CLOSER LOOK

MEMORANDUM

MannKind 3Q17 - Afrezza sales rise 28% sequentially to $2 million, $4.7 million YTD; Huge commercial opportunity with ultra-rapid-acting label update - November 13, 2017

Executive Highlights

- In 3Q17, sales of inhaled insulin Afrezza grew 28% sequentially and more than tripled YOY to $2 million. Management emphasized strong volume growth, with new-to-brand prescriptions up 37% sequentially and total prescriptions up 29% sequentially from 2Q17. That said, management also mentioned that full year Afrezza revenue will likely come in at the low end of $6-$10 million guidance (YTD sales in 2017 sum to $4.7 million).
- Perhaps the most exciting news for MannKind in 3Q17 came from FDA, with the approval of a label update reflecting Afrezza's ultra-rapid-acting time action profile. We imagine this will be powerful on the commercial front. The company began rollout of the new label almost immediately, and announced that all sales teams were trained on the ultra-rapid-acting claim at live meetings throughout October.
- A pediatric PK study of Afrezza was initiated in 3Q17, while the investigator-led STAT study using CGM to compare time-in-range between Afrezza vs. Novo Nordisk's NovoLog (insulin aspart) completed earlier this month and will report results in 2018.

MannKind provided its 3Q17 financial update in a recent call led by CEO Mr. Michael Castagna. Sales of inhaled insulin Afrezza grew 28% sequentially to $2 million, from a base of $1.5 million in 2Q17. Year-over-year (YOY), sales more than tripled from $600,000 in 3Q16, though this only covered ~two months of the quarter following MannKind's relaunch of Afrezza in late July 2016. Management anticipates full year 2017 sales at the lower end of the $6-$10 million guidance previously provided - Afrezza has posted $4.7 million YTD ($1.2 million in 1Q17, $1.5 million in Q2, and $2 million in Q3). Thus far, the company has recorded revenue on the product when patients pick up their insulin prescription at a pharmacy, but beginning January 1, 2018, sales will be recorded as Afrezza is shipped to wholesalers. This implies greater commercial traction for the product, with stronger patient uptake. Indeed, management shared that new-to-brand prescriptions (NBRx) were up 37% sequentially between 2Q17 and 3Q17 and that total prescription volume (TRx) was up 29% sequentially. In our view, this is good progress considering the various commercial and financial challenges that MannKind has encountered in the last two years, from discontinuation of the Sanofi partnership in early 2016 (which required the company to build its own commercial infrastructure from scratch, in order to market MannKind-branded Afrezza), to the risk of NASDAQ delisting in September 2016 (this was resolved just in time for the company's 4Q16 update), to sluggish early sales of Afrezza following relaunch. Mr. Castagna emphasized this progress during prepared remarks, stating "this is the first time since I've been here that we've had this much cash on hand, where we can discuss investment opportunities versus conserving cash." MannKind had $20.1 million in cash and cash equivalents as of September 30, which does not include the $57.7 million in net proceedings gained from the registered direct offering of common stock in October.

Perhaps the most exciting news for MannKind in 3Q17 came from FDA, with the approval of a label update reflecting Afrezza's ultra-rapid-acting time action profile. The revised product label includes data showing onset of insulin action within 12 minutes, peak effects within 35-45 minutes, and a return to baseline PK/PD ~1.5 hours after dosing with a 4-unit cartridge or ~3 hours after dosing with a 12-unit cartridge. Management suggested that HCPs have been particularly interested in this last component of the label change, because the long tail associated with other mealtime insulin options leads to greater

unpredictability and heightened hypoglycemia risk. Elaborating further, management explained that it's extremely helpful for patients/providers to have a clear and quantified sense of how long it will take to return to baseline after bolusing. On a call with investors shortly after the label change was announced, Mr. Castagna referred to the FDA approval as a "pivotal moment" in MannKind's history- promotional activities around Afrezza will no longer have to state that the product's time action profile is comparable to that of insulin lispro (Lilly's Humalog), when in fact it is meaningfully faster. We imagine this will be powerful for MannKind on the commercial front. The company began rollout of the new label almost immediately, and announced that all sales teams were trained on the ultra-rapid-acting claim at live meetings throughout October. We hope the revised label and MannKind's revamped commercial strategies serve to make more patients aware of Afrezza as a very viable mealtime insulin option (expanded patient choice is almost always a win, in our view, and we note that patient feedback on Afrezza to-date has been quite positive).

- **MannKind's clinical program for Afrezza is progressing on track, with a pediatric PK study initiated in 3Q17 and expected to complete in January 2021, per ClinicalTrials.gov.** Estimated enrollment for this phase 2 trial is 46 children, between 4-17 years-old, with type 1 diabetes. According to management, four participants have been enrolled already, and the study will be extended to seven additional sites in the next 30-60 days. The company plans to launch the phase 3 pediatric program in 2018.
    - **Moreover, management announced that the investigator-led STAT trial wrapped-up earlier this month, and that data will be presented in 2018.** We are very eager to see these results, comparing time-in-range (a key outcome beyond A1c - we can't emphasize this enough) between Afrezza vs. Novo Nordisk's NovoLog (insulin aspart) using CGM. There were some heavy-hitters conducting the STAT study, including renowned diabetes thought leaders Drs. Satish Garg, Bruce Bode, and Anne Peters.
    - **MannKind also announced a new investigator-initiated trial during the company's 3Q17 update, the open-label Levin study, which will evaluate new initiation of Afrezza mealtime therapy in type 2 diabetes patients uncontrolled on oral agents, basal insulin, and/or GLP-1 treatments.** Estimated enrollment is 40 adults with type 2, and the trial is expected to complete in April 2018 according to ClinicalTrials.gov. MannKind seems focused on expanding Afrezza uptake within the type 2 patient population, with studies like this, promotion of higher-count cartridges to support higher bolus doses, and previous comments from management about how the split between Afrezza users with type 1 vs. type 2 diabetes is about 50/50 right now, even though type 2 represents >90% of diabetes in the real world. Management remarked that the RCT with One Drop (n=~400), beginning in October 2017 and expected to complete in February 2019, is also a way to focus on people with type 2 diabetes.
    - **A study incorporating Afrezza into closed loop systems is slated to start at Yale within the next few weeks.**
- **In July, MannKind debuted its first television campaign for Afrezza, using a theme of "unexpected moments" when inhaled rapid-acting insulin comes in handy.** You can also watch the ~one-minute commercial on YouTube. Management shared that a targeted TV campaign has been accelerated up from 1Q18, and launched early. Knowing that Afrezza is commercially-responsive, the company is confident investing in these TV campaigns and in the swift commercial rollout of the label update.
- **Management also shared that the company has submitted Afrezza to regulatory authorities in Brazil.** MannKind is in "late-stage discussions" with other ex-US regulators, and we look forward to seeing how Afrezza performs in global markets.

-- by Payal Marathe and Kelly Close