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Zacks Small-Cap Research

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MannKind Corp (MNKD-NASDAQ)

ADA Presentations: Positive Pediatric Data Lends Support for Anticipated Pivotal Study. Add'l Adult Data Supporting Benefits, Safety of Uptitrating

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 (06/13/19)	$1.17
Valuation	**$4.00**

OUTLOOK

New data from three different studies of Afrezza was announced at the American Diabetes Association's 79th Scientific Sessions (June 7 – 11) in San Francisco. This includes safety and PK data from MannKind's ongoing pediatric study. This pediatric data, which comes from the first of three age-based patient cohorts is particularly insightful as it provides one of the initial meaningful glimpses of utility of Afrezza in younger populations. Importantly, these results appear to largely mirror efficacy and safety as seen in adult Afrezza studies and provide additional confidence of regulatory greenlighting of the anticipated pivotal U.S. phase 3 pediatric study.

The other presentations come from a small investigator-initiated Afrezza dosing protocol optimization study in type 2 diabetics – which could presumably help inform Afrezza prescribers in dialing-in the most effective dosing regimens for these patients – and an oral abstract related to mixed meal tolerance testing. Data from both of these studies add further support that uptitration and increasing dosing of Afrezza can further improve upon glucose control and do so without a compromise to safety or tolerability, including incidence of hypoglycemia.

SUMMARY DATA

52-Week High	**$2.25**
52-Week Low	**$1.01**
One-Year Return (%)	**-39.90**
Beta	**2.53**
Average Daily Volume (sh)	**2,106,932**
Shares Outstanding (mil)	**188**
Market Capitalization ($mil)	**$218**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**27**
Insider Ownership (%)	**1**
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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Pediatric Study Data (Poster presentation)
As a reminder, MannKind's ongoing safety and pharmacokinetics (PK) pediatric study is anticipated to lead to an FDA registration study for similarly aged populations. The current study is expected to include a total of 46 patients with type 1 diabetes across three cohorts; cohort 1 encompasses children ages 13 – 17 years, cohort 2 covers ages 8 – 12 years and cohort 3 includes patients 4 – 7 years. Cohort 3, which completed testing in September 2018, was the subject of the just-presented data.

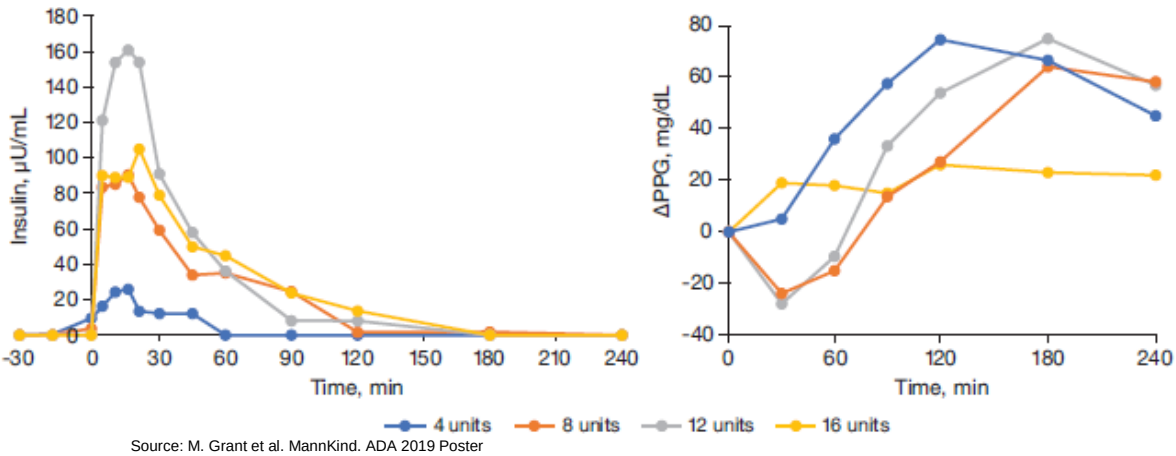
This is an open-label, interventional study evaluating the PK and safety of Afrezza in patients under the age of 18. Primary outcomes are the number of patients with treatment-emergent adverse events and number of patients with hypoglycemic events. Inclusion criteria included use of insulin for at least one year and on a stable regimen of basal-bolus insulin therapy via multiple daily injections for at least six weeks prior to study enrollment.

Patients were followed over a 4-week titration period (following initial PK assessment). Of the 15 patients in cohort 1 (average age of which was 15 years), two received 4-unit doses, six received 8-unit doses, another six received 12-unit doses and one received 16-unit doses).

Results showed;

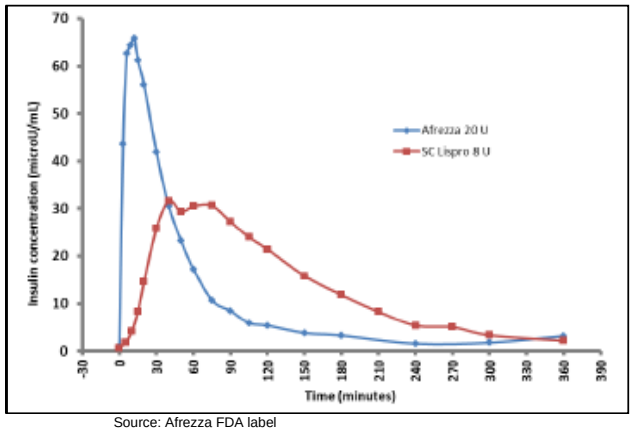
- Rapid onset, peak serum insulin concentrations, rapid glucose knockdown and swift insulin clearance all appeared to largely mimick what we have seen in adult Afrezza studies – which, in-turn, largely mirror the action of endogenous insulin. Specifically, peak insulin concentration was reached within approximately 30 minutes following Afrezza administration and insulin levels returned to baseline within two hours. This quick onset (i.e. peak) and rapid insulin clearance appears nearly identical to what has been observed in earlier adult studies (for comparison, we have included the PK graph from an Afrezza adult T1D study) and reflects the ability of Afrezza to quickly control glucose and do so without the 'long tail' of injected insulin (which is often associated with hypoglycemia).
- Glucose knockdown, as measured by postprandial glucose (PPG) levels is depicted in the graph on the right (below). Both the 8 and 12-unit doses (n=6 in each) show markedly decrease in PPG within 30 minutes following administration (demonstrating rapid glucose control).

Rapid peak serum insulin concentration (L) and glucose control (R)



Source: M. Grant et al. MannKind. ADA 2019 Poster

Afrezza Adult T1D PK Profile (vs. SC Lispro)



Source: Afrezza FDA label

- Safety
    - Overall safety appeared acceptable and largely similar to that of prior adult Afrezza studies. Of the 19 reported treatment-emergent adverse events, there was one serious event; diabetic ketoacidosis. It is our understanding that this particular patient was not compliant with dosing treatment guidelines. And, importantly the DA was not related to Afrezza
    - Two of the fifteen patients discontinued due to adverse events (diabetic ketoacidosis and coughing)
    - Importantly, while there were seven reported cases of coughing, all resolved over time and there were no 'clinically relevant declines in pulmonary function'
    - No serious hypoglycemia events were observed

T2D Dose Optimization Study (Late-breaking Poster)

This was an n=14 study of T2D patients which failed to control HbA1c with oral and/or injected therapies. Patients with HbA1c levels between 7.5% and 11.5% and which were already using two or more diabetes therapies were enrolled in the study, which was funded by MNKD and conducted in a real-world practice setting (and led by Dr. Phil Levin). Afrezza was added to patients' current treatment regimens, which for one-half of participants, included basal insulin. Patients initially received Afrezza in 4-unit doses per meal and graduated to 12-units per meal over seven days. After eight days, the Afrezza dose was adjusted once per week (for up to twelve weeks) based on PPG control.

Key outcomes were time-in-range (TIR, or the amount of time that a patient's HbA1c is at the recommended 70-180 mg/dL) as measured by (blinded) continuous glucose monitoring (CGM), optimal dosing of Afrezza and safety (as measured by hypo and hyperglycemia).

Results showed:

- Optimal dosing: between 16 and 20 units per meal
- HbA1c control
    - Afrezza use resulted in a (significant) mean HbA1c decrease of 1.6% (p=0.001) by week 12
        - Baseline HbA1c of 9.1% fell to a mean of 7.5% by week 12
    - 93% of patients (13/14) achieved HbA1c levels of less than 8%
    - Time-in-range (70-180 md/dL): Afrezza increased TIR by 76% (p<0.0001)
    - No significant change in hypoglycemia
- CGM found that
    - Hyperglycemia
        - Hyperglycemia (glucose >180mg/dL) incidences decreased by 47% (p<0.0001)
        - Severe hyperglycemia (glucose >250mg/dL) incidences decreased by 74% (p=0.0005)
    - Mean daily glucose fell by 23% (p=0.0002) from baseline through week 12 (208 mg/dL at baseline to 161 mg/dL at 12 weeks)

These results in our opinion not only further add to the growing body of evidence showing that use of Afrezza (either alone or in combination with other diabetes therapies) can increase time-in-range and/or reduce rates of hyperglycemia (and, in many cases, also reduce rates of hypoglycemia), but also provides physicians with additional insight into dosing protocol optimization. Afrezza's novel PK profile (as compared to injected insulin) and

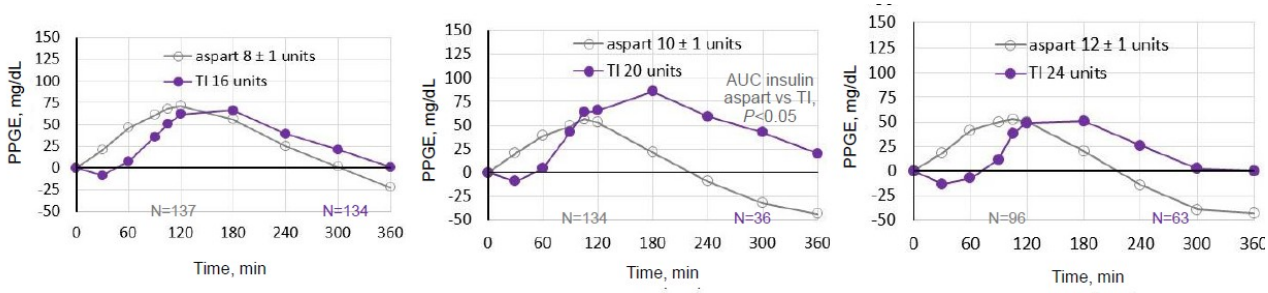
ultra-rapid mode of action has often dictated a trial-and-error approach to dialing-in a particular patient's optimal dosing. As that can act as headwind to adoption, additional learnings towards streamlining that process, such as this study provides, may help facilitate initial uptake and repeat prescriptions of Afrezza.

This study lends support for uptitration and, potentially, increasing dosing of Afrezza as a way to further improve upon glucose control – and do so without a significant compromise to risk of hypoglycemia. Results of this study also appear to support the reasoning behind the recently observed increasing demand for higher volume cartridges (i.e. 12-unit cartridges) – specifically that physicians are becoming more comfortable with the idea that increasing Afrezza dosing can further benefit glucose control without compromise to safety and tolerability (an all but antithetical proposition to dosing injectable insulin). This is a phenomenon that we will be closely watching as physician (and patient) comfort with adjusting dosing is likely to be a progressive step towards optimizing prescribing protocol – and one that can have significant influence in driving switching from injected to inhaled insulin.

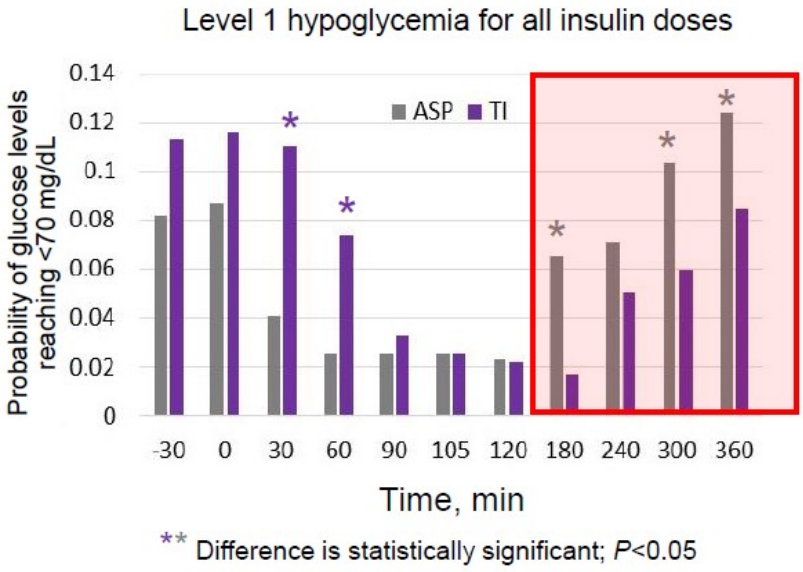
Afrezza's Superior Glucose Control More Pronounced at Higher Doses (w/o compromise to hypo)
This data supports prior evidence showing Afrezza's rapid-action profile (i.e. fast onset and relatively short duration) largely mimics that of endogenous insulin, resulting in superior glucose control as compared to subcutaneously administered insulin. The 151 Oral Abstract presentation focused on postprandial glucose control in T1D patients – specifically, within two hours following a meal and highlighted how separation of efficacy (and hypoglycemia) between Afrezza and injected insulin becomes more pronounced (favoring Afrezza) at higher doses.

The data is from a mixed meal tolerance study (i.e. each patients' glucose intake was regulated), comparing different dose groups of Afrezzza to insulin aspart. The slides below illustrate that the superiority of Afrezza to that of insulin aspart on glucose control (as measured by PPG) increases at with increasing doses. And importantly, despite Afrezza dosed at twice the dose of aspart, rates of hypoglycemia (>2 hours) were significantly higher in the aspart cohorts. This higher hypoglycemia incidence is indicative of the shorter tail of Afrezza and relatively long tail of injected insulin.

Superiority of Afrezza efficacy becomes more pronounced at higher doses



Long tail of injected insulin results in significantly higher rates of >2hr hypoglycemia



Source: MannKind, ADA 2019 Oral Abstract

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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