofi's side.

Q: So it's revenue minus COGS minus SG&A minus R&D? And MannKind will be made whole for COGS?

MannKind: We will transfer those materials to Sanofi at our costs. We will be reimbursed and made whole on that. We will share in the profits once there are profits on sales of products.

Q: How much Afrezza inventory is on hand?

MannKind: We don't have a whole lot of finished goods on hand. It's a couple of steps to do the final validation steps for manufacturing. That is underway right now.

Q: Can you estimate the value of that on hand?

MannKind: That's a little tricky. You won't see it on the balance sheet, since we've expensed it. From the point of approval, that will change. In the past, we had lots of raw materials and did not carry them on the books. We have in excess of five metric tons of insulin. It's pretty tricky to value that. A great deal of it came from the

Pfizer transaction. It's not yet approved for use in our product. It's very much upside to our model. We have not attempted to value it.

Q: Can you confirm that MannKind will not have its own sales force?

MannKind: Correct.

Q: Regarding the commercial effort, will it be an endocrinologist detail or a primary care detail? What will be the positioning of Afrezza for the sales force - is there a dedicated group for whom Afrezza will first be detailed?

Sanofi: We cannot disclose the commercial effort. We'll make sure that it's a progressive effort. We must make sure, and want to make sure, that the first experience with Afrezza is a positive experience from a patient and physician standpoint. We will do everything to ensure they have a positive experience with Afrezza.

MannKind: Disclosing those commercial efforts are not very good from a competitive standpoint. They did disclose them to us, and we are quite thrilled with their planned approach. That's about as much as we can say about it.

Q: Congrats on securing this deal for Afrezza. Looking at the partnership from a bigger picture perspective, this was a multi-player process. Sanofi was selected because it could deliver something others could not. What attracted Sanofi to this opportunity? How do we ensure that the interests of both companies are aligned. Any sales force commitment detail would be helpful, if you can provide it. Is there an estimate of what post-market studies will cost?

Sanofi: What attracted Sanofi - we have a current portfolio and products to come that include Toujeo and LixiLan, and we want to expand our integrated care solution. There is something absolutely innovative for us. We know insulin quite well and we know patients and physicians. The fact that you can provide people living with diabetes with an insulin that does not need to be injected is something that has real value. It's a very nice fit with our portfolio. It's a really nice upgrade and combination in Sanofi's portfolio. This is quite clear. On the commercial efforts, I understand that you have the question, but for competitive reasons we cannot really disclose anything. We know our customer, we know the patients, we know the physicians, and we know the barriers.

MannKind: On the partnering process, we really conducted a robust process. Diabetes is global and the opportunity attracted a lot of companies. We feel very comfortable with the opportunity to work with Sanofi. There are not competing activities from inside the company. Another significant feature of Afrezza is the kinetics and dynamics. It's the first insulin that really rises to a peak about as fast as pancreatic insulin, and it doesn't last in the postprandial period causing hyperinsulinemia (a major cause of hypoglycemia in current therapy). It fills a poorly met need.

Questions and Answers - MannKind 2Q14 Call

Q: Can you give any commentary on the post-approval studies? What are the projections on what the total cost might be, how long they might take; are these included in the cost-sharing agreement?

A: They are absolutely included in the cost-sharing agreement. It's difficult to predict the precise costs. Those efforts are underway with the FDA. Early next year we will be at a better point to estimate costs. It's too speculative right now. They are certainly included in collaboration agreement.

Q: What do you think your longer term G&A and R&D costs run rate might be, once this agreement is established.

A: Some do and some don't. Most of the costs through the agreement are COGS. Product development work could flow through that. What our future P&L will look like is complex. Some is being formed as we speak. Look at our recent cash G&A (we had some extraordinary non-cash expenses from stock compensation), and that's somewhat representative. But some of those costs will go away as well. Continuing R&D is primarily non-Afrezza R&D. It's not a tremendous amount. I don't think the R&D numbers will drop to nothing by tomorrow, but as we shift costs to Sanofi, or capitalize them into inventory, they will disappear off the P&L.

Q: When you're profitable, what would be the diluted share count, if you include options in the money and warrants in the money?

A: Oh boy, I should have that number. Once you reach profitability, you will rope in those securities...Why don't I get back to you with the right number.

Q: Will Sanofi make an effort to sell Afrezza? What is optimal way to market Afrezza?

A: We have really good answers to those questions, but they are not things we can talk about. We spent a dramatic amount of time going over this with Sanofi, getting comfortable with their approach, and the amount of resources they are going to devote. As you heard on the call from their global head of diabetes, they consider much if not all of that proprietary. I can tell you, we are pleased and thrilled and excited with some of the approaches that they are taking. There is nobody literally in the world that can do a better job marketing it and making it the huge success that has the potential to be. We have to wait and see.

Q: How should we view R&D going forward? Afrezza focused?

A: We definitely have plans to do R&D. There are exciting possibilities for using the technology in other applications. We view this as a platform technology with exciting applications; you will hear more from us in the future. That's the obvious next question post-Sanofi. Sanofi does have right of first negotiation if we take a formulation of inhalable GLP-1 forward. But they don't have rights for other compounds.

Al Mann: They also have rights to our new process.

We have not disclosed that yet, Al. [Laughter] If there are other enhancements to Afrezza, you can anticipate that would be included in an agreement like this.

Q: Is there engagement with their pipeline for your technology?

A: Nothing formal in the agreement. There are the customary things that we are not trying to compete against each other in the space. You'll see the customary things in the agreement.

Q: Is Sanofi contractually obligated to provide PCP details? Or is it just commercial best efforts?

A: It's difficult to prescribe certain limits like that into an agreement like this beyond "commercial best efforts." That said, these efforts are dictated by a joint advisory committee of which we have an equal amount of representation - so we have a lot to say about it. They have certainly presented their initial plans to us and satisfied us with what they're going to. It will be difficult to back away from that in the near-term. But you won't see it in the agreement.

Q: Regarding the income statement, how will that look in terms of revenues once they start to appear for Afrezza?

A: You've hit the most common question for people trying to model this deal. That's also the one we have the greatest trouble answering. We were making minor tweaks to this arrangement as recently as last week - some of which the auditors have used as an excuse to go back and re-evaluate and question how we might do some of this. It may end up appearing in different places on the income statement. I could speculate, but I could prove to be wrong too. We know mechanically how it will work, but how it will appear on an income statement is harder to answer.

Q: How should we think about modeling COGS?

A: We haven't given a lot of disclosure there. It's a supply agreement, and we are obliged to sell product to Sanofi at cost. That is our intention. The ultimate profit for such sales will flow through and drop down to the bottom line. We will sell at costs, and we have not said what our cost structure is at this point.

It's important to note that one of the unique aspects of this arrangement with Sanofi is their ability to help us in the supply chain and drive down our costs. I'm hoping that number will change and go down over time. If I had to pick two highlights of this agreement - it's their ability to make that sales number larger than anybody

else I can think of, but also the ability to make the margin percentages larger than anyone else I can think of. That also influenced why we ended up in a joint venture kind of arrangement.

Q: Is there some kind of cap on annual expenditures from MannKind? Is there any way to prevent Sanofi from forcing you to spend too much?

A: Our obligations are somewhat limited other than manufacturing, and some enhancements in the product itself, which Al alluded to earlier. We don't see that as a major problem. There are protections on both sides for overspending. We will be spending according to a budget. We both have caps. They cannot charge an infinite amount for sales and marketing. Those are all pretty customary.

There is a joint Afrezza committee, and as part of that, each fall we will be looking at the annual budget for the upcoming years. We will be reach an agreement based on the plans in place for spending that would be forthcoming. If it changes dramatically, the companies can get together and determine where an intelligent investment is going forward. We do have some say in what that budget says.

Q: What is the composition of your senior notes, maturities, interest rates, etc.? If I recall it's pretty complicated.

A: Deerfield was pretty complicated. Other than that, it's pretty simple. We have one convertible debt out there that matures in August of 2015. We hope that it will in fact convert, as it's mostly been in the money in recent months. Our debt to Deerfield is coming in different tranches; it's all essentially six year debt. The earlier tranche was at an interest rate of 9.75%; the later debt is at 8.75%. The debt to Al is under $50 million, which is small compared to what it once was. The debt to Al doesn't have a certain maturity, and we pretty much dictated that we cannot pay that debt until we pay off Deerfield.

Q: So only August is convertible and everything else is straight debt?

A: Right, everything else is straight debt.

Q: What is the fully diluted share count? It went from 34 million in 2011 to 128 million in 2012, down to 78 million last year. Do you have a sense directionally since end of last year?

A: As you might guess, a lot of those things will have flown through - non-cash expenditures, warrants, and options outstanding. The numbers are down substantially, but I'm not sure what they're down to. You can see the quarter end numbers, but they have changed significantly in the intervening months.

Q: Regarding labeling, have you had any additional discussions with Sanofi? What do payers and endocrinologist think about the current label? What about the need for pulmonary function tests?

A: They did extensive market research, both qualitative and quantitative, prior to getting into the depth of negotiations with us. I don't necessarily have the information - it's proprietary But Sanofi is very comfortable in regards to the opportunity, and they got feedback from endocrinologist and diabetologists. That's the only information I have at this point in time. There is a comfort level within Sanofi.

Q: Can you update us on the 12-unit cartridge? How much additional preparation is needed with that application?

A: Regarding the 12-unit prep for the supplemental NDA, that is completed; we are talking days, maybe weeks, but that will be submitted. That is well underway and is part of plans going forward.

Appendix

DQ&A DATA ON AFREZZA

Below, we have summarized recent dQ&A patient, diabetes educator, and PCP panel data related to Afrezza. Overall, the data really underscores that unmet patient and provider needs that Afrezza fulfills. We believe the drug should be fairly well received among type 2 patients, diabetes educators, and PCPs once it comes to market next year. For more information, please email clients@d-qa.com or call +1 415 817 1246.

- **In 3Q13, dQ&A conducted a product concept test of "inhaled insulin" in 2,334 patients with type 2 diabetes.** After describing and showing the product profile (that of Afrezza, but unnamed), the phase 3 results, and its key risks (cough, decrease in lung function) and benefits (similar A1c reduction to injected rapid-acting analogs, less hypoglycemia for some patients, a small weight loss), patients were asked:
    - **If this new form of insulin were approved as safe and effective by the FDA, and recommended by your doctor as an additional blood glucose control medicine, how likely would you be to take it?** Only 10% of those on orals said they would definitely take this inhaled insulin, compared to 15% of those on orals+basal insulin and 21% in those on orals+MDI. A sizeable number of patients said they would be more likely to take the inhaled insulin if it allowed them to stop one of their other diabetes medications - 38%-59% reported they would be more likely to take the drug, compared to 33%-50% that were neutral.
- **Diabetes Educators (n=401) were asked for their opinions on starting and intensifying insulin therapy in type 2 diabetes.** On average, educators said that about a quarter of their patients should be starting insulin, and another quarter should be intensifying insulin. This group reported that a striking 42% of patients resist or postpone starting insulin, and another 34% of patients resist or postpone intensifying insulin. The biggest patient concern in starting insulin is "needles or injecting," followed by "disease is now more serious," "impact on lifestyle," "cost," and other criteria.
- **Primary care physicians (n=138) were also asked for their opinions on starting and intensifying insulin therapy in type 2 diabetes.** Notably, 88% of respondents reported that the PCP is the only provider that decides to start insulin (vs. 11% for "PCP and endocrinologist" and 1% for "endocrinologist only"). The same trend was true for insulin intensification. Similar to the educator data, the biggest patient concern in starting insulin is "needles or injecting," followed by "disease is now more serious." Respondents report that on average, 30% of their patients delay starting on basal insulin therapy (median), 25% delay starting on premix insulin, and 30% delay their start on basal-bolus insulin.

KEY QUESTIONS

Q: How will Sanofi price Afrezza? If Sanofi prices at parity to other rapid-acting insulins, we do not envision reimbursement in type 2 diabetes will be an issue.

Q: Regarding commercialization, will Sanofi pursue a similar strategy as that used for Lantus? Will learnings from the commercialization of Lantus be translatable to Afrezza?

Q: At what point in the spectrum of type 2 diabetes will Sanofi position Afrezza? How will it complement Sanofi's Lantus, U300 glargine, Lyxumia, and Lixi/Lan?

Q: How will Sanofi approach the label, both from a clinical and reimbursement perspectives? The current label's hypoglycemia and weight sections only discuss the type 2 diabetes data - at what pace will Sanofi seek to expand the label?

Q: How will Sanofi work toward obtaining a more-rapid-acting claim for Afrezza vs. current rapid-acting analogs? (the current label does not have this, as noted in our report on the approval)

Q: How will payers perceive the advantages of Afrezza for type 1 and type 2 diabetes? Who will be the first payer to reimburse Afrezza as a "complement" for type 1s rather than a substitute for their current insulin? How loudly will type 1 patients demand this?

Q: Could compelling adherence data be collected that would demonstrate significant advantages of Afrezza?

Q: How much of a hassle will pulmonary function testing be?

Q: What role will MannKind play in automated insulin delivery?

RECENT CLOSER LOOK COVERAGE OF AFREZZA

- FDA approval of Afrezza (June 27)
- MannKind's 1Q14 call
- April 1 FDA Advisory Committee

-- by Adam Brown and Kelly Close