CLOSER LOOK

MEMORANDUM

MannKind 2Q16 - Afrezza relaunch begins to positive early indicators; cash goal to last as far into 2017 as possible; label update filing in Sept-Oct with titration & PK/PD updates - August 9, 2016

Executive Highlights

- MannKind had ~$64 million in cash remaining as of June 30, with the goal of lasting as far into 2017 as possible.
- Management outlined early performance indicators for MannKind-branded Afrezza, which relaunched last week: a 40% rise in new-to-brand prescriptions (up "roughly from 84 to 116" in the past few weeks); over 300 requests from the new sample program; and an increase in co-pay card claims and enrollments. It's still very early, and execution will be the name of the game as the new sales force works to gain traction in 3Q and 4Q16.
- MannKind will file for an Afrezza label update with the FDA in September or October, seeking to include PK/PD data and better instructions on titration and dose optimization. The company also plans to file with the FDA for pediatric indication though we don't have timing on this.

MannKind provided its 2Q16 update yesterday in a call led by CEO Mr. Matt Pfeffer. Management shared an optimistic, albeit very early view on Afrezza performance. The inhaled insulin was relaunched by the company last week, following Sanofi's partnership termination earlier this year. We include our top six highlights from the call, followed by Q&A.

1. MannKind has ~$64 million in cash remaining as of June 30, which it hopes to extend as far into 2017 as possible.

2. Management outlined early performance indicators for MannKind-branded Afrezza (relaunched last week) and cited a very small rise in new-to-brand prescriptions - up "from roughly 84 to 116" in the past few weeks. The company has received over 300 sample requests (we assume from in-the-know HCPs) in two weeks. While it's hard to read too much into these metrics at this stage, given how challenging access and logistics have been, and given that former partner Sanofi put relatively little resources into both, it's positive for MannKind to see this increase, even from a very small base.

3. The company has also seen a small increase in co-pay card claims and enrollments and redemptions: claims rose from 69 as of July 29 to 80 as of August 5, while actual rose from 17 to 37 over the same weeklong period. The new program prices Afrezza as low as $15 for each prescription, depending on insurance coverage. We look forward to learning more on this front.

4. In rebranding Afrezza, the company will shift its strategy from underscoring the "inhaled" piece to instead highlighting the "fast-acting" piece. We think this is astute to distance Afrezza from Exubera, and of course, to appeal to what patients desire: faster insulin. The first consumer-facing print ad will come in mid-to-late September; direct mail ads will target patients aged 45-55 years.

5. MannKind plans to file for a label change with the FDA in September or October, including the PK/PD studies presented at ADA as well as better instructions on how to titrate Afrezza.

6. The company intends to file for a pediatric indication for Afrezza in the US and possibly other jurisdictions. The filing will be based on the company's JDRF-partnered study of Afrezza in pediatric patients.

TOP SIX HIGHLIGHTS

1. MannKind has ~$64 million in cash remaining as of June 30, which it hopes to extend as far into 2017 as possible. This shows some improvement from 1Q16, when the company had ~$28 million in cash as of March 31. The influx of cash is primarily from ~$47 million in net proceeds from a new public offering in May, ~$9 million from Sanofi for the sale of insulin inventory following termination of the Sanofi License Agreement, and ~$1 million from a Connecticut R&D tax credit. Management was optimistic about cash burn moving forward, noting that within 3-4 weeks of new sales reps marketing MannKind-branded Afrezza in the field, the company saw the end of a nine-month period of declining profits that began in September 2015 and finally stabilized in July of this year. That said, net loss in 2Q16 totaled $30 million, up from $25 million in 1Q16. Through an agreement with The Mann Group, MannKind has ~$30 million available for borrowing, plus $50 million available from an at-the-market facility. The company owes $70.3 million to Sanofi (including $4.3 million in accrued interest), which is fortunately not due until August 2024.

- **The call further shared that, with the exception of its inhaled epinephrine formulations, other pipeline projects were intentionally decelerated in 2Q16 to preserve cash** and channel resources into setting up Afrezza for commercial success. During Q&A, management shared that the "bottom line" for the company is a "laser focus" on Afrezza - "everything else will follow." No surprise there.

2. Management outlined early performance indicators for MannKind-branded Afrezza (relaunched last week) and cited a very small rise in new-to-brand prescriptions (NBRx) - up "roughly from 84 to 116" in the past few weeks. It's obviously still in the extremely early days post re-launch and strong sales in 3Q and 4Q16 will be critical. Remarks noted, however, that the incremental rise in NBRx occurred without meaningful distribution of samples over the last six months. Management shared that in the time since the sample program launched two weeks ago, the company has received over 300 requests for samples (we assume from in-the-know, savvy HCPs). Distribution will be ramped up in the next couple weeks.

- **Management said that the decline in prescriptions between January and June of this year stemmed from provider uncertainty** as to whether or not Afrezza would still be commercially available in the second half of 2016. Now that MannKind is commercializing on its own, we'll be interested to see if prescriptions ramp faster than they did with Sanofi at the helm.

3. MannKind has also seen an increase in co-pay card claims and enrollments. According to presentation slides, claims for a co-pay card rose from 69 as of July 29 to 80 as of August 5, an increase of about 15%, while actual enrollments in the co-pay program more than doubled from 17 to 37 over the same weeklong period. Co-pay cards are only available online right now though physical cards will be available in doctor's offices this week, which may prompt further upswing in claims and enrollments. As we noted last week, the company is promoting the MannKind Cares patient reimbursement support program to tackle one of the key obstacles patients have faced to date - access to better reimbursement. The co-pay card program can reduce out-of-pocket expenses to as low as $15/month, depending on insurance (if patients do not have any insurance plan, the cost is far higher). As part of the re-launch effort, MannKind is also streamlining the prior authorization process for Afrezza, with the goal of shortening a patient's wait time to a few days at most. Notably, the company is also offering a better in-office spirometry solution.

4. In rebranding Afrezza, MannKind will shift its strategy from underscoring the "inhaled" element of the marketing to instead highlighting the "fast-acting" nature of the product. Marketing and communication about the product will focus on speed of action, drawing on data presented at ADA 2016 that demonstrated the faster onset and shorter duration of action of Afrezza vs. Humalog. As a reminder, the label does not currently contain this data, limiting "ultra fast insulin" marketing - we think this is unfortunate, since the "real world" feedback on Afrezza is all about the speed of Afrezza as well as the lack of hypoglycemia. Moving forward, the company will pursue dose optimization trials and other efforts to allow for more aggressive titration of Afrezza. The goal is to position the product as a convenient and easy-to-titrate mealtime insulin option. We think this is prudent to distance Afrezza from Exubera, which was hard to use, hard to titrate, not faster acting, and an inhaled delivery mechanism with safety problems.

- **Management also discussed other strategic advertising efforts (mostly digital) that will play out in 3Q and 4Q16:** (i) the first consumer-facing print ad is expected in mid- to late-September - as we understand this, this delay related to FDA requirements, not a decision by former partner Sanofi; (ii) the consumer website will be updated and will emphasize Afrezza's faster speed of action; (iii) a digital campaign using various social media will pop up by mid-September; and (iv) MannKind will promote Afrezza through direct mail ads, targeting patients aged 45-55. Execution will be the name of the game as the new sales force must gain substantial traction to put up strong numbers in 3Q and 4Q16 - it will be interesting to see how successful tactics involving social media are.

5. MannKind plans to file for a label change with the FDA in September or October to include the PK/PD studies presented at ADA and better instructions on how to optimize dose and titrate Afrezza. This is an example of what management characterized, quite aptly in our view, as capitalizing on market trends that will favor Afrezza. For example, new technologies such as CGM have resulted in patients being more aware of glucose out of range; as a result, some patients are seeking tighter control and HCPs may work to create personalized care strategies that involve Afrezza. If granted by the FDA, a revised label that makes clear the fast-acting nature of the insulin product and that enhances dosing and titration will greatly expand the market potential for Afrezza. Management also mentioned two other studies on Afrezza published in June and July: a post-meal dosing simulation published in DT&T and a paper on Afrezza's PK/PD profile published in JDST. In our view, anything that enables the company to discuss more broadly the faster-acting nature of Afrezza is terrific. Although we aren't sure if the studies showed this, real-world feedback on Afrezza nearly always includes the lower rates of hypoglycemia that patients on the insulin seem to experience.

6. MannKind intends to file for a pediatric indication for Afrezza in the US and possibly other jurisdictions. No timing was shared. The filing will be based on the company's JDRF-partnered study of Afrezza in pediatric patients. Undoubtedly, as management implied, the JDRF partnership will be important in establishing Afrezza as a safe and efficacious mealtime insulin that will enable providers and patients to more easily reach treatment goals.

Questions and Answers

Q: Can you tell us more about other applications of Technosphere?

A: We would expect to see a similar PK/PD profile for other agents with this technology that we see for Afrezza, so we have targeted drugs to include in our portfolio where this very rapid change in blood levels would be effective. This includes migraine, parathyroid hormones, some pain medications are also being considered. At the JP Morgan conference, we did provide a longer list. Necessarily, however, we've been starved of resources and dollars for these other candidates in our portfolio. We need to concentrate on Afrezza first. The bottom line is our laser focus on Afrezza, and everything else will follow.

-- by Payal Marathe, Helen Gao, Adam Brown, and Kelly Close