Zacks Small-Cap Research
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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Milestone Payments from Legacy Gene Therapy Assets…

Based on our probability adjusted DCF model that takes into account potential future revenues from MN-166 in ALS, progressive MS, and addiction; and MN-001 in NASH and IPF, MNOV is valued at $26.50/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (04/26/21)	$4.43
Valuation	**$26.50**

OUTLOOK

On April 22, 2021, MediciNova, Inc. (MNOV) announced it had recently received two milestone payments from the assignment agreement with Genzyme Corporation, a subsidiary of Sanofi. The milestone payments totaled $4 million and are the result of the successful achievement of two clinical development milestones for a gene therapy product based on adeno-associated virus vector technology originally developed by Avigen Inc. MediciNova acquired Avigen in 2009. Under terms of the assignment agreement, MediciNova is eligible to receive milestone payments as well as royalties on the sale of products derived from the assignment agreement.

SUMMARY DATA

52-Week High	**$11.00**
52-Week Low	**$4.39**
One-Year Return (%)	**-18.72**
Beta	**1.45**
Average Daily Volume (sh)	**289,472**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$216**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
Insider Ownership (%)	**16**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 E	0 E	0 E	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.06 A	-$0.10 A	-$0.08 A	-$0.07 A	-$0.31 A
2021	-$0.07 E	-$0.08 E	-$0.09 E	-$0.10 E	-$0.34 E
2022					-$0.35 E
2023					-$0.39 E

WHAT'S NEW

Business Update

Milestone Payments from AAV Assets

On April 22, 2021, MediciNova, Inc. (MNOV) announced the receipt of two milestone payments that totaled $4 million as a result of the successful achievement of two clinical development milestones for a gene therapy product based on adeno-associated virus (AAV) vector technology. The AAV technology was developed by Avigen, Inc., which MediciNova acquired in 2009. In 2005, Avigen signed an assignment agreement with Genzyme Corporation, now a subsidiary of Sanofi, for the AAV technology and a large family of patents that included milestone and royalty payments for any products covered by the claims of those patents. In 2014, MediciNova received a $6 million milestone payment from Genzyme related to a gene therapy program under this agreement.

Gene therapy is an exciting area of research as it is becoming possible to replace defective genes that cause debilitating diseases that were once very difficult, if not impossible, to treat. There are a number of vectors available to deliver genes inside of cells, including adenoviruses, AAV, retroviruses, and lentiviruses. AAV is a non-enveloped virus that is able to infect both dividing and non-dividing cells. It contains a small, single-stranded DNA genome that is approximately 4.8 kilobases, which is approximately the limit for the size of a gene that can packaged efficiently inside it. The genes delivered by AAV persist as extra-chromosomal episomes in the nucleus of transduced cells and do not integrate into host genomes (Choi *et al*., 2006). However, transgene expression is potentially long lasting when delivered by AAV, which is an advantage over other vectors such as adenovirus.

Thus far, the FDA has approved two products that utilize AAV as a vector, with a third submission receiving a CRL due to additional data requirements:

- Luxturna® (voretigene neparvovec-rzyl): In December 2017, the FDA approved Luxterna for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy, a genetic retinal disorder that affects approximately 1,000 to 2,000 patients in the U.S. Revenues for Luxturna were $38 million in 2020 (EvaluatePharma).

- Zolgensma® (onasemnogene abeparvovec-xioi): In May 2019, the FDA approved Zolgensma for the treatment of spinal muscular atrophy (SMA) in pediatric patients less than two years old. SMA is caused by a rare mutation in the survival motor neuron 1 gene. Novartis reported revenues for Zolgensma of $920 million in 2020 with projected revenues of $2 billion in 2025 (EvaluatePharma).

- Valoctocogene roxaparvovec: In August 2020, the FDA issued a complete response letter (CRL) to Biomarin for its severe hemophilia A treatment. The CRL was in regard to additional clinical trial data the agency requested and was not related to any safety issues from the AAV vector.

In December 2020, REGENXBIO, Inc. sold a portion of the royalty rights from the net sales of Zolgensma (derived from its AAV technology) to Healthcare Royalty Management, LLC for $200 million. REGENXBIO received $61.6 million in royalties from the sale of Zolgensma in 2020 (approximately 6.7%). We believe this is an excellent example of how a company can monetize rights to approved AAV products.

Conclusion

The rights to the AAV assets that MediciNova acquired from Avigen represent underappreciated upside potential for investors as not many are even aware of their existence. We do not have access to the unredacted agreement between Avigen and Genzyme, thus we do not know the exact amounts that are possible for milestone and royalty payments, or even which specific products in development are covered by the agreement, however the fact that MediciNova recently received two payments for clinical development milestones is very encouraging and means that the potential exists for these payments to occur again in the future. Our valuation remains at $26.50.

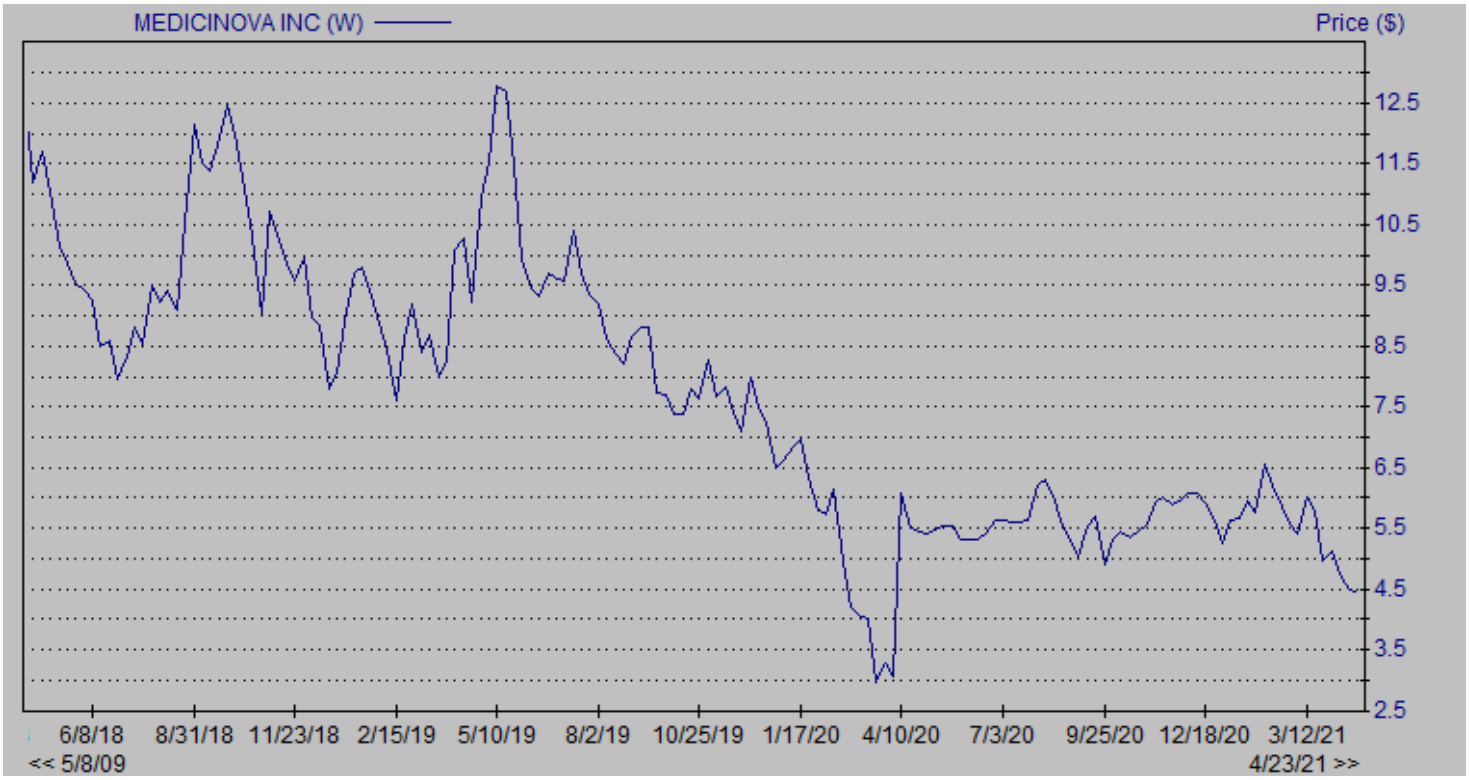
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2020 A	Q1 E	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
MN-166 (Multiple Sclerosis)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (ALS)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (Addiction)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (NASH)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (IPF)	$0	$0	$0	$0	$0	$0	$0	$0
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$7.5	$2.0	$2.3	$2.5	$2.8	$9.6	$11.0	$13.0
General & Administrative	$6.7	$1.7	$1.8	$1.9	$2.0	$7.4	$8.0	$9.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14.2)	($3.7)	($4.1)	($4.4)	($4.8)	($17.0)	($19.0)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.3	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($13.9)	($3.6)	($4.0)	($4.3)	($4.7)	($16.6)	($18.6)	($21.6)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($13.9)**	**($3.6)**	**($4.0)**	**($4.3)**	**($4.7)**	**($16.6)**	**($18.6)**	**($21.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.07)**	**($0.08)**	**($0.09)**	**($0.10)**	**($0.34)**	**($0.35)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	44.413	48.600	48.800	49.000	49.200	48.900	53.000	55.000

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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