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Zacks Small-Cap Research

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MannKind Corp (MNKD-NASDAQ)

Update From Our Meeting w/ Management at JPM

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 $106M, which values the Afrezza portion at approximately $3.65/share. Our 10-year DCF uses a 15% discount and values the TreT collaboration at approximately $98M, or ~$0.60/share. Our sum-of-the-parts calculation puts total value of the company at ~$4.25/share.

OUTLOOK

We met with Steven Binder, MannKind's CFO at the annual JP Morgan Healthcare Conference as well as The Biotech showcase conferences in San Francisco during the week of January 7th. We talked in depth on a number of topics including the details of the investor call held just a few days earlier. We gathered some interesting insights from our meeting that we have shared below.

Current Price (01/18/19)	$1.35
Valuation	**$4.25**

SUMMARY DATA

52-Week High	**$4.05**
52-Week Low	**$0.94**
One-Year Return (%)	**-44.18**
Beta	**2.43**
Average Daily Volume (sh)	**2,368,363**
Shares Outstanding (mil)	**186**
Market Capitalization ($mil)	**$250**
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)
2017	3 A	2 A	2 A	5 A	12 A
2018	3 A	4 A	5 A	5 E	17 E
2019					35 E
2020					71 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.22 A	-$0.35 A	-$0.31 A	-$0.28 A	-$1.13 A
2018	-$0.25 A	-$0.16 A	-$0.16 A	-$0.17 E	-$0.71 E
2019					-$0.63 E
2020					-$0.68 E

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

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MNKD: 2019 Outlook

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DTC push to gain ground…

The International Diabetes Federation's (IDF) Diabetes Atlas (8th edition) has estimated that approximately 30 million people were living with diabetes in 2017 in the U.S. According to the CDC, about 1.5 million new cases are diagnosed per year. Although insulin injection pens are ubiquitous and generally convenient to carry around, adherence to therapy has remained a challenge primarily due to hypo/hyperglycemia and, to some extent, as a result of anxiety associated with an injection, local sensitivity, pain and bruising.

One of the biggest challenges for the company has been accelerating growth of Afrezza. Our conversation with management included a discussion of their sales and marketing strategy for 2019. Included in their strategy is targeted DTC campaigns. As a reminder, the company had debuted its pilot TV commercial late in 2017 in twelve markets which resulted in an increase in new prescriptions and sales within eight weeks following airing. The most recent campaign began earlier this week on 26 national cable networks and local TV stations – the fruits of which we expect to see early next quarter.

The need for physician engagement is crucial to fully accelerate adoption of Afrezza and as part of their effort to do so, management has decided to restructure and reorganize the sales teams. This is expected to enhance the team's ability to build deep relationships and help educate physicians of the clinical and quality of life benefits of Afrezza. A key part of this is educating prescribers about the substantive differences between Afrezza and subcutaneously-delivered insulin, including the proven superior time-action profile of MannKind's inhaled insulin.

The strategy includes increasing the team's productivity. In order to do so, the company exited 14 states at the end of 2018 and is now focusing on 30 states that they have identified as a driver of over half of the rapid-acting insulin market. Further, management has decided to reevaluate territories and create 15 new ones in order to zero-in on high-potential segments including California, Florida, New York and Texas.

PBMs and payors have been a substantial barrier to adoption between patients and Afrezza. Several of MannKind's contracts with PBMs (CVS and Anthem) expired or begin to expire at the end of 2018-2019 period. The company has engaged in meaningful discussions with payors such as Kaiser regarding a mutually beneficial pricing arrangement and anticipates positive payor coverage beginning this year.

Previously, Afrezza had been saddled with prior authorizations (PAs). According to Fingertip Formulary, the leading provider of access and insight into the U.S. formulary data, Afrezza has unrestricted access to ~50% of commercial lives nationwide. Additionally, the company launched a two-in-one card this month that automatically applies co-pay assistance when a patient presents their prescription at the pharmacy for as low as $15. Easy implementation at the national level and electronic co-pay savings at the drug dispensing site increases patient awareness and improves adherence to therapy. MannKind also just launched a direct-purchase program, allowing patients to purchase Afrezza directly from the company for just $4 per day – providing affordable access to those on low incomes or without health insurance.

International expansion…

The company anticipates a regulatory filing for Afrezza in Canada in 1H 2019 and in E.U. in the latter half of the year. MannKind is also pursuing commercialization in India and Brazil. An underutilized manufacturing facility is one of the key elements that impacts costs and expanding the customer base internationally should help reduce this overcapacity and benefit margins.

Study results…

MKND is pursuing a pediatric indication for Afrezza, which could expand the aggregate size of their target markets. Clinical studies are underway and the company anticipates the program to be Phase III-ready by the end of 2019. MannKind is also investigating the use of Afrezza and One Drop's integrated digital diabetes care platform, which includes a mobile app, Bluetooth custom glucose monitoring meter called Chrome, test strips and an expert coaching service. The A-One study randomized T2D patients into two treatment groups with one group using the

One Drop platform alone, while the other used Afrezza along with One Drop. The results of this six months study are expected sometime this year.

Dr. Phil Levine initiated a trial in T2D patients whose HbA1c levels were not within recommended guidelines when treated with oral agents, basal insulin or GLP-1 for 6 months. About 40 subjects were treated with Afrezza and we anticipate the readout from this study this year.

Moving the pipeline forward in 2019…

MannKind has three products with which they have partnered with United Therapeutics for PAH and Receptor Life Sciences in the cannabinoid space. In addition, the company has four development candidates in its pipeline - a triptan for acute migraine, a 5HT3 inhibitor for chemotherapy-induced nausea and vomiting (CINV), inhaled tobramycin for cystic fibrosis (CF) and an undisclosed compound targeting a large consumer driven market. While committed to executing their clinical development and pipeline strategies, management is also cognizant of making sure that they use their capital efficiently and effectively.

Capital Raise…

In order to execute on their strategy in the upcoming quarters as well as being aware of the volatility in equity markets, which could impact fund raising, management decided to raise capital in December of last year. From the support of existing shareholders as well as new investors, the company was able to raise $40 million and entered 2019 with roughly $70 million of cash on their balance sheet. Assuming Afrezza sales ramp as expected, the cash runway might extend to early 2020. Nonetheless, we believe the company is sufficiently funded for at least the current year.

Reiterating Price Target…

As we had already incorporated an assumed substantial equity raise, which was reflected in the forecasted outstanding share count in our model, this recent financing has no effect on our calculated fair value. As such, we are reiterating our $4.25/share price target.

MannKind Financial Model

	2017 A	Q1A	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E
Product sales	$9.2	$3.4	$3.8	$4.4	$4.6	$16.2	$35.0	$70.4
YOY Growth	385.1%	184.4%	142.4%	121.5%	3.6%	75.9%	116.6%	101.1%
Collaboration revenue	$0.3	$0.1	$0.1	$0.1	$0.1	$0.3	$0.3	$0.3
YOY Growth	-99.9%	0.0%	38.1%	32.3%	61.3%	32.8%	-9.6%	0.0%
Other revenue	$2.3	$0.0	$0.1	$0.0	$0.0	$0.1	$0.1	$0.1
YOY Growth	156.5%	-100.0%	-90.4%	-	-100.0%	-97.7%	88.7%	0.0%
Revenue	$11.7	$3.5	$3.9	$4.5	$4.7	$16.6	$35.4	$70.8
YOY Growth	-93.3%	15.2%	80.0%	118.7%	4.4%	41.0%	114.0%	99.9%
Cost of Goods Sold	$17.2	$4.0	$5.1	$5.3	$5.4	$19.8	$31.2	$58.1
Cost of collaboration rev	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	($5.5)	($0.5)	($1.2)	($0.8)	($0.7)	($3.3)	$4.3	$12.7
Gross Margin	-46.7%	-15.7%	-30.9%	-18.7%	-15.0%	-19.9%	12.0%	18.0%
R&D	$14.1	$2.6	$3.0	$2.0	$2.7	$10.4	$18.4	$22.2
R&D % sales	120.2%	76.3%	76.2%	45.7%	57.1%	62.5%	51.9%	31.3%
SG&A	$75.0	$20.6	$21.7	$19.4	$24.2	$86.0	$103.5	$140.2
SG&A % Sales	638.2%	595.0%	558.2%	434.0%	512.0%	519.2%	292.2%	198.0%
Operating Income	($94.6)	($23.8)	($25.9)	($22.3)	($27.6)	($99.6)	($117.7)	($149.7)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income, net	$1.6	($6.6)	$3.5	$0.7	($0.5)	($2.9)	$5.7	$0.2
Pre-Tax Income	($117.3)	($30.4)	($22.4)	($24.2)	($27.1)	($102.2)	($123.4)	($149.9)
Taxes (benefit)	$0.1	$0.0	$0.2	$0.0	$0.0	$0.2	$0.0	$0.0
Tax Rate	0.0%	0.0%	-1.1%	0.0%	0.0%	-0.2%	0.0%	0.0%
Net Income	($117.3)	($30.4)	($22.7)	($24.2)	($27.1)	($102.4)	($123.4)	($149.9)
Net Margin	-999.0%	-876.9%	-582.5%	-540.8%	-573.5%	-618.8%	-348.2%	-211.6%
EPS	($1.13)	($0.25)	($0.16)	($0.16)	($0.17)	($0.71)	($0.63)	($0.68)
YOY Growth		-	-	-	-			
Diluted Shares O/S	104.2	120.9	140.1	153.6	161.5	144.0	195.0	220.0

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