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INmune Bio, Inc. (INMB-NASDAQ)

INMB: Potential Link Between Obesity and Neuroinflammation Shown in Mouse Model of Alzheimer's…

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 (11/25/19)	$3.91
Valuation	**$19.00**

OUTLOOK

On October 21, 2019, INmune Bio, Inc. (INMB) announced a presentation at the Society for Neuroscience that appears to show treatment with XPro1595 leads to a mitigation of Alzheimer's-like pathology triggered by a high fat and high fructose diet in mice. XPro1959 is an anti-inflammatory drug that selectively neutralizes soluble tumor necrosis factor (TNF) and is currently being evaluated in a Phase 1 clinical trial in patients with mild to moderate Alzheimer's disease.

INmune is also evaluating TNF neutralization in combination with checkpoint inhibitor therapy, for which a Phase 2 trial is set to initiate in 1H20 and for the treatment of NASH, for which a Phase 2 clinical trial will initiate in the 2H20.

SUMMARY DATA

52-Week High	**$11.00**
52-Week Low	**$3.56**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**10,270**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$42**
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	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	-$1.43 A
2019	-$0.20 A	-$0.04 A	-$0.28 A	-$0.18 E	-$0.72 E
2020					-$0.75 E
2021					-$0.63 E

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WHAT'S NEW

Business Update

Link Between Obesity and Alzheimer's Presented at Society for Neuroscience Annual Meeting

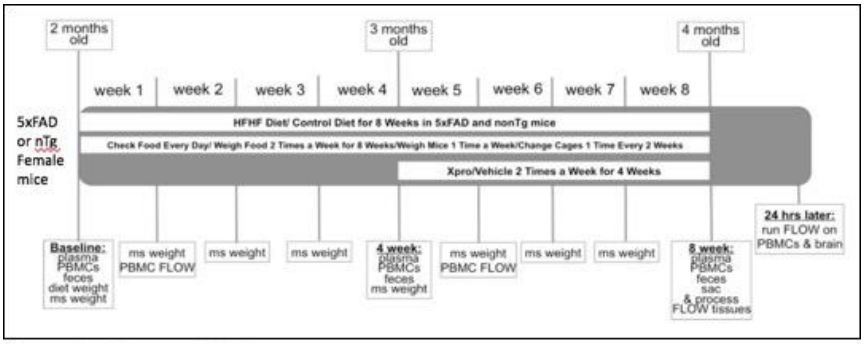
On October 21, 2019, INmune Bio, Inc. (INMB) announced a presentation at the Society for Neuroscience 49th Annual Meeting showing the company's lead compound, XPro1595, appears to mitigate Alzheimer's-like pathology brought on by a high-fat and high-fructose diet in a mouse model of Alzheimer's disease (AD). A diet high in fat and sugar dysregulates several signaling pathways that results in an increase in inflammation and metabolic syndrome, thus investigators hypothesized that targeting one of the key cytokines that regulates inflammatory response, tumor necrosis factor (TNF), may ameliorate the effects of neuroinflammation in a mouse model of AD.

Inflammation has been an underappreciated and often overlooked mediator in patients with AD (Akiyama *et al*., 2000). A multitude of inflammatory markers are found in AD patients' brains and a number of studies have shown a link between chronic inflammation and an increased risk of developing AD (Walker *et al*., 2017; Tao *et al*., 2018). Neuroinflammation is mediated by microglia cells, resident phagocytes of the central nervous system (CNS), which are the major source of cytokines in AD, particularly TNF.

A number of preclinical studies have shown an association between inflammation and AD pathology in several animal models of AD, including APPV717F mice (Qiao *et al*., 2001), APPSwe Tg2576 mice (Sheng *et al*., 2003), and 3xTgAD mice (Kitazawa *et al*., 2005). An elevation in TNF mRNA is seen in 3xTgAD mice prior to the appearance of AD pathology (Janelsins *et al*., 2005) and is correlated with cognitive deficits (Billings *et al*., 2005). Those results led to a number of experiments that examined the inhibition of TNF in preventing AD pathology. In 3xTgAD mice, inhibition of soluble TNF (sTNF) with XPro1595 prevented inflammation-induced accumulation of C-terminal amyloid beta protein (McAlpine *et al*., 2009). In TgCRND3 amyloid transgenic mice, treatment with XPro1595 for four weeks starting at age 1 month prevented synaptic deficits at age 6 months (Cavanagh *et al*., 2016).

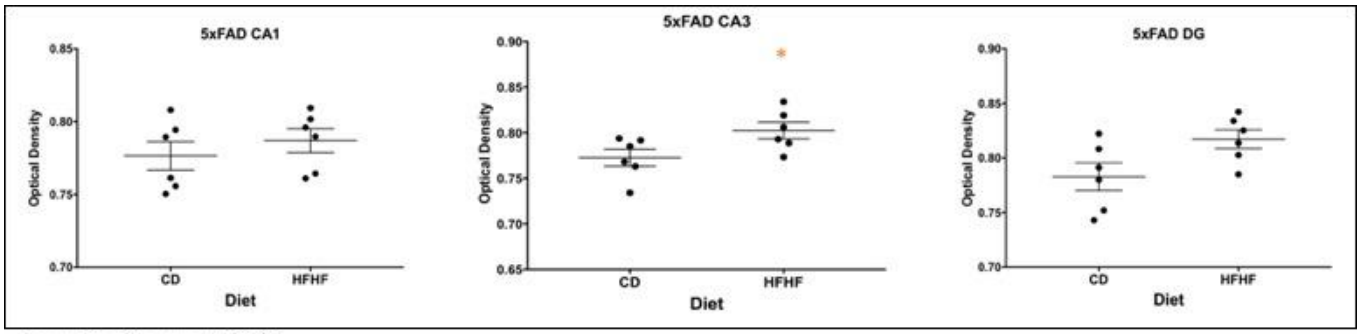
An association between TNF and AD is also seen in the clinic. Elevated levels of TNF are found in the serum of AD patients (Fillit *et al*., 1991), a TNF promoter polymorphism was found to be associated with AD (Ma *et al*., 2004), elevated TNF serum levels are associated with an increased risk of conversion from MCI to AD (Tarkowski *et al*., 2003), and a small, open label pilot study of etanercept in patients with mild-to-severe AD showed improvement in a number of AD outcomes (Tobinick *et al*., 2006). We also previously discussed how researchers at Pfizer observed the use of etanercept was associated with a 64% decreased risk of developing AD. Thus, there is ample rationale for investigating therapeutics that target TNF for the treatment of AD.

The following figure gives an overview of the experiment recently presented by INmune Bio. 5xFAD mice express human amyloid precursor protein (APP) and presenilin-1 (PSEN1) genes with a total of five AD-linked mutations. The mice recapitulate many AD-related phenotypes including amyloid plaques, neuron loss in multiple brain regions, and a range of cognitive and motor deficits. The pathology is more severe in female mice than males. For this experiment, two-month-old female 5xFAD mice were fed a high-fat, high-carbohydrate (HFHC) diet or a control diet (CD) for eight weeks. After four weeks of diet, the mice were treated with XPro1595 or vehicle two times a week for four weeks.



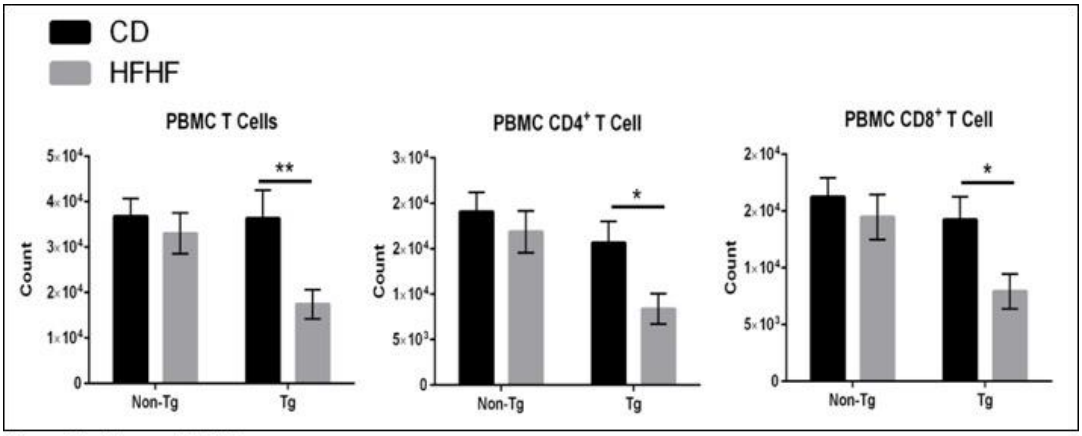
Source: MacPherson *et al*., 2019

The following figure shows that 5xFAD mice fed a HFHC diet develop statistically significantly more amyloid plaques than 5xFAD mice fed a standard diet in both the CA3 and Dentate Gyrus (DG) regions of the hippocampus, showing the detrimental effects that type of diet can have.



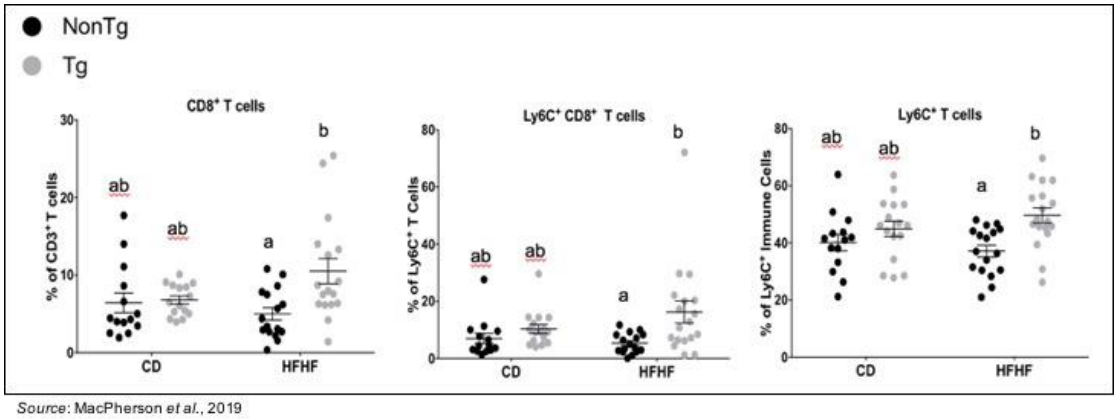
Source: MacPherson *et al.*, 2019

The obesogenic diet also impacts the immune system. The following charts show that 5xFAD mice fed the HFHC diet have decreased numbers of peripheral T cells, both CD4+ and CD8+, while 5xFAD mice fed a standard diet did not see any effect on T cell populations. In addition, the HFHC diet does not affect T cell counts in control mice (Non-Tg).



Source: MacPherson *et al.*, 2019

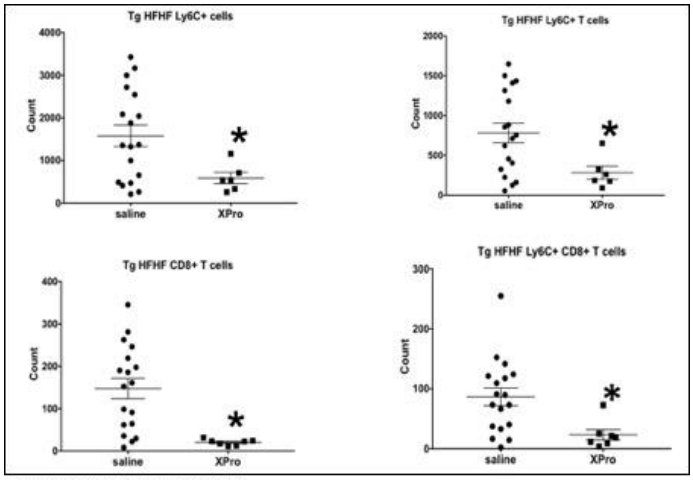
While peripheral T cell counts are decreased in 5xFAD mice fed a HFHC diet, the number of CD8+ T cells in the brain is increased. The following charts show that only 5xFAD mice fed a HFHC diet had increased counts and frequencies of CD8+ T cells, Ly6C+CD8+ T cells, and Ly6C+ T cells in the brain. There were no other combined gene x diet interactions on brain immune cell populations analyzed.



Source: MacPherson *et al.*, 2019

Treatment with XPro1595 ameliorates the diet-induced T cell trafficking to the brain. The following charts show that 5xFAD mice fed a HFHC diet and treated with XPro1595 have statistically significantly fewer CD8+ T cells, Ly6C+

cells, Ly6C+ T cells, and Ly6C+CD8+ T cells compared to 5xFAD mice fed a HFHC diet and treated with saline, thus showing that XPro1595 can decrease the diet-induced neuroinflammatory response.



Source: MacPherson *et al.*, 2019

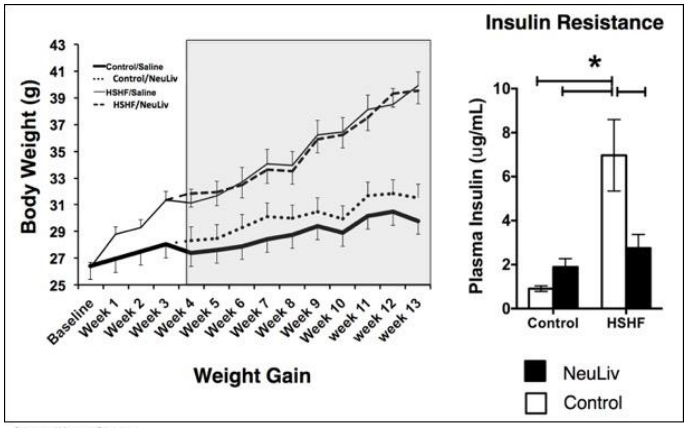
In summary, the results of these experiments utilizing a combination of a diet-induced obesity and an AD model support earlier reports of a link between inflammation and AD pathology, and that this inflammatory response can be mitigated through treatment with XPro1595. There are currently 93 million obese individuals in the U.S., thus understanding the link between obesity, inflammation, and AD is of paramount importance and it is encouraging to see that targeting inflammation may be one avenue to treat neurodegenerative diseases such as AD.

INmune Bio is currently conducting a biomarker-directed Phase 1 clinical trial of XPro1595 in 18 patients with mild to moderate AD (NCT03943264). The primary endpoint for the trial is safety with key secondary endpoints including a decrease in inflammation as measured in the blood, cerebrospinal fluid (CSF), the brain, and the breath. Additional secondary endpoints include measures of cognition, psychiatric symptoms, and quality of life, however since the trial is only 12 weeks it is doubtful cognitive benefits will be seen. We anticipate topline data in the second half of 2020.

NeuLiv™ for the Treatment of NASH

NeuLiv™ is the company's third program to derive from the dominant negative-TNF (DN-TNF) platform, which includes XPro1595 for the treatment of AD and INB03 for the treatment of patients with advanced cancer. NueLiv™ will be utilized for the treatment of nonalcoholic steatohepatitis (NASH), which is inflammation and damage in the liver brought on by a buildup of fat and is the most severe form of nonalcoholic fatty liver disease (NAFLD). NASH is an often "silent" liver disease as most people with NASH feel well and are not aware that they have a liver problem. Nevertheless, NASH can be severe and can lead to cirrhosis, in which the liver is permanently damaged and scarred and no longer works properly, liver failure, and hepatocellular carcinoma.

Data from mice fed a HF-high fructose (HFHF) diet shows that while not affecting weight gain, treatment with NeuLiv™ leads to decreased insulin resistance, as well as decreased hepatic steatosis.



Source: INmune Bio, Inc.

We anticipate the company initiating a Phase 2 clinical trial of NeuLiv™ in biopsy-confirmed NASH patients in the second half of 2020 and anticipate additional updates regarding the details of this trial in the coming months.

New Addition to Board of Directors

On Nov. 19, 2019, INmune Bio announced the appointment of Marcia Allen to the company's board as an independent director. Ms. Allen is the CEO and founder of Allen & Associates and for the past 20 years has been involved in various aspects of venture capital and corporate financing as a Managing Director of Elite Capital, Inc. and a principal at Allen/Brenner, Inc. She was previously CFO of The Movie Group, which is today Lionsgate Entertainment, W.R. Grace & Co., and Taco Bell, Inc, where she helped facilitate the acquisition of Taco Bell by PepsiCo. Her extensive experience in corporate financing and acquisitions will provide INmune with a unique insight as the company advances its pipeline through clinical development.

Financial Update

On November 8, 2019, INmune Bio announced financial results for the third quarter of 2019. As expected, the company did not report any revenues during the third quarter of 2019. Not loss for the three months ending Sep. 30, 2019 was $3.1 million, compared to $1.5 million for the third quarter of 2018. R&D expenses for the third quarter of 2019 were $1.2 million, compared to $0.7 million for the third quarter of 2018. The increase was primarily due to the advancement of the company's pipeline. G&A expense for the third quarter of 2019 were $1.9 million, compared to $0.9 million for the third quarter of 2018. The increase was primarily the results of increased costs associated with being a public company.

INmune Bio exited the third quarter of 2019 with approximately $7.4 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into the second quarter of 2020. As of November 8, 2019, INmune had approximately 10.8 million shares of common stock outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 13.3 million.

Conclusion

The data presented by INmune showing a link between diet-induced obesity, inflammation, and AD is very interesting, and it is refreshing to see new approaches to treating AD being tested in the clinic. We look forward to seeing results from the ongoing Phase 1 clinical trial of XPro1595 in AD patients in the second half of 2020. In addition, we anticipate INmune Bio initiating a Phase 2 clinical trial of INB03 in combination with checkpoint inhibitor therapy in the first half of 2020, while a Phase 2a trial of NeuLiv™ in NASH patients is anticipated to begin in the second half of 2020. Our current valuation for INmune Bio is $19/share.

PROJECTED FINANCIALS

INmune Bio, Inc.
Income Statement

INMune Bio, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 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	$1.1	$0.1	$0.3	$1.2	$0.3	$1.9	$2.0	$2.5
General & Administrative	$11.3	$1.8	$1.7	$1.9	$1.6	$7.0	$7.0	$7.0
Other (Income) Expense	$0.0	$0.0	($1.5)	$0.0	$0.0	($1.5)	$0.0	$0.0
Operating Income	($12.4)	($1.9)	($0.4)	($3.1)	($1.9)	($7.3)	($9.0)	($9.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	$0.0	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($12.4)	($1.9)	($0.4)	($3.1)	($1.9)	($7.3)	($9.0)	($9.5)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($12.4)**	**($1.9)**	**($0.4)**	**($3.1)**	**($1.9)**	**($7.3)**	**($9.0)**	**($9.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.43)**	**($0.20)**	**($0.04)**	**($0.28)**	**($0.18)**	**($0.72)**	**($0.75)**	**($0.63)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	8.7	9.4	10.2	10.8	10.4	10.2	12.0	15.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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