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INmune Bio, Inc. (INMB-NASDAQ)

INMB: Multiple Milestones Ahead in 2020…

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 (03/16/20)	$3.10
Valuation	**$19.00**

OUTLOOK

On March 11, 2020, INmune Bio, Inc. (INMB) announced financial results for 2019 and provided a business update. Looking ahead to the six to 12 months, we anticipate a number of key milestones for the company, including: topline results from a Phase 1 study of XPro1595 in patients with Alzheimer's Disease in the second half of 2020; the initiation of a Phase 2 clinical trial of INB03 in combination with another agent in patients with trastuzumab-resistant HER2+ breast cancer in mid-2020; initiation of a Phase 2 clinical trial of LIVNate for the treatment of NASH in mid-2020; and the initiation of two clinical trials of INKmune in high risk MDS and ovarian cancer in the second half of 2020.

SUMMARY DATA

52-Week High	**$11.00**
52-Week Low	**$3.10**
One-Year Return (%)	**-56.22**
Beta	**N/A**
Average Daily Volume (sh)	**60,276**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$33**
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-Value**
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

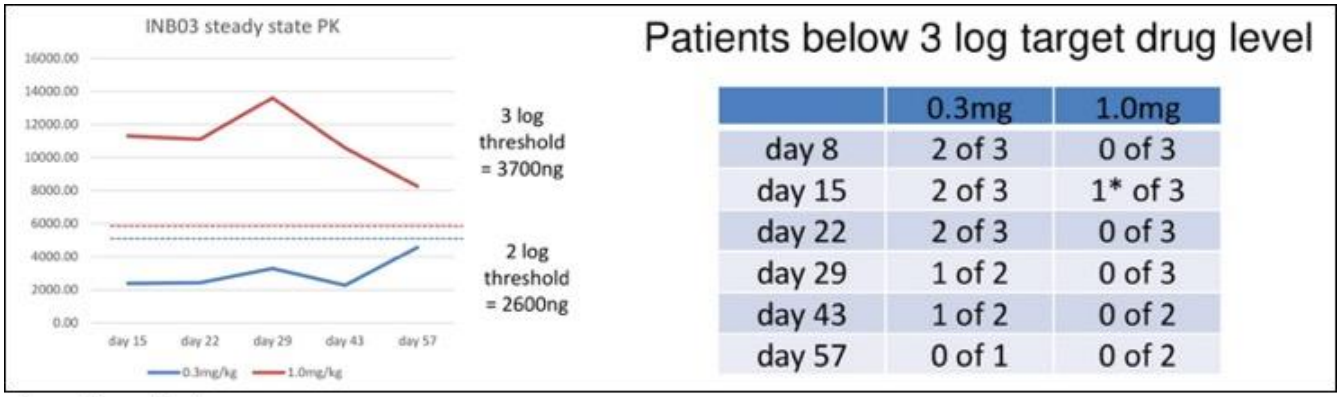
Data from Phase 1 Trial of XPro1595 in Alzheimer's Disease in 2H20

INmune Bio, Inc. (INMB) is currently conducting a Phase 1 clinical trial of XPro1595 in patients with Alzheimer's Disease (AD). The trial is supported by a $1 million grant from the Alzheimer's Association, which is derived from the Part the Cloud grant, which is intended to accelerate novel preclinical research findings into clinical testing. The ongoing Phase 1 trial is a biomarker-directed study in 18 patients with mild-to-moderate AD (NCT03943264). XPro1595 will be administered once a week at three different doses (0.3 mg/kg, 1.0 mg/kg, 3.0 mg/kg) for three months and biomarkers of inflammation will be assessed at 0, 6, and 12 weeks. The primary endpoints for the trial are safety and a decrease in inflammation as measured in the blood, cerebrospinal fluid (CSF), the brain, and the breath. 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 being reported in the second half of 2020. If successful, we believe INmune will advance to a longer and larger Phase 2 trial to test for effects on slowing or preventing cognitive decline.

INB03 Trial in Breast Cancer to Initiate in mid-2020

INmune is planning to initiate a Phase 2 clinical trial of INB03 in patients with trastuzumab-resistant HER2+ breast cancer. We anticipate the trial getting underway in mid-2020. In December 2019, the company announced final results from the Phase 1 clinical trial of INB03, which was an open label, dose escalation trial in patients with advanced solid tumors. The goals of the trial were to determine the safety of INB03, the dose of INB03 to utilize in a Phase 2 trial, and to look for evidence of biological activity. Importantly, there were no reports of serious adverse events and INB03 was well tolerated. Discontinuation of INB03 in all patients was due to tumor progression. IL-6, a biomarker of tumor necrosis factor (TNF) function, decreased by >50% in half of the patients, which is indicative of a biological effect.

The dose for the Phase 2 program has been set at 1 mg/kg based on a goal of having the trough blood concentration of INB03 be at least two logs greater than the concentration of TNF. The following graph shows that the 1.0 mg/kg dose keeps the concentration of INB03 at least 3-log's above the TNF blood concentration and that only 1 patient in the 1.0 mg/kg cohort experienced one time point below the 3-log level.



Patients below 3 log target drug level

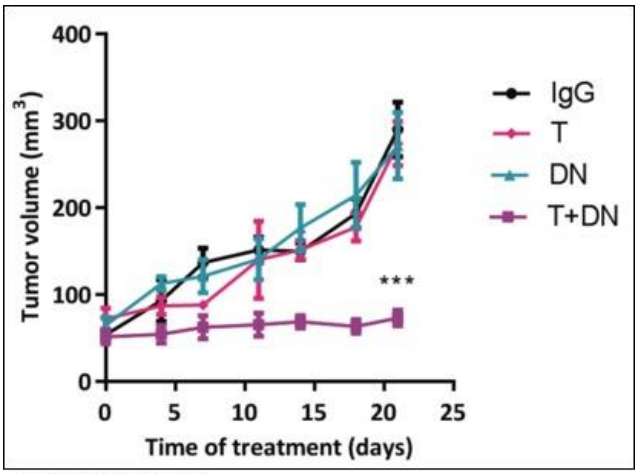
	0.3mg	1.0mg
day 8	2 of 3	0 of 3
day 15	2 of 3	1* of 3
day 22	2 of 3	0 of 3
day 29	1 of 2	0 of 3
day 43	1 of 2	0 of 2
day 57	0 of 1	0 of 2

Source: INmune Bio, Inc.

INB03 Potential in Breast Cancer

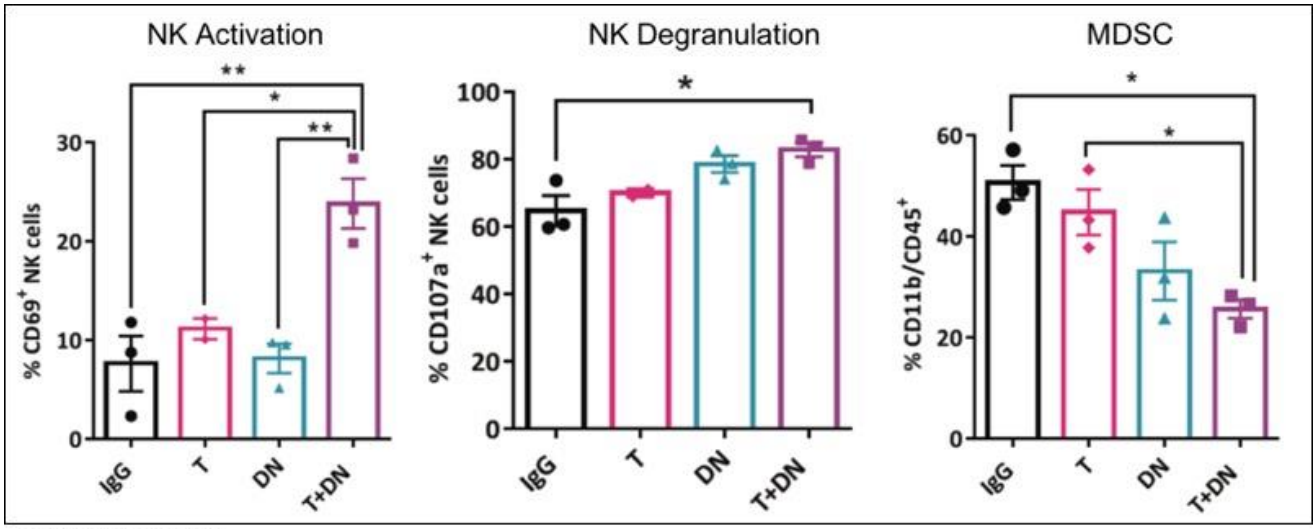
A poster presented at the 2018 San Antonio Breast Cancer Symposium investigated whether INB03 treatment could cause trastuzumab-resistant breast cancer cells to become trastuzumab-sensitive (Schillaci *et al*., 2018). This was a follow-up study to one that showed TNF overexpression resulted in trastuzumab-sensitive breast cancer cells becoming trastuzumab-resistant (Mercogliano *et al*., 2017). Trastuzumab resistance is driven by TNF-induced mucin 4 (MUC4) overexpression and MUC4 expression in HER2-positive breast cancer patients is associated with reduced disease-free survival and is an independent predictor of poor outcome in patients treated with trastuzumab.

The following figure shows that combined treatment with trastuzumab (T) and INB03 (DN) in mice injected with JIMT-1 cells (trastuzumab-resistant) resulted in significantly decreased tumor growth compared to mice treated with control IgG, only trastuzumab, or only INB03.



Source: Schillaci *et al.*, 2018

The anti-cancer effect shown by combined treatment with trastuzumab and INB03 appears to be the result of both an improvement in the innate immune response along with a less immunosuppressive tumor microenvironment. The following graphs show that combination treatment with trastuzumab and INB03 results in a significant increase in the percentage of activated and degranulated natural killer (NK) cells in the spleen (denoted through an increase in CD69- and CD107a-positive cells, respectively) and a significant decrease in the percentage of myeloid-derived suppressor cells (MDSC) in the tumor microenvironment.



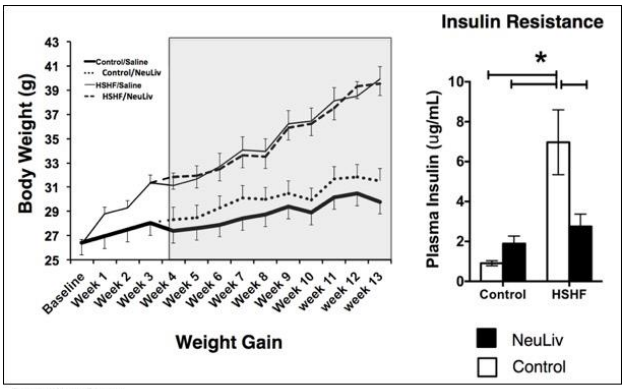
Source: Schillaci *et al.*, 2018

The results from these studies show that there is ample evidence to potentially treat HER2+ breast cancer patients with INB03 to either prevent or overcome trastuzumab resistance.

LIVNate for the Treatment of NASH

LIVNate 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 breast cancer. LIVNate 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 LIVNate (denoted as 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 LIVNate in approximately 20 NASH patients with F2 or F3 disease that are selected based on a non-invasive diagnosis (i.e., no biopsies) and analyses will be performed after six and 12 weeks of treatment to determine decreases in fibrosis. We anticipate the trial initiating in mid-2020.

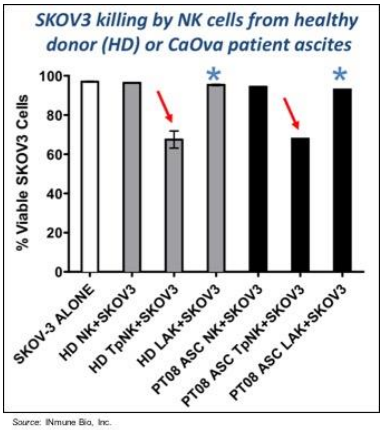
INKmune Trials to Initiate in 2H20

INKmune is a proprietary, replication deficient cell line that supplies the priming signal to natural killer (NK) cells *in vivo* to convert them from a 'resting' to an 'active' state. The main advantage of INKmune is that in comparison to cytokine- or monoclonal antibody (mAb)-primed NK cells, which require the presence of the cytokine or mAb to maintain the NK cells in a primed state, once activated by INKmune the NK cells maintain their primed state.

A first-generation therapy utilizing tumor primed NK (TpNK) cells was tested in two Phase 1 clinical trials in patients with acute myelogenous leukemia (AML) (Kottaridis *et al*., 2015; Fehniger *et al*., 2018). In both trials, haplo-identical NK cells from a first degree relative were primed *ex vivo* using a lysate of a tumor cell line (CTV-1). Following infusion of the TpNK cells, prolonged (>1 yr) relapse-free survivals (RFS) were noted in four patients, with three patients having RFS >33 months and two patients with continuing CRs >48 months.

The primary conclusions from the Phase 1 studies were that activated NK cells were clinically active, a majority of the patients relapse (thus multiple treatments are necessary), and a personalized therapy is cumbersome, thus an "off-the-shelf" treatment is ideal.

Two Phase 1 clinical trials of INKmune will be initiating in the second half of 2020: one in patients with relapsed or refractory ovarian cancer who have a low burden of residual disease and another in patients with high risk myelodysplastic syndrome (MDS). In support of the trial in ovarian cancer, the following graph shows killing of SKOV3 cells (an ovarian cancer cell line) by NK cells, from either healthy donors or ovarian cancer patients, primed with INKmune. Interestingly, NK cells primed with IL-2 do not kill SKOV3 cells (depicted by the blue star).



Source: INmune Bio, Inc.

For the ovarian cancer trial, INKmune will be administered through intraperitoneal delivery to determine safety and the optimal dose to advance to a Phase 2 trial. We anticipate six patients being treated in the study (which may be increased up to 18 patients). Secondary endpoints will be evidence of improved immunologic function, improved NK mediated cell killing in an *in vitro* assay, a decrease in tumor burden, and change in CA125 levels. CA125 is a blood biomarker that is elevated in most patients with ovarian cancer (Scholler *et al*., 2007). Decreasing levels of CA125 in the blood are generally indicative of a positive response to therapy.

For the MDS trial, patients will be enrolled who have a low burden of disease after completion of conventional therapy. INKmune will be administered as intravenous infusions and the patients will be monitored for changes in peripheral NK activation, NK function, and changes in residual blast counts in blood and bone marrow.

Grant from ALS Association to Study XPro1595 in ALS Preclinical Models

On Feb. 10, 2020, INmune Bio announced it was awarded a $500,000 grant from the ALS Association to study XPro1595 in proof-of-concept preclinical studies. We anticipate the studies taking approximately 18-24 months to complete and once done the company will be in a position to move into the clinic to test the compound in ALS patients.

Financial Update

On March 11, 2020, INmune Bio announced financial results for the fourth quarter and full year 2019. As expected, the company did not report any revenues during the fourth quarter or full year 2019. Net loss for the fourth quarter of 2019 was $2.3 million, compared to $1.9 million for the fourth quarter of 2018. R&D expenses for the fourth quarter of 2019 were approximately $0.9 million, compared with approximately $1.0 million for the fourth quarter of 2018. The decrease was due to INmune Bio recording $0.3 million of contra R&D expense due to receipt of a grant from the Alzheimer's Association. G&A expenses in the fourth quarter of 2019 were approximately $1.5 million, compared to approximately $0.9 million for the fourth quarter of 2018. The increase was primarily due to costs associated with being a public company and higher compensation expense.

As of Dec. 31, 2019, the company had approximately $7.0 million in cash and cash equivalents with no debt. Cash burn during the fourth quarter of 2019 was only approximately $0.4 million due to the receipt of $0.4 million of cash proceeds from Australia and $0.4 million of cash proceeds from the United Kingdom, both as the result of research and development tax credits. As of March 10, 2020, INmune Bio had approximately 10.7 million common shares outstanding and when factoring stock options and warrants a fully diluted share count of approximately 13.3 million.

Conclusion

INmune Bio has a number of milestones upcoming over the next 6 to 12 months and we look forward to the data read out for XPro1595 in Alzheimer's Disease in the second half of 2020 along with the initiation of clinical trials throughout the year for INB03 in breast cancer, LIVNate in NASH, and INKmune in MDS and ovarian cancer. 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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