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Zacks Small-Cap Research

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MannKind Corp (MNKD-NASDAQ)

Q1 2019 Update: Product Sales Up 49% on 71% Growth in Demand. Product Margin Continues to Expand

LLY and NVO trade at an average of ~5.5x forward sales. Given MNKD's much more rapid estimated percentage revenue growth, we apply that same multiple to our forecasted 2021 Afrezza sales of $116M, which values the Afrezza portion at approximately $3.40/share. Our 10-year DCF uses a 15% discount and values the TreT collaboration at approximately $105M, or ~$0.56/share. Our sum-of-the-parts calculation puts total value of the company at ~$4.00/share.

Current Price (05/13/19)	$1.23
Valuation	**$4.00**

OUTLOOK

Management's priority in the near term will be to continue their marketing strategy aimed at educating prescribers and patients on the benefits of Afrezza and, ultimately, on driving adoption and usage. While greater marketing spend is benefiting higher sales, it does come at the expense of increased cash burn and an elevated expense base. The company plans to fine tuning TV ad campaigns strategically in their various territories.

We continue to think MNKD's approach will pay dividends over the long-term and we support their strategy of leading their awareness-building efforts with a science-based approach. While educating entrenched 'old-school' injected-insulin delivery prescribers on the clinical benefits of inhaled insulin (specifically of Afrezza) is undoubtedly an uphill climb, we think the ever-growing database of proven clinical benefits of Afrezza will progressively soften the traditional insulin-only mindset. Meanwhile, indications are that patients that try Afrezza largely do find quality-of-life benefits – this stickiness, we continue to think, represents the major catalyst to steepening the adoption and utilization curves for the product.

SUMMARY DATA

52-Week High	**$3.04**
52-Week Low	**$0.94**
One-Year Return (%)	**-32.43**
Beta	**2.56**
Average Daily Volume (sh)	**3,112,965**
Shares Outstanding (mil)	**188**
Market Capitalization ($mil)	**$231**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**30**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Medical Technology**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	3 A	4 A	5 A	16 A	28 A
2019	17 A	15 E	16 E	18 E	66 E
2020					96 A
2021					145 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.25 A	-$0.16 A	-$0.16 A	-$0.06 A	-$0.60 A
2019	-$0.08 A	-$0.06 E	-$0.08 E	-$0.08 E	-$0.31 E
2020					-$0.22 E
2021					-$0.12 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q1 2019 Update: Product Sales Up 49% on 71% Growth in Demand. Product Margin Continues to Expand..

MannKind reported financial results for their first quarter ending March 31st and provided a business update. As it relates to the financials, total revenue was $17.4M, which included $5.1M in product sales and $12.4M in collaboration revenue. This compares to our estimates of $21.6M of total revenue, $5.7M in product sales and $27.3M in collaboration revenue. Our sizeable miss on collaboration revenue is largely immaterial as it reflects a difference in anticipated-versus-actual timing of recognition of the $12.5M initial milestone under the UTH TreT development agreement. As a reminder, that agreement paid MNKD $45M upfront plus up to an additional $50M in development milestones. MNKD received the first $12.5M in Q1 and anticipates receipt of the second and third in 2H'19 and 1H'20, respectively.

Meanwhile, while product sales (i.e. Afrezza sales) of $5.1M were about 10% ($590k) shy of our estimate, it appears that based on prescription demand, all of the difference is attributable to inventory burn-through at the wholesale and retail channels. While net product sales increased 49% yoy, management noted on the call that prescription demand actually increased an even more robust 71% (which compares with our estimated 66% yoy growth rate).

The Afrezza ad campaign ran for 11 weeks, spanning the end of January through the end of March of this year. The campaign was targeted at ten markets with a goal to build awareness and drive utilization of Afrezza. While management is awaiting data from Symphony to provide an update on the specific outcomes of the DTC campaign, CEO, Mike Castagna indicated that the early metrics have been positive as they have been witnessing growth in prescribers.

Voucher programs have also aided in adoption. Afrezza total prescriptions increased by 28% and 37% yoy with and without vouchers, respectively to 7,736 and 7,118 TRx. While TRx fell by about 11% from Q4'18 to Q1'19, the decline may be related to challenges associated with seasonality occurring in the first six weeks of the quarter as it relates to reauthorizing patients. Management is of the opinion that ad campaigns can slowly-but-surely change the way patients manage their diabetes as they get acquainted with Afrezza. Also, informing patients through ads can change their conversations with physicians, who might be more willing to write prescriptions. We continue to be encouraged by MNKD's evidence-based approach towards educating both physicians and patients of the clinical and quality of life benefits of Afrezza as compared to traditional insulin delivery.

Also encouraging is that COGS related to Afrezza remained largely flat at roughly $4 million. Q1 marked the second consecutive quarter (and second quarter in history) of Afrezza generating positive gross profit. Gross margin expanded from 62% in Q4 2018 to 68% in Q1 2019. Product margin grew from 13% to 21% over the same period. Management expects that continued growth of Afrezza sales and, absent any significant inventory write-offs, that they will generate positive product gross income in every quarter of 2019.

Research and development expenses came in around $1.6 million, declined 37% quarter-over-quarter and were 60% below our estimates. The decline in expenses was driven by reduced clinical trial activity. We had forecasted higher expenses related to commencement of work of TreT and possibly RLS' candidate. Selling expenses increased by 70% (18.6 million), compared to the same quarter in the prior year, largely related to $9.3 million spend on television ad campaigns for Afrezza. Some of that was offset by a restructuring of sales territories and personnel which resulted in a decrease of $1.2 million. General and administrative expenses for the quarter were ~$7 million. Total SG&A was largely inline with our $23.3M estimate.

As it relates to liquidity, the company exited the quarter with more than $59M in cash and short-term investments, which includes the initial $12.5M UTH milestone. MNKD used $11.6M in cash (or $13.8M, ex-changes in working capital) for operating activities in Q1. Subsequent to Q1, MannKind repaid the $2.5M Tranche B Deerfield note. Another $9M comes due in July. Near-term capital should be bolstered by another $25M in UTH milestones, which are anticipated over the next ~12 months.

Business Update

A-One, an investigator-initiated randomized control trial, was conducted in 400 Type 2 diabetics (T2D) patients to evaluate inhalable insulin and digital therapy. Results demonstrated that people with T2D using the integrated digital diabetes care platform with Afrezza improved their A1c. The results were presented at the 2019 Advanced Technologies & Treatments for Diabetes (ATTD) conference in February 2019.

Subsequent to quarter-end, MNKD presented additional data supporting the ultra-rapid acting profile of Afrezza at the American Association of Clinical Endocrinologists (AACE 2019) annual scientific meeting. The data continues to demonstrate that Afrezza closely approximates the time-action profile of physiologic insulin needs after a meal in patients with T2D, provides significantly better control of early post-prandial glucose levels and its onset uniquely affects early post-prandial glucose levels.

Interim results from Dr. Phil Levine's study involving 40 subjects will be presented at the ADA. In this trial, T2D patients' HbA1c levels were not within recommended guidelines when treated with oral agents, basal insulin or GLP-1 for 6 months. Pediatric study data could also be available in the near term. As a reminder, cohort 1 (ages 13 – 17 years) of their ongoing (safety and PK) pediatric study completed in September 2018. MannKind is guiding for cohort 2 (ages 8 – 12 years) to complete in the coming months and follow with commencement of cohort 3 (ages 4 – 7 years). If all goes well, a Phase III pediatric study could commence before current year-end. Assuming eventual positive results of the Phase III study, this could significantly expand the market for Afrezza and provide a meaningful complementary revenue source for MannKind.

Management's priority in the near term will be to continue their marketing strategy aimed at educating prescribers and patients on the benefits of Afrezza and, ultimately, on driving adoption and usage. While greater marketing spend is benefiting higher sales, it does come at the expense of increased cash burn and an elevated expense base. The company plans to strategically fine tune TV ad campaigns in their various territories.

We continue to think MNKD's approach will pay dividends over the long-term and we support their strategy of leading their awareness-building efforts with a science-based approach. While educating entrenched 'old-school' injected-insulin delivery prescribers on the clinical benefits of inhaled insulin (specifically of Afrezza) is undoubtedly an uphill climb, we think the ever-growing database of proven clinical benefits of Afrezza will progressively soften the traditional insulin-only mindset. Meanwhile, indications are that patients that try Afrezza largely do experience quality-of-life benefits – this stickiness, we continue to think, represents the major catalyst to steepening the adoption and utilization curves for the product over the long term.

Valuation

We use a sum-of-the-parts methodology to value MNKD, applying a P/S multiple to the Afrezza portion of the business while using DCF to value the UTHR collaboration related to TreT. Our model and valuation are subject to updating, including incorporating other collaboration candidates, if and when we feel there is enough information with which to base reasonably-confident assumptions (including related to RLS) – which could provide upside to our current target price.

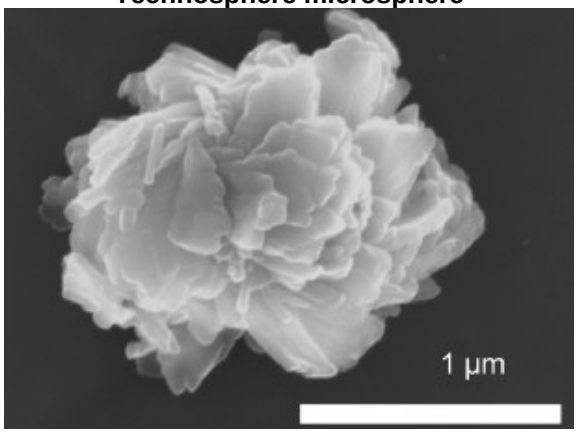
LLY and NVO trade at an average of approximately 5.5x forward sales. Given MNKD's much more rapid estimated percentage revenue growth, we apply that same multiple to our forecasted 2021 Afrezza sales of $116M, which values the Afrezza portion at approximately $3.40/share. Our 10-year DCF uses a 15% discount and values the TreT collaboration at approximately $105M, or ~$0.56/share (which is subject to our 35% risk-of-failure discount). Our sum-of-the-parts calculation puts total value of the company at ~$4.00/share.

INVESTMENT THESIS

Technosphere technology

MannKind's Technosphere drug delivery technology is built around a proprietary excipient called fumaryl diketopiperazine. FDKP is a pH-sensitive organic molecule that, when exposed to acidic conditions, self-assembles into small particles (i.e. 'microparticles') through a hydrogen bonding process. These microparticles have a large surface area and high porosity (~60% - 80%), allowing for the absorption of a variety of therapeutic substances. Certain therapeutic peptides and proteins, such as human insulin, can be combined with FDKP and encapsulated within the microspheres. These microparticles (with a median diameter of ~2.0mcm to 2.5mcm) are then freeze-dried into a powder formulation suitable for pulmonary inhalation.

Technosphere microsphere



Inhaled drug delivery…

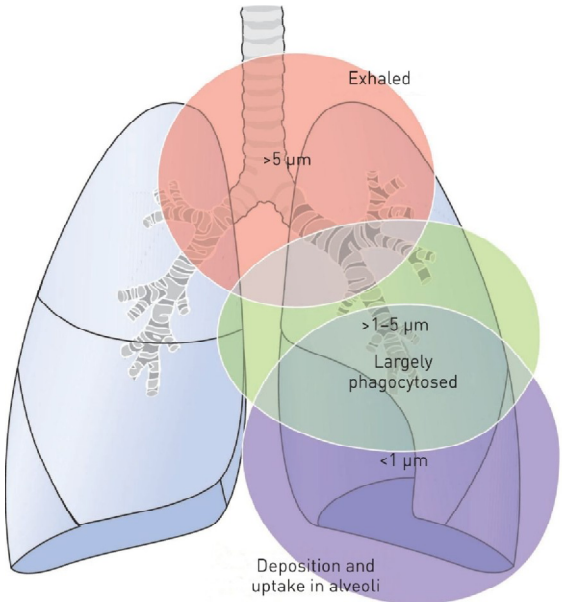
Inhalation not only represents an alternative to traditional drug delivery, but offers significant advantages to both oral and injected (i.e. subcutaneous, or sc) administration. Delivery into the lung circumvents the harsh environment of the gastrointestinal tract and, given that levels of metabolism are much lower in the lung, inhaled delivery avoids hepatic first-pass metabolism. User-friendliness including ease of self-administration and pain-free dosing are attractive features as compared to subcutaneous and intravenous methods. But inhalation's benefits go beyond patient convenience and can also include significant clinical advantages – much of which is possible due to the extraordinary gas-exchange efficiency of the lungs.

Keep in mind that while inhalation avoids certain difficulties that other forms of administration must overcome (such as hepatic metabolism), that they face an environment riddled with it its own challenges and characterized by the likes of mucus, macrophages, lung volume, air flow, absorption and coughing, among others.

Unique properties of Technosphere Insulin…

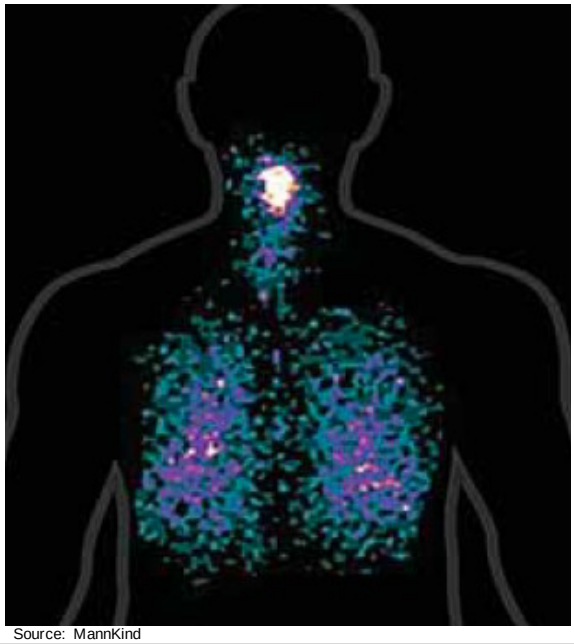
It is the unique properties of Technosphere that separate it from other inhaled delivery medium's (such as that used for Exubera) and which make it such a particularly effective and versatile inhaled therapeutic platform. The size and aerodynamic shape of Technosphere microparticles allows for fast and efficient travel through the air and into the lungs. And with more than 90% of the microparticles in the respiratory range (i.e. >0.5 µm and <5.8 µm), Technosphere technology is optimized for deep inhalation into, and uniform dispersion throughout, the lungs. Additionally, Technosphere pH-activated powders are quickly dissolved in the interstitial fluid immediately after inhalation and coming into contact with the characteristically neutral pH conditions of the lung. This results in ultra-rapid absorption into the circulatory system, avoidance of peripheral circulatory degradation and high bioavailability.

Technosphere particles have an average diameter of~2.5 µm, well within the 1 µm to 5 µm range that is necessary for inhaled therapies to reach the deep lungs



Source: Sabine H. van Rijt et al. Eur Respir J 2014;44:765-774

Image of technetium-labeled Technosphere insulin particles shows deep penetration into and uniform dispersion throughout the lungs

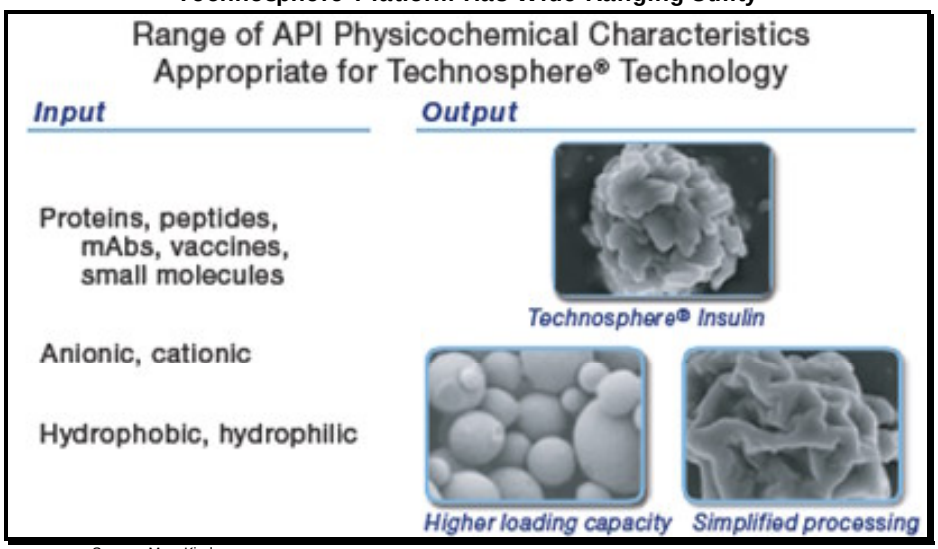


Source: MannKind

Technosphere is a platform technology…

Technosphere was developed as a platform technology applicable to a large assortment of various therapeutic biologics. While peptides and proteins (most notably insulin and, more recently, treprostinil) have been the most significant focus for MannKind, Technosphere has shown to be capable of absorbing molecules of various types and sizes. In addition to peptides and proteins, this includes anionic and cationic drugs, hydrophobic and hydrophilic drugs and small molecules and ranging in molecular weight from 500 to 140k Da.

Technosphere Platform Has Wide-Ranging Utility



Source: MannKind

Afrezza…

Afrezza, built on the Technosphere platform technology, is a prescription rapid-acting dry powder form of human insulin. Unlike traditional insulin therapy, which is administered by subcutaneous injection, Afrezza dry powder insulin is inhaled into the lungs through the use of a proprietary small portable inhaler. It is the only inhaled insulin available in the U.S. Afrezza, received FDA approval in June 2014 to control high blood sugar in adults with both type 1 and type 2 diabetes and became available in U.S. retail pharmacies in February 2015.

Afrezza is protected by more than 566 issued patents in the U.S. and elsewhere and is the subject of over 200 pending patent applications. Among these are composition patents and inhaler and cartridge patents which expire at various dates through the year 2032. Method of treatment patents extend out to 2031.

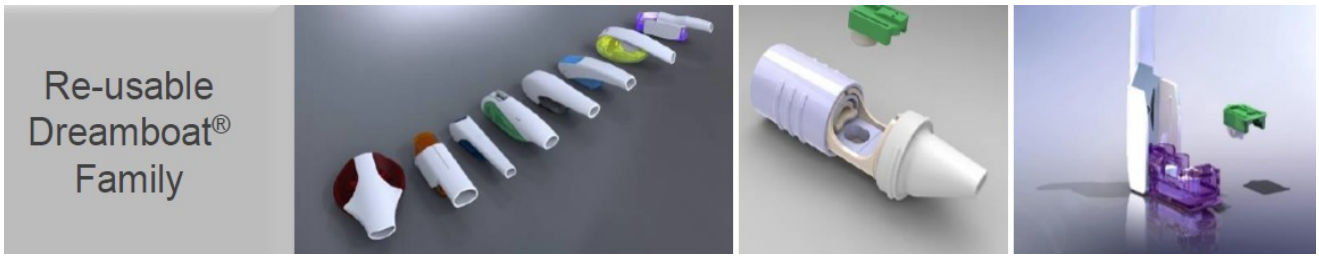
The dry powder is packaged in single-use cartridges and color-coded for three different starting doses. A supplied conversion table (below) allows users to estimate the appropriate Afrezza starting dose based on corresponding injected insulin dose (note that Afrezza's label was recently updated to include language on adjusting dosing).

Converting from injected mealtime insulin

INJECTED MEALTIME INSULIN DOSE	AFREZZA DOSE	# OF CARTRIDGES NEEDED		
		4 UNIT (BLUE)	8 UNIT (GREEN)	12 UNIT (YELLOW)
UP TO 4 UNITS	4 UNITS			
5-8 UNITS	8 UNITS			
9-12 UNITS	12 UNITS	+		OR
13-16 UNITS	16 UNITS			
17-20 UNITS	20 UNITS		+	
21-24 UNITS	24 UNITS			

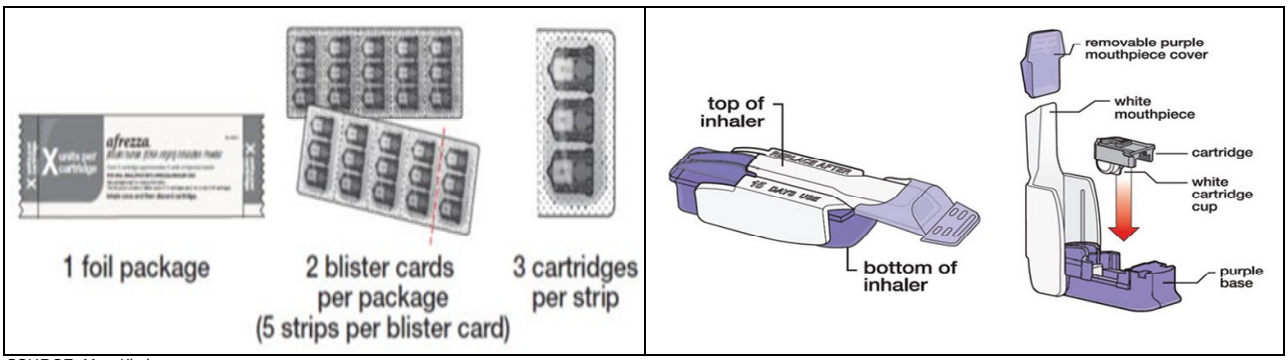
Source: MannKind

Two (Dreamboat) reusable (for up to 15 days) inhalers are included in each Afrezza package. MNKD's proprietary inhalers were designed to be inexpensive, efficient and simple to use – all attributes that are important for driving patient compliance. MNKD's marketing literature notes that their Dreamboat inhalers deliver more than 90% of powder formulations to the patient with approximately 70% of that in the respirable range. This, again, speaks to the unique properties and related benefits of the Technosphere technology including the size and shape of the microparticles and their ph-activation.



Source: MannKind

Each foil package of Afrezza insulin contains a total of 30 cartridges (3 cartridges per blister strip x 5 blister strips per card x 2 blister cards). Afrezza insulin has a minimum shelf life of 24 months if refrigerated and 10 days if stored at room temperature. To administer, a patient simply removes a dose-appropriate number of cartridges from their package and, with the mouthpiece lifted to a vertical position, loads a cartridge into the inhaler. After the mouthpiece is closed, the user exhales, places their lips around the mouthpiece, then inhales deeply and holds their breath. The spent cartridge is discarded and, depending on an individual's particular prescription, the process is repeated.



SOURCE: MannKind

Primer on blood glucose and insulin glucose control
The benefits of inhaled insulin (as compared to subcutaneous insulin) are largely two-fold; more user-friendly administration and clinically-proven 'superior glucose control'. While we cover Afrezza's action profile in more detail later in this report, a quick primer of what we characterize as 'superior glucose control' might be helpful to fully understand the benefits of Afrezza in the context of managing diabetes and in improving diabetics' quality of life.

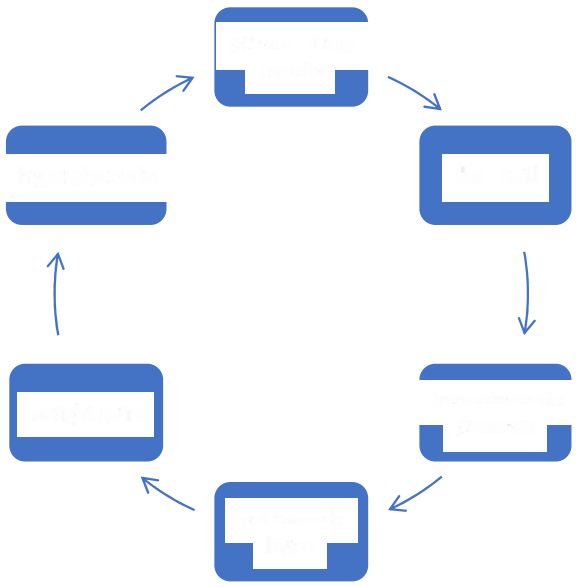
Glucose is created when the body breaks down carbohydrates. In healthy individuals, excess glucose is stored in the liver, which it then releases into the blood as-needed. Insulin and glucagon are hormones that regulate how much and when glucose is stored and how much and when glucose is released into the blood. Diabetics have compromised insulin function, which means if not controlled with exogenous insulin, their blood glucose will rise to unhealthy levels (hyperglycemia).

Fear of hypoglycemia increases risk of severe health outcomes associated with hyperglycemia…
Hyper- and hypoglycemia result if a diabetic's blood sugar is not properly controlled. Hypoglycemia is when blood glucose has become too low – generally considered 70 md/dl or lower. Initial symptoms include hunger, tiredness, sweating, nausea and irritability. If not addressed, hypoglycemia can result in severe confusion, seizures and unconsciousness. Unfortunately, 'addressing' hypoglycemia for diabetics usually means eating and eating, of course, results in weight gain and risk of hyperglycemia.

When glucose rises above 180 mg/dl a person has become hyperglycemic (frequently referred to as 'high blood sugar'). Initial symptoms may not be noticeable and if they are, are mostly confined to annoyances or slight discomfort – such as frequent urination, increased thirst and headaches. Chronic hyperglycemia, which insulin-using diabetics are at-risk of if the disease is not properly controlled, can be much more serious and result in severe weakness, chronic wounds, nerve and organ damage, blindness and even death.

In the context of this report, the important take-aways relative to these two potential outcomes is that hypoglycemia is largely confined to being an unpleasant side effect of exogenous insulin – as a result, diabetics often either skip mealtime insulin in order to avoid hypoglycemia (risking serious hyperglycemia outcomes) or take their mealtime insulin and then eat more (often 1 to 2 hours after a meal), often resulting in weight gain. Neither choice is a healthy option. As such, if an exogenous insulin were shown to significantly reduce the risk of hypoglycemia, diabetics would be less prone to skipping mealtime dosing and, by extension, would not be exposed to the serious health risks associated with hyperglycemia or the never-ending cycle of fighting high blood sugar with (too-long tailed) mealtime insulin and the resultant hypoglycemia with food.

Viscious Cycle of Injected Insulin

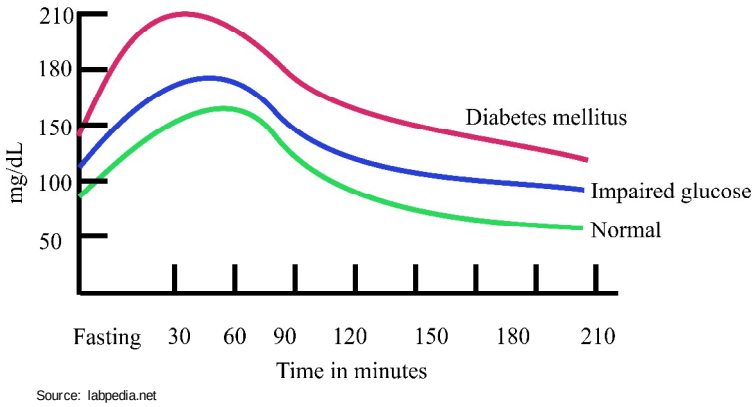


The most common risk of meal-time insulin (as disclosed on the labels of each product) is hypoglycemia which is a significant contributor to lack of adherence to treatment guidelines. Despite the feverish pace of technological advancements in diabetic care, including introduction of 'novel' rapid and long-acting injectable insulin, personal mini-pumps and continuous glucose monitoring, there has been no significant change in the percentage of

diabetics (~50%) that regularly reach their A1c goals. In fact, some studies (Carls et al., Casagrande et al.) indicate that among diabetics that use injected insulin, fewer are actually reaching recommended the HbA1c target of <7% today as compared to a decade (or more) ago. Much of the reason why so many diabetics do not reach their A1c goals has to do with them skipping mealtime insulin – and, as discussed, much of skipping mealtime insulin has to do with fear of hypoglycemia. This is what makes Afrezza such a compelling product – as detailed below, Afrezza's time-action-profile directly addresses the issues of hypoglycemia and resultant health risks of hyperglycemia.

Insulin functioning: healthy versus diabetic…

The chart below illustrates blood glucose curves of a healthy individual compared to that of someone with impaired insulin function and with that of a diabetic. As the graph illustrates, blood glucose spikes to peak levels within 30 minutes after a meal and, in the case of diabetics, can rapidly exceed the recommended maximum of 180 md/dl. However, even the impaired and diabetic insulin curves, while elevated, begin to return to baseline within 60 minutes and have nearly returned to baseline within two hours. Below, compare these to how Afrezza and subcutaneous insulin control blood glucose.



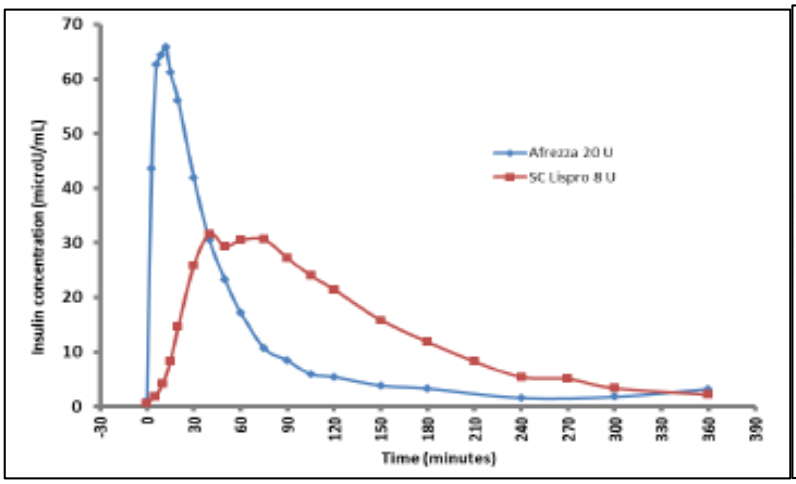
Source: labpedia.net

The graphs below compare Afrezza (at different doses) to subcutaneously-delivered insulin on two of the most significant parameters related to how well insulin manages blood glucose and, by extension, how it effects a diabetics' quality of life. These graphs (dose-ranging study vs human insulin) were included as supportive documentation in the regulatory filing seeking FDA approval of Afrezza in 2013.

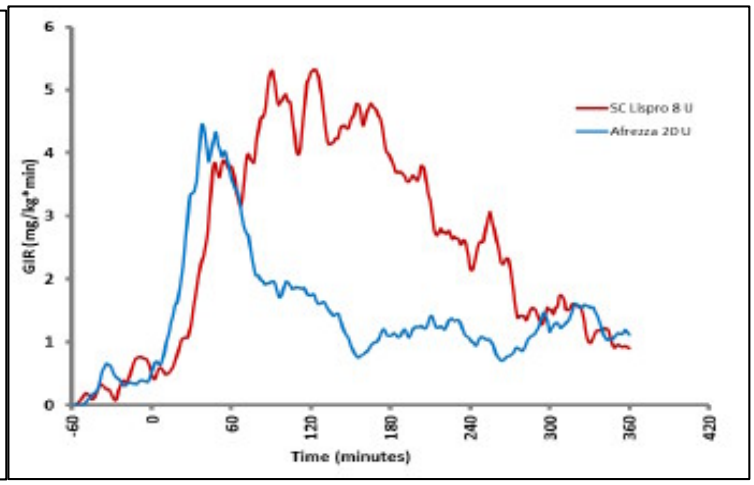
The graph on the left depicts insulin concentration in the blood following administration while the graph on the right depicts the ability of each therapy to control glucose. As illustrated (L), Afrezza reaches maximum insulin concentration very rapidly, corresponding almost exactly to the near-immediate timeframe of the increase in blood glucose following a meal. Meanwhile, the subcutaneous insulin curve shows that peak concentration is reached between approximately 30 and 60 minutes, or not until the diabetic glucose curve (red line above) is well into the unhealthy zone – resulting in hyperglycemia.

Both charts below also depict Afrezza's more rapid dissipation from the blood. This is important as too much insulin over too long will result in hypoglycemia, a significant drawback (and contributor to lack of adherence) of traditional endogenous insulin therapy. Hypoglycemia, characterized by fatigue, sweating, irritability, shakiness and other unpleasant symptoms, is a major contributor to lack of patient compliance. As many diabetics would rather skip mealtime insulin than risk feeling nauseous, hypoglycemia is implicated as one of the most significant contributors to ~50% of diabetics not meeting their A1c targets.

Afrezza Quickly Knocks Down Glucose, Reducing Hyper Risk



Afrezza Rapidly Dissipates, Reducing Hypo Risk



Insulin

Insulin has been used to treat diabetes since the 1920's when it was first isolated from the pancreas of a dog. Evolution of therapeutic insulin over the following years largely related to optimizing its sourcing, purity, immunogenicity and pharmacokinetics. The overlying goal has been to develop an exogenous insulin therapy that acts identical to that of endogenous insulin (of a healthy person) in maintaining glucose homeostasis and without any side effects. While advances have been made, most of the recent innovation has focused on novel ways to deliver liquid insulin. Meanwhile, the last several decades have witnessed only very incremental improvements of rapid-acting injectable insulin as it relates to glucose control.

Insulin comes in several different forms, based on their function, and is typically delivered subcutaneously via syringe, pens, pumps and patches. For type 1 and some type 2 diabetics, two or more different types of insulin may be used; rapid-acting, regular (or short)-acting, intermediate-acting, long-acting or a combination (pre-mixed) of these. The intermediate and long-acting insulin are basal doses used for maintenance of energy throughout the day with onset and duration of effect as long as 4 hours and 12 hours, respectively. These longer-acting insulins are designed to maintain 'fasting plasma glucose' (FPG) within a specified range (see below). FPG is blood sugar level when a person has not eaten for at least 8 hours.

Rapid-acting and short-acting insulin, also known as meal-time insulins, are taken at the same time and within 30-60 minutes of eating, respectively. These faster-acting insulins are designed to maintain 'postprandial plasma glucose' (PPG) within a specified range. PPG is blood sugar level measurement one to two hours following a meal.

Recommended Glucose Ranges

	ADA	AACE
FPG	80 - 130 mg/dl	<110 mg/dl
PPG	<180 mg/dl	<140 mg/dl
A1c	**<7%**	**<6.5%**

Exogenous **meal-time insulin** helps to control the extra glucose that enters the blood as a result of the breakdown of carbohydrates following a meal. In addition to Afrezza, other rapid-acting insulins include Lispro (Humalog) from Eli Lilly (LLY), Aspart (Novolog) from Novo Nordisk (NVO) and Glulisine (Apidra) from Sanofi-Aventis (SNY). Humulin R, regular insulin, is also marketed by Lilly. Together these four injected meal-time insulins generate more than $7.5B in annual sales, including ~$4.4B in the U.S.

Rapid-acting insulin sales

	2017 Revenue (millions)			
	U.S.	**Europe**	**ROW**	**Total**
NovoLog	$1,632	$660	$799	$3,091
Humalog	$1,718	NA*	$1,147	$2,865
Apidra	$117	$157	$160	$434
Humulin R	$885	NA*	$450	$1,335
Total	**$4,352**	**NA***	**$2,556**	**$7,725**

*LLY does not disclose European sales

Importance of meal-time insulin…
Optimally, meal-time insulin will be able to do two things well; quickly knock down glucose as it rapidly rises following eating and then rapidly dissipate, allowing for glucose levels to stabilize back within recommended guidelines. The risk of not coming on quick enough is that glucose will rise above recommended ranges (i.e. experience hyperglycemia) while not dissipating fast enough risks falling bellow recommended ranges (hypoglycemia).

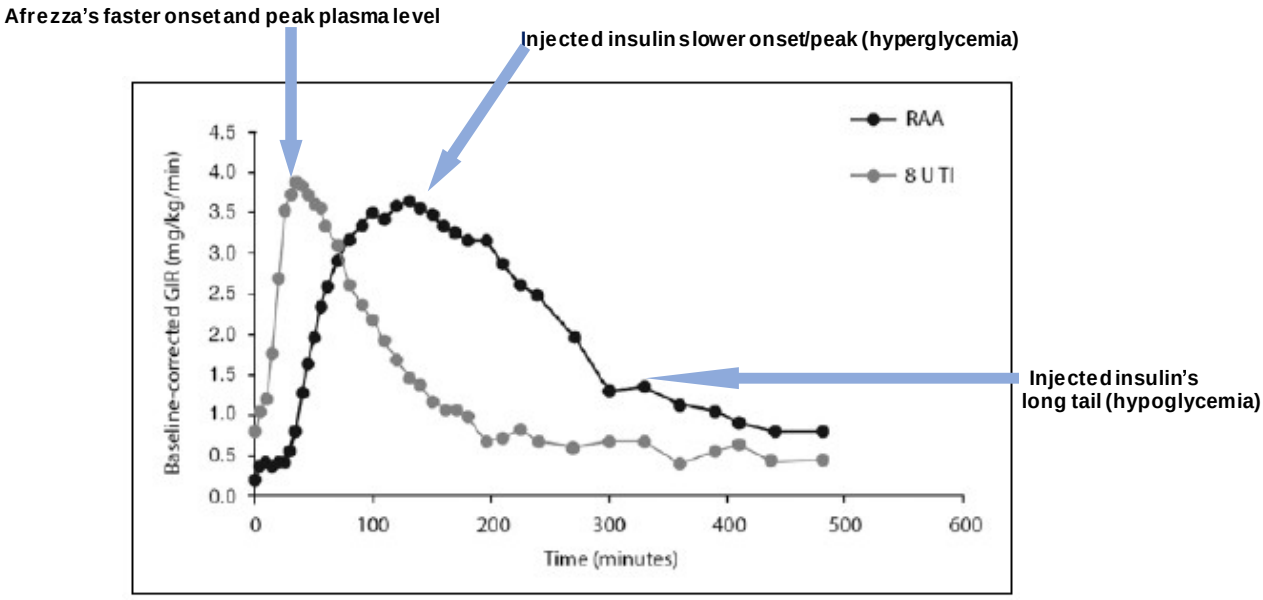
How well a particular meal-time insulin performs these two functions largely depends on its 'time-action profile.' That is, how quickly does it get into the bloodstream, how quickly does it begin knocking down the spiking glucose and how effectively does it bring glucose back to pre-prandial (i.e. before eating) levels (without overshooting).

Afrezza's Pharmacodynamics and Pharmacokinetics Profile
Studies have firmly established that Afrezza comes on much quicker and reaches peak insulin concentration faster than its subcutaneous counterparts. It also eliminates from the body similar to regular human insulin. As explained earlier, its faster onset of action and more rapid dispersion means that Afrezza controls blood glucose better and reduces risk of hypoglycemia. And it's not just subcutaneous insulin that Afrezza outperforms on these measures. It also has a superior on/off profile to that of Exubera, the first inhaled insulin to make it to the U.S. market (see the Appendix in our Dec 10, 2018 initiation report for a comparison between Afrezza and Exubera).

Afrezza's onset of action is approximately 12 minutes, it reaches peak plasma insulin concentration (i.e. T_{max}) in about 50 minutes and has duration of around two hours. While rapid-acting injectable insulin also has a rapid onset – in about 10 to 15 minutes – studies have shown that it may not reach peak plasma concentration until two or more hours after administration - much later than that of Afrezza, and risks hyperglycemia. Additionally, subcutaneous insulin has a notoriously 'long tail' – that is, it lingers too long, combating blood glucose which is now in-range and, hence, results in hypoglycemia.

Glucose clamp studies illustrates Afrezza's rapid on/off compared to lispro…
Glucose clamp studies are used to evaluate PD profiles of exogenous insulin therapy. In these studies, glucose is artificially infused into the bloodstream at a rate that maintains (i.e. 'clamps') blood sugar at a preset level. Continuous glucose monitoring is used to determine glucose infusion rates throughout the duration of the study. Effectiveness of insulin therapy is measured by the amount and timing of glucose infusion required (i.e. glucose infusion rate, or GIR) to clamp it at the preset level. The superiority of Afrezza's PD profile is demonstrated in a glucose clamp study comparing it to injected insulin lispro in 25 patients with type 1 diabetes.

Results showed that among patients receiving Afrezza, the glucose infusion rate (which, again, is a proxy for glucose-controlling efficacy) peaked at 30 minutes after administration. By contrast, the GIR among patients receiving subcutaneous rapid-acting insulin peaked at an average of 150 minutes following administration. Moreover, the time to 50% of maximum effect was 19 minutes among Afrezza patients and 50 minutes among those receiving injected insulin. The long-tail of injected insulin is illustrated by the fact that GIR baseline was not reached until about 300 minutes after administration – by contrast, GIR baseline was reached within approximately 180 minutes among those receiving Afrezza. Additionally, at 120 minutes after administration, 60% of Afrezza's total glucose lowering effect had been delivered but only 33% of lispro's had.

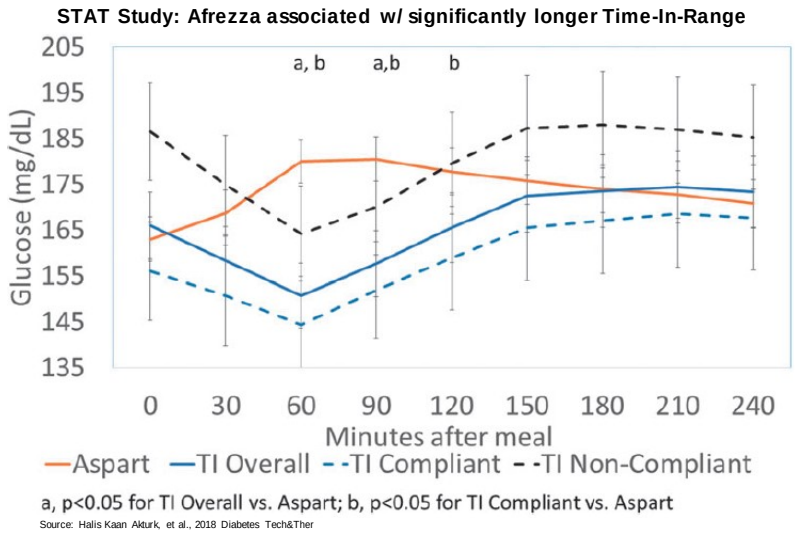


Source: Heimemann, et al. Journal Diab Science & Tech 2016

STAT Study Highlights Afrezza's Dosing Flexibility, Results in Less Hypoglycemia, Superior TIR
Traditional mealtime insulin is taken within 30 minutes of a meal and, due to the risk of hypoglycemia, is not typically supplemented with additional dosing. However, unlike traditional mealtime insulin therapy, Afrezza's quick peak onset and shorter duration allows for supplemental dosing without the same risk of hypoglycemia.

The STAT study, published in November 2018 in Diabetes Technology & Therapeutics, showed that the greater flexibility afforded by Afrezza's rapid on/off action which allows for supplemental dosing resulted in superior time-in-range (i.e. less hypo and hyperglycemia), and even less weight gain, as compared to injected insulin. The primary outcomes were time-in-range (TIR: 70–180 mg/dL) and post-prandial glucose excursions (PPGE) in 1 to 4 hours after eating. Glucose was measured with continuous glucose monitoring (CGM).

Patients in the open label, multicenter study were randomized to either Afrezza (n=26) or insulin aspart (n=34). Of the 26 Afrezza patients, evaluable data were available on 22 (i.e. intent-to-treat). Patients in the Afrezza cohort were instructed to take supplemental inhalations at one and two hours after meals if CGM values showed glucose excursions above goal. Not all Afrezza patients ended up complying with instructions to take supplemental doses. As a result, at the end of the study, investigators assessed what ended up being three cohorts; Afrezza total intent-to-treat (n=22), Afrezza non-compliant (n=15) and aspart.

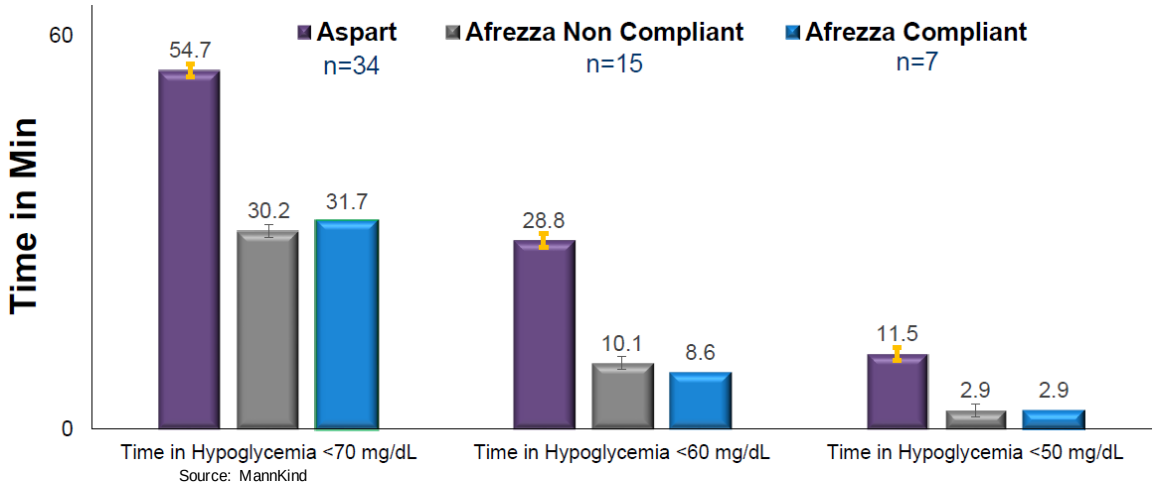


Source: Halis Kaan Akturk, et al., 2018 Diabetes Tech&Ther

Results showed that while time-in-range (TIR) was similar between both the Afrezza total and aspart cohorts, Afrezza total patients spent significantly less time in hypoglycemia (<60 and <50 mg/dl, p<0.05). Afrezza-

compliant patients fared even better. In the Afrezza-compliant group, TIR was significantly greater (63% vs 54%, p=0.009) and time in hyperglycemia (i.e. >180 mg/dl) was significantly less (34% vs 41%, p=0.045) than the aspart cohort.

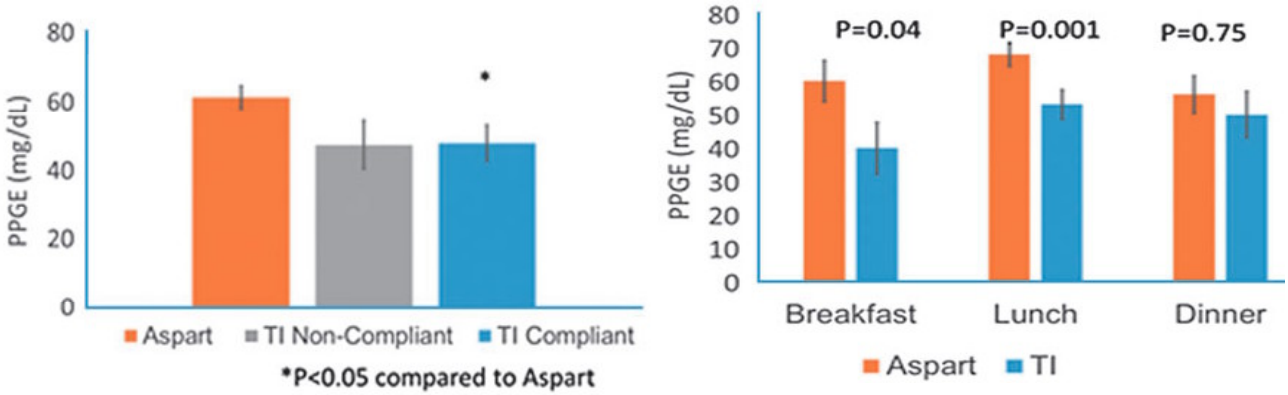
STAT Study: Afrezza associated w/ significantly less hypoglycemia



Source: MannKind

In addition, PPG was significantly lower in the total Afrezza cohort at both 60 and 90 minutes after a meal and PPGE was lower in the Afrezza-compliant group over 1 to 4 hours post-meal (p<0.05). PPGE-control is arguably one of the most telling measures when comparing one mealtime insulin to another as, as the name implies, it's post-meal efficacy that is most important. On this measure Afrezza was not only significantly superior to aspart on average over three meals, but was also superior at both breakfast and lunch (although not dinner).

STAT Study: Afrezza associated with significantly less post-prandial excursions (PPGE)



Source: Halis Kaan Akturk, et al., 2018 Diabetes Tech&Ther

Afrezza patients also did better when it came to weight gain. While aspart patients gained weight, the total Afrezza group actually lost weight (p=0.006). The difference on the weight measure is compelling given that Afrezza patients administered higher prandial doses - which typically, with subcutaneous insulin, will cause overeating due to hypoglycemia, which in- turn results in weight gain.

Key takeways were that Afrezza's rapid onset and short duration allows for supplemental dosing shortly after a meal – something that is considered antithetical to how subcutaneous rapid-insulin therapy is used (given resultant hypoglycemia – and this supplemental dosing significantly increases time-in-range (i.e. reduces hyper and hypoglycemia), reduces post-prandial excursions (which is the true test of a mealtime insulin) and reduces weight gain as compared to subcutaneous insulin. This, in our opinion, provides substantive additional evidence of Afrezza's superior time-action profile as well as bolstering the case that inhaled insulin is indeed a much different class than its subcutaneously administered counterparts.

AFFINITY-1 Subset Data Further Supports Afrezza's Superior Hypoglycemia Profile

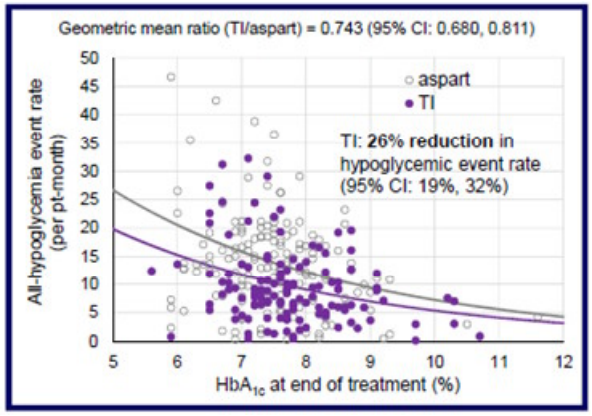
For background, the AFFINITY studies (AFFINITY-1 in T1D, AFFINITY-2 in T2D) were used as primary support for MNKD's regulatory application seeking FDA approval of Afrezza with use of the Dreamboat inhalers. Earlier in

2018 MNKD presented data (poster session at ADA 78th, June 22 – 26th) from a subset of patients from AFFINITY-1 study.

This subset study evaluated the overall and severity of hypoglycemic event rates in patients treated with Technosphere Insulin (TI, i.e. Afrezza) relative to sc insulin. The results revealed that Afrezza allows for better HbA1c control and significantly lower rates of hypoglycemic. Rates of hypoglycemia associated with Afrezza were 26% lower across all levels of HbA1c. For some patients, HbA1c levels could be reduced by 1.2% from 8% at baseline with no increase in hypoglycemic rates while for others, who were already at or below 7% HbA1c levels, would expect to experience four fewer hypoglycemia events per month.

AFFINITY-1 Subset: Further supports Afrezza superior hypoglycemia profile

	Parameter	Aspart	TI	*P* value
	N	150	129	
All hypoglycemia	Incidence, n (%)	150 (100)	129 (100)	1
	Events	11,723	6983	<0.001
	Events per patient	78.2	54.1	
Severe hypoglycemia	Incidence, n (%)	47 (31.3)	28 (21.7)	0.071
	Events	127	59	0.114
	Events per patient reporting at least 1 severe hypoglycemic event	2.7	2.1	



Source: Blonde L. et al. MannKind. ADA 78th Poster Presentation

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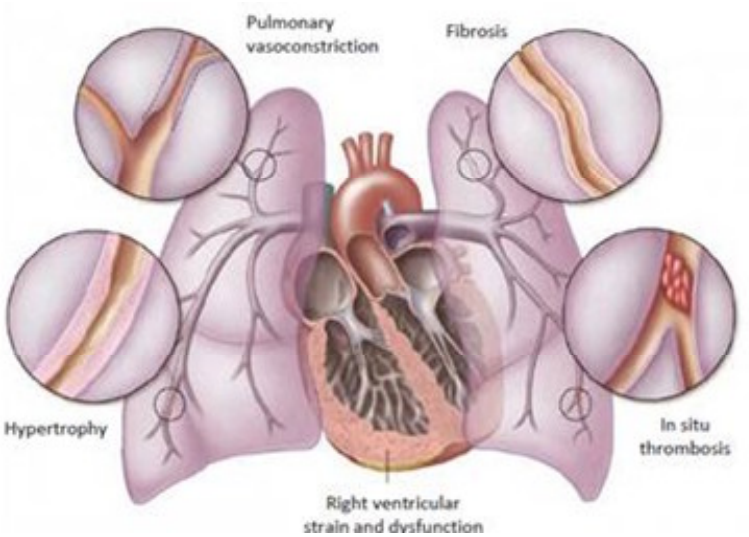
MannKind's Pipeline

Low hanging fruit: TreT

Inhaled treprostinil (Tyvaso), a drug-device combination for the treatment of pulmonary arterial hypertension, was approved by the FDA in 2009 and is the most widely prescribed product for that condition since its launch. United Therapeutics has relentlessly worked on improving the system's design to improve patient compliance. In October 2017, the FDA approved a third-generation device which was designed around feedback from both physicians and patients. Focused on user-friendliness, it has an ergonomic design with single button operation, an intuitive user interface as well as a graphical display that helps patients follow the correct inhalation procedure. The new device also allows patients to keep track of their last treatment and is equipped with an internal, rechargeable battery.

Pulmonary Arterial Hypertension (PAH): The CDC describes PAH, a rare, progressive disease, as having high blood pressure in the pulmonary arteries. Under normal conditions, blood flows from the right ventricle of the heart to the lungs for oxygenating blood. The blood pressure in the lungs is much lower than the systolic or diastolic pressure since pulmonary vascular resistance (PVR) is low. However, abnormal changes in the pulmonary arteries such as vasoconstriction, cell proliferation, and thrombosis (platelet activation and aggregation) cause the arterial walls within the lungs to become non-compliant (stiff and narrow). This leads to restrictions in the blood flow to the lungs. The resulting increase in blood pressure in the lungs leads to remodeling of the right ventricle, followed by decreased ability of the heart to pump blood. This results in volume overload, right ventricular adaptation, and death. Multiple factors including heart or lung diseases, metabolic, hematologic, or systemic disorders are associated with PAH. It has been shown that early intervention may be beneficial in improving clinical outcome for PAH patients.



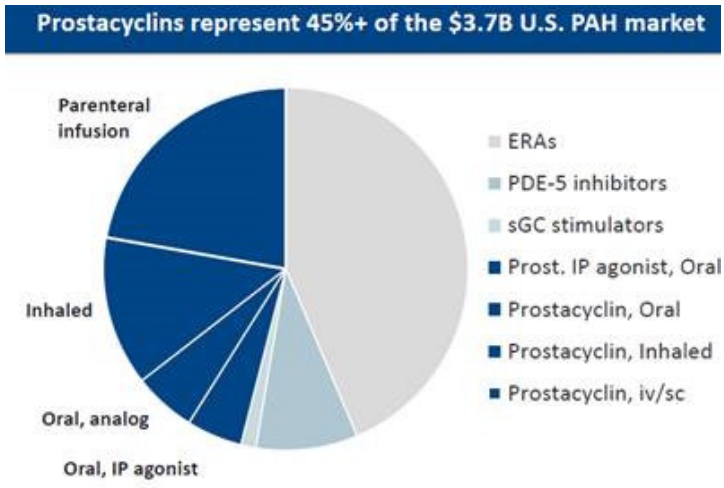
Source: Liquidia August 2018 Presentation

PAH Market size

Despite PAH being categorized as a rare disease, the FDA has granted marketing approval for more than ten drugs to provide multiple therapeutic options for managing the disease. The types of drugs, which address PAH-specific pathways, include

1. endothelin receptor antagonists (ERAs; bosentan, ambrisentan, macitentan),
2. phosphodiesterase type-5 inhibitors (PDE5Is; sildenafil, tadalafil),
3. soluble guanylate cyclase stimulators (sGCs; riociguat),
4. prostacyclins (epoprostenol, iloprost, treprostinil) and
5. prostacyclin receptor agonists (selexipag).

ERAs and PDE5Is are typically recommended for patients classified under WHO patient Class II and III while prostacyclin therapy is generally advised for patients falling under WHO Class II-IV[1,2].



Source: Liquidia August 2018

Role of Prostacyclin:

Prostacyclin (prostaglandin I2) has been identified as a vasodilator, an anti-proliferative agent, and an anti-thrombotic agent. Evidence indicates that prostacyclin is dysregulated (body does not produce sufficient

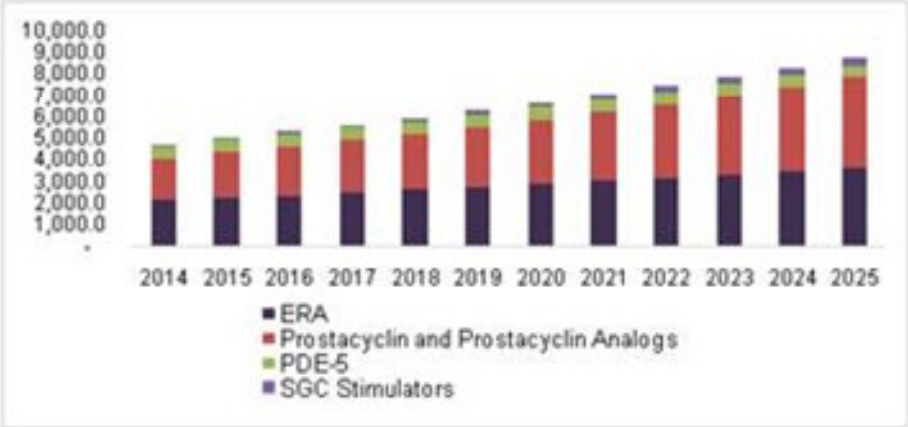
[1] Harrison W. Farber, Wendy Gin-Sing, Practical considerations for therapies targeting the prostacyclin pathway, European Respiratory Review 2016, 25: 418-430;

[2] Zamanian R.T., et al, An observational study of inhaled-treprostinil respiratory-related safety in patients with pulmonary arterial hypertension, Pulmonary Circulation. 2016, 6(3): 329–337.

prostacyclin) in PAH[3]. As mentioned earlier, one of the synthetic analogs of prostacyclin, treprostinil, has been approved by the FDA for the treatment of PAH.

Grand View Research estimates the global PAH market size to be ~$8 billion by 2025. Research conducted by the consulting company, Decision Resources Group, indicated that sales for all major PAH drugs in 2016 amounted to more than $6 billion globally.

Pulmonary Arterial Hypertension market, by drug class, 2014 - 2025 (USD Million)



Source: Grandview Research

Decision Resources Group valued the U.S. market for PAH drug therapies at approximately $4 billion as of 2016. The company also assessed that more than 50% of patients with PAH in the U.S. were prescribed treprostinil (oral, inhaled, and parenteral infusion). Drug therapies approved to treat PAH via the prostacyclin deficient pathway generated close to $2 billion in sales in the U.S. in 2016, of which, treprostinil contributed to the bulk of total sales. The drug Tyvaso (treprostinil inhalation solution), accounted for more than 80% of the U.S. market for PAH inhaled treatments in 2016[4].

Despite having positive risk-benefit profile and a long history of being in the market, prostacyclin analogs have relatively under-performed in this continuously evolving and growing marketplace. One of the reasons for clinical under-use is the requirement for dosage up-titration based on a patient's response to the initial dose. Adding to this hurdle is the idea that higher doses result in greater pain at the injection site when administered subcutaneously.

Is inhaled treprostinil better than traditional (injectable) version?

Inhaled prostacyclin analogs have demonstrated clinical benefits such as decreased frequency in dosing and shorter duration of inhalation. The inhaled drug reaches the target directly, reduces ventilation/perfusion mismatch in the lungs, minimizes systemic hypotension, circumvents site pain/allergic reaction from IV/SC route of administration, and could be potentially used in critical care. However, duration of inhalation and device maintenance, which are time intensive for the patient, have compromised patient compliance and resulted in slower than expected adoption.

Inhaled prostacyclin analog therapies in the market…

Two inhaled formulations of prostacyclin are available in the U.S. Ventavis (inhaled iloprost) has been available since 2005. It uses the I-neb adaptive aerosol delivery system. Ventavis is indicated for patients with PAH with NYHA Functional Class III-IV symptoms. Inhaled iloprost (5µg of prostacyclin analog per breath) has a short half-life (20–30 min) and hemodynamic effect (30 to 60 min) demanding up to nine inhalation exercises /day with a minimum of two hours between doses. This cumbersome procedure combined with the unavoidable break during the night is regarded as the major drawback of inhaled iloprost therapy[5].

Tyvaso (inhaled treprostinil) has been available since 2009. It uses the TD-100 ultrasonic pulmonary delivery device. Tyvaso is indicated for patients with severe PAH who are categorized as WHO functional class IV. Tyvaso

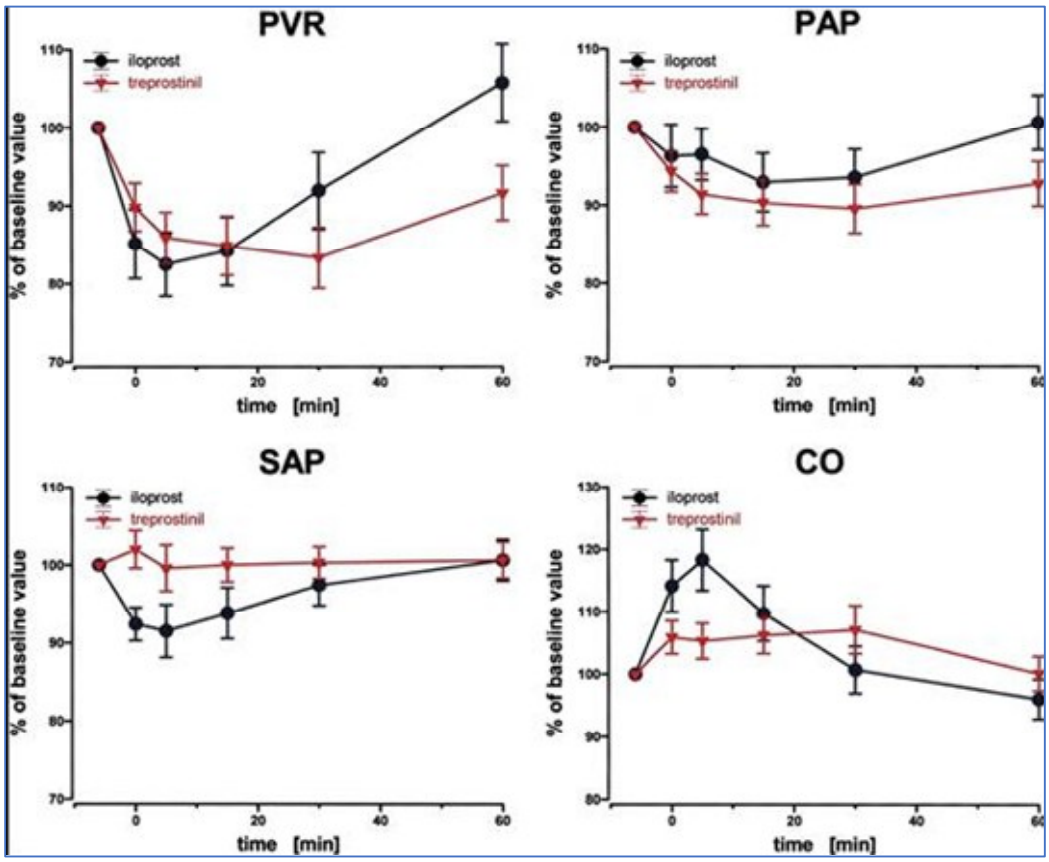
[3] Chan SY, Loscalzo J. Pathogenic Mechanisms of Pulmonary Arterial Hypertension. Journal of molecular and cellular cardiology. 2008;44(1):14-30. doi:10.1016/j.yjmcc.2007.09.006.
[4] Liquidia SEC filings
[5] Newman SP1, Chan HK,In vitro/in vivo comparisons in pulmonary drug delivery, Journal of Aerosol Medicine and Pulmonary Drug Delivery. 2008 Mar;21(1):1-12

offered a more favorable administration exercise with the initial dose being three breaths (18µg), four times daily with a minimum of four hours between doses[6]. Doses up to 60µg could be safely delivered in one single inhalation. Tyvaso has a half-life of approximately 44-52 minutes and hemodynamic effect lasting up to three hours[7].

Clinical studies with inhaled prostacycling analog therapies for PAH:

- ***Study 1(Iloprost Vs. Treprostinil):*** A randomized, open-label, single-blinded, crossover study with 44 PAH patients was conducted in 2006 in Germany to compare the acute hemodynamic and systemic side effects of inhaled treprostinil with inhaled iloprost at similar doses. Iloprost was inhaled at a concentration of 4µg/ml (6 min inhalation time; n = 44) and treprostinil was inhaled at concentrations of 4µg/ml (6 min inhalation; n = 14), 8µg/ml (6 min inhalation; n = 14) or 16µg/ml (3 min inhalation; n = 16).

The inhalation of both drugs was done using the Optineb ultrasonic nebulizer (Nebutec, Elsenfeld, Germany). Data from the 44 patients who had inhaled both drugs in randomized order, revealed a rapid decrease in PVR and pulmonary arterial pressure (PAP). A more sustained effect on PVR and increase in cardiac output was recorded after treprostinil inhalation. The results revealed a prolonged drug effect of treprostinil compared with iloprost.



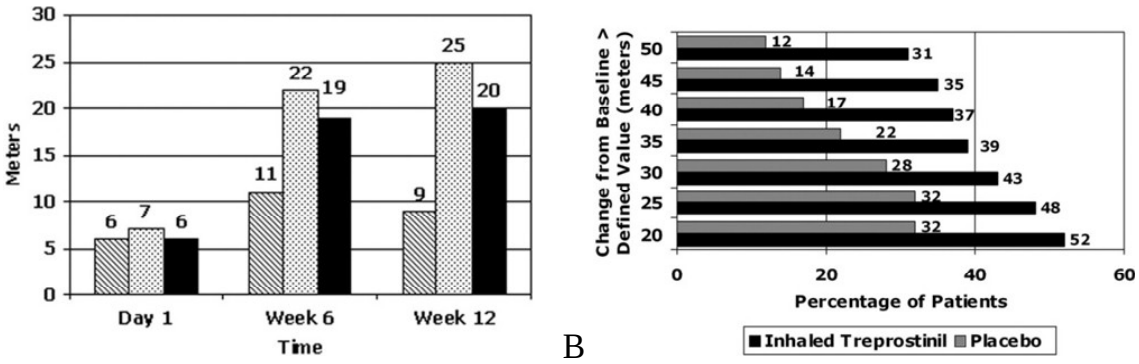
Source: JAMC Volume 48(8), 2006, P1672-1681

- ***Study 2 (TRIUMPH I trial)*****:** In 2007, a double-blind placebo-controlled clinical study was conducted to investigate the efficacy and tolerability of inhaled treprostinil in patients with severe PAH receiving therapy with either bosentan or sildenafil. The primary outcome was the change in 6-minute walk distance from baseline to week 12.

Two hundred thirty-five PAH patients treated with bosentan (70%) or sildenafil were randomized to inhaled treprostinil (up to 54µg) or inhaled placebo 4 times daily. The patients belonged to the New York Heart Association (NYHA) functional class III (98%) or IV with a 6-min walk distance (6MWD) of 200 to 450m.

[6] Tyvaso U.S. package insert
[7] Channick RN, Voswinckel R, Rubin LJ. Inhaled treprostinil: a therapeutic review. Drug Design, Development and Therapy. 2012;6:19-28.

Results indicated that inhaled treprostinil for 12 weeks among patients who remain symptomatic on oral monotherapy was safe and well-tolerated. The primary end point had an H-L between-treatment median difference of 20m. The change in 6MWD improved the exercise capacity as early as week 6. Inhaled treprostinil was beneficial for patients already on oral PAH therapy.



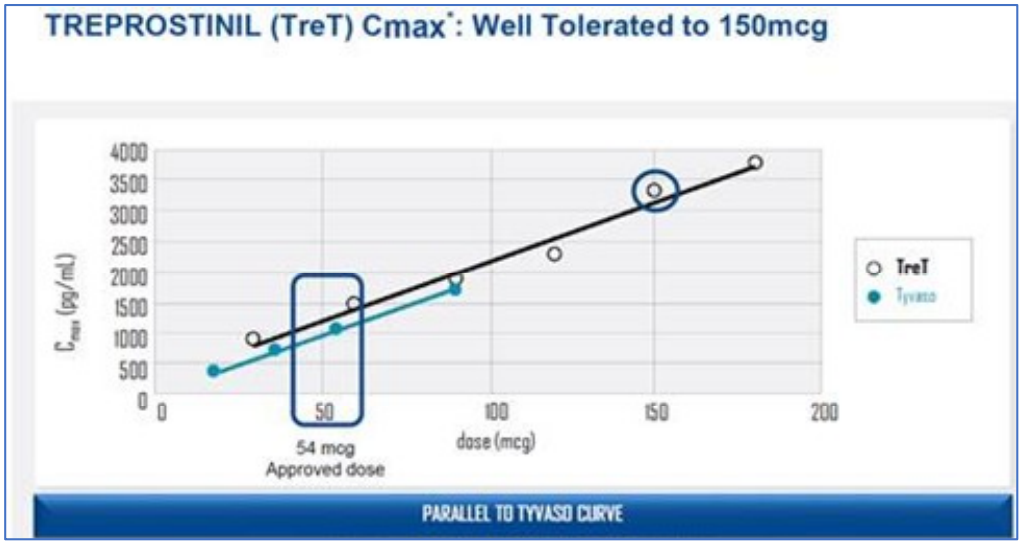
A: Patients on sildenafil (ruled bars),bosentan (dotted bars), all patients (solid bars)

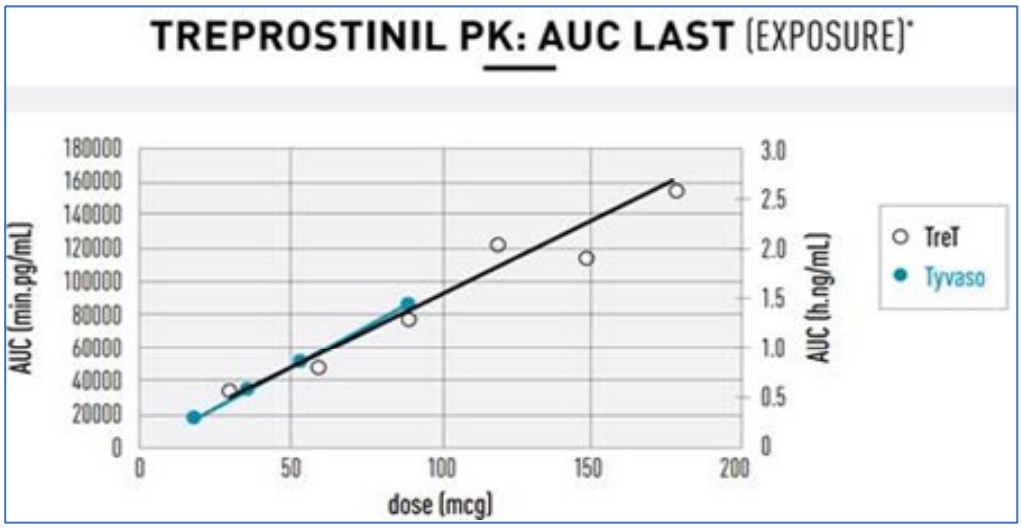
(Source: Journal of the American College of Cardiology, Volume 55(18),2010, P1915-1922)

MannKind's Technosphere Treprostinil (TreT): Based on the company's Technosphere platform, treprostinil is being developed as a dry powder formulation for PAH patients.

MannKind investigated the safety, tolerability, and bioavailability of TreT in a Phase 1 single ascending dose study with healthy volunteers. The study aimed to deliver TreT within 1-2 inhalations in less than ten seconds. In March 2018, the single site study enrolled 36 healthy, normal subjects. The volunteers were divided into 6 groups having 6 subjects each. The trial intended to establish the maximum tolerated dose, starting at 30µg and going up to 180µg. Each subject received one dose of TreT during the treatment period. Twelve blood samples were collected from each subject and analyzed for treprostinil.

The study achieved its primary endpoint of acceptable safety and tolerability. Additionally, TreT closely mimicked the PK profile of Tyvaso. Peak plasma levels of TreT significantly exceeded the corresponding levels of Tyvaso inhalation solution.





Source: MannKind

For PAH sufferers, reducing the frequency of inhalation and duration as well as eliminating the treatment-gap during night time could improve patient compliance and QoL. TreT promises delivery of large dose with fewer inhalations in shorter time as compared to Ventavis, Tyvaso or LIQ861. We think this speaks to the benefits of the Technosphere technology – specifically the size and aerodynamic shape of Technosphere microparticles and MNKD's inhaler technology which allows for fast and efficient travel through the air and into the lungs. And with more than 90% of the microparticles in the respiratory range (i.e. >0.5 µm and <5.8 µm), Technosphere technology is optimized for deep inhalation into, and uniform dispersion throughout, the lungs. Additionally, Technosphere pH-activated powders are quickly dissolved in the interstitial fluid immediately after inhalation and coming into contact with the characteristically neutral pH conditions of the lung. This results in ultra-rapid absorption into the circulatory system, avoidance of peripheral circulatory degradation and high bioavailability.

TreT Update

As a reminder, in September 2018, United Therapeutics entered into a worldwide exclusive license and collaboration agreement with MannKind for the development and commercialization of a dry powder formulation of treprostinil called Treprostinil Technosphere (TreT) for the treatment of PAH. UT has undertaken the responsibility for global development and regulatory and commercial activities. As per UT's 10-K, they plan to commence a clinical study (called BREEZE) during the first half of 2019 to evaluate the safety of switching PAH patients from Tyvaso to TreT, as well as a PK study in healthy volunteers. The FDA has indicated that these two studies, if successful, will be the only clinical studies necessary to support FDA approval.

While MannKind has agreed to manufacture clinical and initial commercial supplies of TreT, UT will be manufacturing long-term commercial product. Per terms of the agreement, MannKind received an upfront payment of $45 million and is eligible to receive milestones of up to $50 million (related to four milestones of $12.5M each) upon the achievement of specific development targets. The initial $12.5M milestone was received in Q1'19. Of the $57.5M received to-date, $14M has been recognized as revenue ($6.4M in Q4'18 and $7.6M in Q1'19). Another $30.5M is expected to be recognized over the next 12 months. Management noted on the Q1'19 call that they expect to receive the next $12.5M milestone in 2H'19 and the third in 1H'20.

MNKD also entered into a research agreement with United Therapeutics to develop other candidates for which it received $10M upfront. MNKD is eligible to receive $30M upon achieving developmental milestones as well as double-digit royalties on net sales of the product. MannKind recognized $3.8M of the upfront payment as revenue in Q4'18 and another $4.7M in Q1'19. Additionally, we expect to hear from MannKind's partner, Receptor Life Sciences, on the development of Dronabinol, an inhaled therapeutic for cancer pain.

Next in line: Dronabinol

Chemotherapy-induced nausea and vomiting (CINV) is one of the adverse effects in 60%-80% of cancer patients undergoing therapy. Several market research studies estimate the size of the global CINV market to be more than $2 billion.

Receptor Life Sciences is developing an inhaled version of cannabinoid for chemo patients dealing with nausea and vomiting. As the table below summarizes, cannabinoids in their natural form promise to provide better relief and offer advantages that their synthetic analogs fail to accomplish. The dry powder formulation of inhalable dronabinol has a rapid onset of action (< 5 min), superior bioavailability and non-inferior safety profile as compared with marketed oral synthetics such as Marinol and Syndros. Marinol is a synthetic cannabinoid (dronabinol) which is associated with certain unpleasant and potentially serious side-effects such as tachycardia and dizziness.



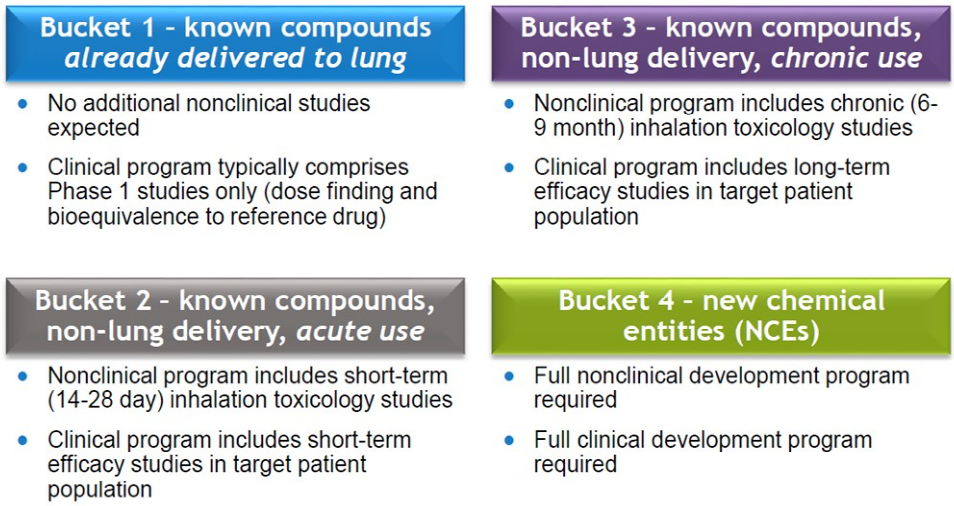
	Marinol	Syndros	RLS / MNKD Dronabinol powder
Indication	CINV and appetite stimulation in AIDS	CINV and appetite stimulation in AIDS	CINV and appetite stimulation in AIDS
Onset of action	0.5 – 1.0 hours (T_{max} fasted = 2.5 hrs)	Onset not reported (T_{max} fasted = 1.0 hrs)	Ultra-rapid (~5 mins)
Food effect	Considerable (T_{max} fed = 5.6 hrs)	Considerable (T_{max} fed = 7.7 hrs)	No food effect
Bioavailability	10 – 20 %	10 – 20 %	Superior to comparators
Safety	• Tachycardia • Dizziness • Euphoria	Non-inferior to Marinol	Non-inferior to Marinol
Storage	Refrigerated	Refrigerated until opened; discard after 28 days at room temperature	Refrigerated during transport; superior room temperature stability
Formulation	Gelatin Capsule	Liquid Solution	Inhaled Dry Powder
CSA Schedule	CIII	CII	?

Source: MannKind

In 2016 MannKind signed a clinical collaboration with Receptor Life Sciences to develop inhaled therapeutic products to treat chronic pain, neurologic diseases and inflammatory disorders. As per the agreement, MannKind is eligible to receive development and commercialization milestones of up to $102 million[8] as well as mid-single to low double-digit royalties on net sales of the product. In late-October 2018, Receptor raised $29 million in its first round of financing to initiate IND-enabling studies related to dry powdered formulation of cannabinoids in the U.S.

[8] http://investors.mannkindcorp.com/news-releases/news-release-details/mannkind-enters-collaboration-and-license-agreement

Other potential pipeline programs…



Source: MannKind

MannKind compiled a broad list of compounds that the company might pursue as potential drug candidates. Management is open to partnering opportunities to further the development of drug candidates towards the clinic. The development programs are categorized into different buckets as shown in the above graphic;

1. Known compounds already delivered to the lung,
2. Non-pulmonary delivery acute use,
3. Non-pulmonary delivery chronic use and
4. New chemical entities (NCEs).

Of this list, MannKind has a patent on Technosphere sumatriptan, an inhalable version of a triptan, a drug that is commonly used in patients suffering from migraine headaches. Preclinical studies have demonstrated Technosphere sumatriptan's rapid acting profile. Currently, triptans are the first line of defense against acute migraine. However, a study[9] conducted on approximately 15,000 migraine sufferers revealed high rates of discontinuity of oral, injectable, and nasal forms of triptan due to adverse side effects including nausea, vomiting and dizziness. This indicates a significant unmet medical need in the treatment and management of acute migraine. This drug candidate could be next in line in MannKind's pipeline.

Valuation

We use a sum-of-the-parts methodology to value MNKD, applying a P/S multiple to the Afrezza portion of the business while using DCF to value the UTHR collaboration related to TreT. Our model and valuation are subject to updating, including incorporating other collaboration candidates, if and when we feel there is enough information with which to base reasonably-confident assumptions (including related to RLS) – which could provide upside to our current target price.

LLY and NVO trade at an average of approximately 5.5x forward sales. Given MNKD's much more rapid estimated percentage revenue growth, we apply that same multiple to our forecasted 2021 Afrezza sales of $116M, which values the Afrezza portion at approximately $3.40/share. Our 10-year DCF uses a 15% discount and values the TreT collaboration at approximately $105M, or ~$0.56/share (which is subject to our 35% risk-of-failure discount). Our sum-of-the-parts calculation puts total value of the company at ~$4.00/share.

[9] Triptan Use and Discontinuation in a Representative Sample of Persons With Migraine: Results From Migraine in America Symptoms and Treatment (MAST) Study

MannKind Financial Model

	2018 A	Q1A	Q2E	Q3E	Q4E	2019 E	2020 E	2021 E
Product sales	$17.3	$5.1	$6.0	$7.8	$9.9	$28.8	$66.0	$116.0
YOY Growth	*87.9%*	*49.2%*	*60.1%*	*78.2%*	*72.6%*	*66.7%*	*129.3%*	*75.6%*
Collaboration revenue	$10.5	$12.4	$9.0	$7.7	$7.7	$36.8	$29.6	$29.3
YOY Growth	*4112.0%*	*19538.1%*	*10273.6%*	*9320.7%*	*-25.0%*	*249.9%*	*-19.7%*	*-1.0%*
Other revenue	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
YOY Growth	*-97.7%*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*-100.0%*	*#DIV/0!*	*0.0%*
Revenue	$27.9	$17.4	$15.0	$15.5	$17.6	$65.6	$95.7	$145.4
YOY Growth	*137.2%*	*403.5%*	*286.2%*	*247.8%*	*9.9%*	*135.6%*	*45.8%*	*51.9%*
Cost of Goods Sold	$19.4	$4.0	$4.6	$5.2	$5.3	$19.1	$21.7	$27.6
Cost of collaboration rev	$1.1	$1.5	$1.4	$1.2	$1.2	$5.2	$4.4	$4.4
Gross Income	$7.4	$11.9	$9.1	$9.2	$11.1	$41.3	$69.6	$113.4
Gross Margin	*26.5%*	*68.2%*	*60.4%*	*59.3%*	*63.1%*	*12.0%*	*72.7%*	*78.0%*
R&D	$8.7	$1.7	$2.4	$3.2	$5.2	$12.5	$18.6	$22.2
R&D % sales	*31.4%*	*9.6%*	*16.0%*	*20.6%*	*29.5%*	*19.0%*	*19.4%*	*15.3%*
SG&A	$79.7	$25.7	$18.4	$21.7	$22.3	$88.0	$101.8	$114.1
SG&A % Prod Sales	*461.4%*	*505.8%*	*306.2%*	*277.4%*	*225.1%*	*292.2%*	*154.2%*	*98.4%*
Operating Income	($81.1)	($15.4)	($11.7)	($15.7)	($16.4)	($59.2)	($50.8)	($22.9)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income, net	($1.9)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.2	$6.8
Pre-Tax Income	($86.7)	($14.9)	($11.7)	($15.7)	($16.4)	($59.2)	($51.0)	($29.7)
Taxes (benefit)	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*-0.3%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($87.0)	($14.9)	($11.7)	($15.7)	($16.4)	($59.2)	($51.0)	($29.7)
Net Margin	*-312.2%*	*-85.3%*	*-78.0%*	*-100.8%*	*-92.8%*	*-90.2%*	*-53.3%*	*-20.5%*
EPS	($0.60)	($0.08)	($0.06)	($0.08)	($0.08)	($0.31)	($0.22)	($0.12)
YOY Growth		-	-	-	-			
Diluted Shares O/S	144.0	187.4	189.7	192.4	196.6	191.5	232.0	245.0

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