Zacks Small-Cap Research
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INmune Bio, Inc. (INMB-NASDAQ)

INMB: Evaluating DN-TNF as COVID-19 Treatment…

Based on our probability adjusted DCF model that takes into account potential future revenues of INB03, XPro1595, and INKmune, INMB is valued at $19/share. This model is highly dependent upon continued clinical success of those compounds and will be adjusted accordingly based upon future clinical results.

Current Price (04/22/20)	$4.27
Valuation	**$19.00**

OUTLOOK

On April 20, 2020, INmune Bio, Inc. (INMB) announced that the company will be evaluating the dominant-negative tumor necrosis factor (DN-TNF) platform as a potential treatment for COVID-19 caused by infection from the novel coronavirus SARS-CoV-2. The company will be targeting patients that are admitted to the hospital with hypoxia in an attempt to decrease the need to transfer patients to the ICU and use mechanical ventilation. The clinical protocol is written and the company is working on contracting clinical sites to initiate the trial as quickly as possible. Soluble TNF is a component of the 'cytokine storm' that is seen in patients hospitalized with COVID-19 and contributes to hypoxia and acute respiratory distress syndrome (ARDS), thus making it a suitable target for treating COVID-19.

SUMMARY DATA

52-Week High	**$11.00**
52-Week Low	**$2.21**
One-Year Return (%)	**-60.08**
Beta	**1.54**
Average Daily Volume (sh)	**20,507**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$46**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**68**
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	**Above Avg.**
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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.20 A	-$0.04 A	-$0.28 A	-$0.21 A	-$0.75 A
2020	-$0.14 E	-$0.14 E	-$0.19 E	-$0.23 E	-$0.71 E
2021					-$0.61 E
2022					-$0.61 E

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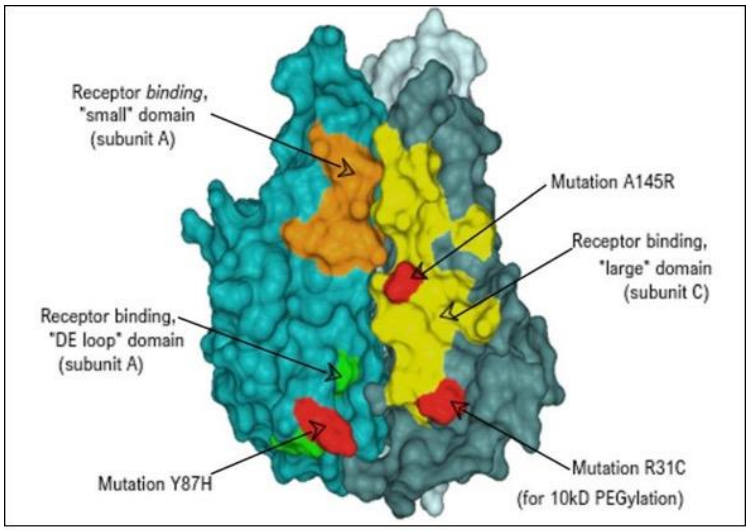
WHAT'S NEW

Business Update

Testing DN-TNF Platform as Treatment for COVID-19

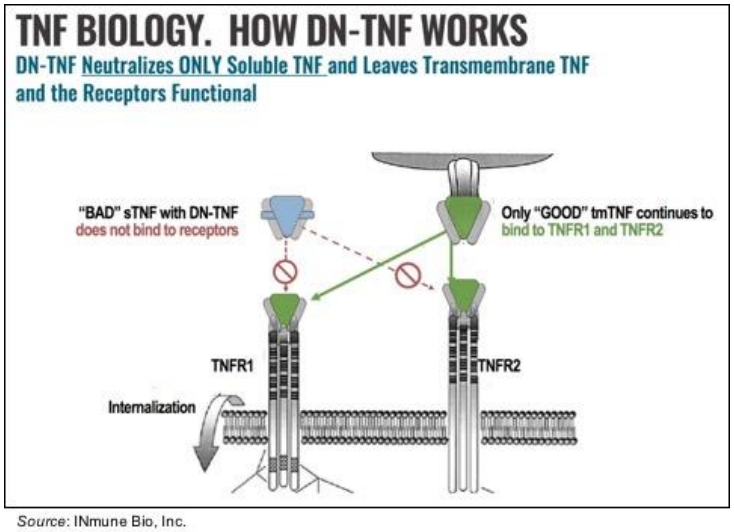
On April 20, 2020, INmune Bio, Inc. (INMB) announced that the company will be testing the company's dominant-negative tumor necrosis factor (DN-TNF) platform as a treatment for COVID-19 caused by the novel coronavirus SARS-CoV-2.

The DN-TNF platform is based on an engineered protein that is nearly identical to soluble TNF (sTNF) except for two point mutations in the coding sequence and the addition of polyethylene glycol (PEG) to increase its half-life in circulation (Steed *et al*., 2003). The following figure shows the crystal structure of the DN-TNF protein.



Source: INmune Bio, Inc.

TNF is an inflammatory cytokine that is expressed on the cell surface (known as transmembrane TNF, tmTNF) and can be cleaved by TNFα-converting enzyme to produce a trimeric sTNF, which is found circulating in the bloodstream. sTNF is predominantly responsible for inflammatory responses while tmTNF is predominantly responsible for immune-mediated responses. DN-TNF only neutralizes sTNF and does not interfere with tmTNF, as shown in the following figure.

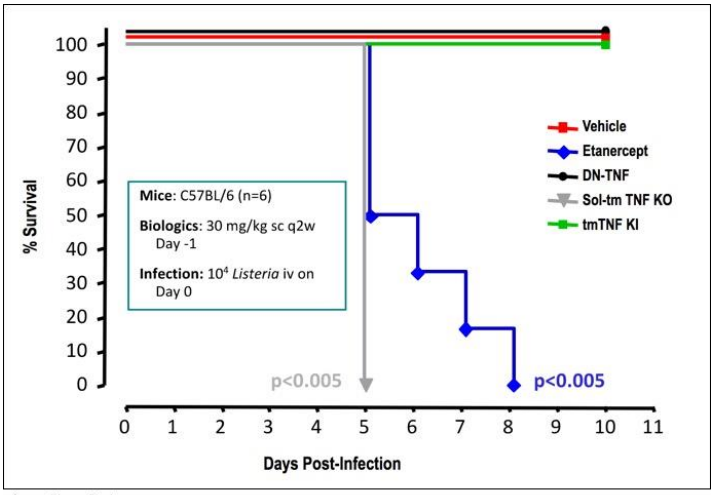


Source: INmune Bio, Inc.

There are numerous pieces of evidence to support targeting TNF in patients with COVID-19. Multiple studies show that COVID-19 patients have elevated levels of pro-inflammatory cytokines in their blood, including IL-1, IL-6, and TNF (Huang *et al*., 2020; Gong *et al*., 2020). A case report from France showed positive results using an anti-IL-6 antibody to treat a COVID-19 patient, thus showing that cytokines are an important mediator of the disease (Michot *et al*., 2020).

TNF is implicated in multiple inflammatory diseases and positive results are seen when inhibiting the molecule. Blockade of TNF in a mouse model of severe respiratory syncytial virus (RSV) and influenza leads to a reduction in weight loss, disease severity, and fluid infiltration (Hussell *et al*., 2001). In rheumatoid arthritis patients, blocking TNF results in decreases in both IL-6 and IL-1 (Charles *et al*., 1999). Lastly, a reduction in adhesion molecules is seen following anti-TNF therapy, which is important as they are involved in capillary leak (Paleolog *et al*., 1998).

While TNF appears to be a valid target for treating COVID-19, there is a risk of immunosuppression with currently available anti-TNF therapies that can lead to opportunistic infections (Ali *et al*., 2013). However, DN-TNF therapy does not carry the risk of immunosuppression. The following graph shows survival in a mouse model of Listeria infection. All mice treated with etanercept die by eight days following infection, however all mice treated with DN-TNF survive the entire experiment, showing that DN-TNF therapy does not cause immunosuppression like other anti-TNF therapies.



Source: INmune Bio, Inc.

Phase 2 Trial

While the details of the trial design are still being finalized, we believe it will be a two-arm trial that will involve approximately 150 patients randomized 1:1 to either standard of care plus placebo or standard of care plus two doses of DN-TNF (the first upon admission to the hospital and the second a week later). Patients will be eligible for the study if they are hypoxic but do not require admission to the intensive care unit (ICU) or the use of mechanical ventilation. The goal of the study is to determine if DN-TNF treatment can prevent patients from progressing to the point where they need mechanical ventilation and/or support in the ICU. INmune Bio has applied for a grant from BARDA to support the trial, and while the study may not be as large without that support we anticipate the company moving forward in this indication regardless whether an award is granted or not.

Conclusion

Testing DN-TNF as a treatment for COVID-19 is certainly warranted given the aforementioned data indicating that cytokines are involved in cytokine storm in COVID-19 patients and the fact that DN-TNF is not immunosuppressive. We look forward to updates regarding the trial, including whether the company is able to secure non-dilutive funding to support the study. Our current valuation is $19/share.

PROJECTED FINANCIALS

INmune Bio, Inc.
Income Statement

INMune Bio, Inc.	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
INB03	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
INKmune	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Other Income	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$3.3	$0.5	$0.5	$1.0	$1.5	$3.5	$3.8	$4.0
General & Administrative	$6.0	$1.0	$1.0	$1.5	$1.5	$5.0	$6.0	$7.0
Other (Income) Expense	($1.5)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.8)	($1.5)	($1.50)	($2.5)	($3.0)	($8.5)	($9.8)	($11.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($7.7)	($1.5)	($1.5)	($2.5)	($3.0)	($8.5)	($9.8)	($11.0)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($7.7)**	**($1.5)**	**($1.5)**	**($2.5)**	**($3.0)**	**($8.5)**	**($9.8)**	**($11.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.75)**	**($0.14)**	**($0.14)**	**($0.19)**	**($0.23)**	**($0.71)**	**($0.61)**	**($0.61)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	10.3	10.8	10.8	13.0	13.0	11.9	16.0	18.0

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

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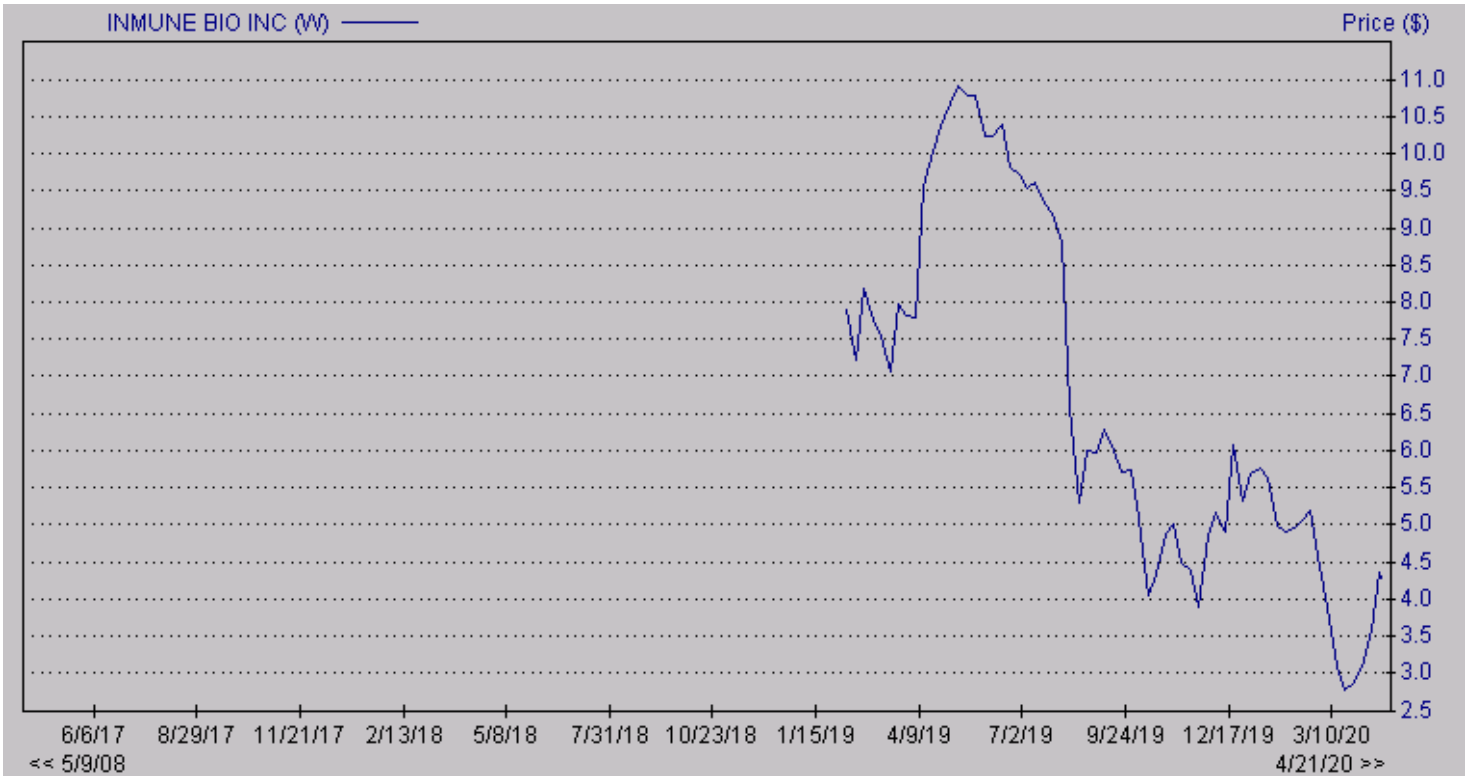
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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