

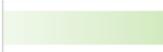
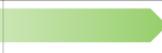
ImmuneBio Inc. INMB on Nasdaq

ImmuneBio is a clinical stage biotech company that focuses on our innate immune system. Their belief is that a dysfunctional immune system is the cause of many human health problems. A dysfunctional immune system often plays havoc with our health. Fix our immune system and many pathologies are eliminated.

Their current focus is on two platforms: Tumor Necrosis Factor and its role in producing inflammation and the consequence of inflammation on many diseases and, two, Natural Killer cell priming to identify hiding cancer cells.

Here is their pipeline:

ACTIVE PIPELINE Therapies that Target the INNATE IMMUNE Response

DN-TNF PLATFORM	DISEASE FIELD	PRE-CLINICAL	PHASE I	PHASE II (POC)	PIVOTAL	EST. NEXT MILESTONE
ImmuneBio for COVID-19 QUELLOR™	COVID-19 Cytokine Storm					P2 underway – data 2021
ImmuneBio for AD XPro1595	Treatment Resistant Depression					P2 Mid-2021
ImmuneBio for AD XPro1595	Alzheimer's Disease CNS					Jan 2021 P1b data P2 start mid-2021

INB03 for treatment of MUC4 positive cancer and LIVNate for NASH Phase II trials begin after resolution of pandemic

NK PRIMING PLATFORM	DISEASE FIELD	PRE-CLINICAL	PHASE I	PHASE II (POC)	PIVOTAL	NEXT MILESTONE
ImmuneBio for High Risk MS INKmune™	Myelodysplastic Syndrome ONCOLOGY					1H21 initiate P1

INKmune for treatment of ovarian cancer Phase I trial begins after resolution of pandemic

Note that all 5 drug candidates are the exact same compound. Different names indicate different uses.

Tumor Necrosis Factor (TNF) is a small protein used by the immune system for cell signaling. TNF is a cytokine. TNF can be split into soluble TNF (bad TNF) and transmembrane TNF (good TNF). TNF is necessary to maintain a healthy immune system, however, the benefits of soluble TNF are questionable and its presence leads to inflammation. Soluble TNF is recognized as a culprit in autoimmune diseases like Rheumatoid arthritis where inflammation runs amok.

ImmuneBio is testing a drug that neutralizes the soluble TNF without suppressing transmembrane TNF. Drugs currently exist that suppress both forms of TNF. Humira and Remicade are two popular TNF inhibitor drugs. Suppressing transmembrane TNF, the good TNF, weakens the immune system's ability to fight disease and consequently exposes the patient to risk. Patients on TNF inhibitor drugs are monitored closely to ensure a weakened immune system does not lead to further problems.

ImmuneBio is currently testing their drug through clinical trials that target therapy for Alzheimer's disease, treatment resistant depression, cytokine storms within Covid 19. The belief is that soluble TNF is at the root cause of these and other diseases.

It is their belief, and there is scientific literature supporting this, that AD and treatment resistant depression have neuroinflammation as a root cause. Neuroinflammation degrades synapses and decomposes neurons. Remove the neuroinflammation and the progression of AD and treatment resistant depression slow and potentially stop. This is a major discovery in the treatment of AD if proven. To date there is no effective treatment for AD.

They recently completed a small sample phase 1 study of their drug on Alzheimer's patients with certain biomarkers. The stock rose on the results. The drug XPro1595 reduced neuroinflammation across multiple measures (it isn't straightforward nor easy to measure change in neuroinflammation). Results were as expected based on previous animal model trials and were positive and warrant progression to a phase two study scheduled for the second half of 2021.

This is a main reason I own the stock. AD is an ugly disease and its cost on society is high. Patients degenerate slowly. If a drug or process is discovered to stop, slow, or, hallelujah, reverse AD's progression, the company's value will skyrocket and rightly so.

What did the phase 1 trial indicate?

1. XPro1595 reduces neuroinflammation across multiple measures and assays.
2. Pathway analyses show a significant effect of XPro1595 in AD relevant pathways and corroborated by novel MRI metrics.
 - a. XPro1595 significantly reduced markers of neuroinflammation, neural injury, improved synaptic proteins.
3. Changes in biomarkers all appear within 3 months and were sustained over the duration of the trial.
4. Safety - well tolerated (AEs - injection site reactions).
5. These data support advancing to Phase 2 (2H2021). The phase 1 trial was extremely small.

Other trials are ongoing using the same compound for different purposes. INB03 and Inkmune are the same drug as XPRO1595 but are used in the fight against cancer.

INB03 suppresses Myeloid-Derived Suppressor Cells (MDSC). Neutralizing soluble TNF is a key part of the process. By preventing MDSC, InmuneBio believes the immune system will better respond to cancer cells.

INKmune helps Natural Killer cells to detect cancer cells. When a cancer tumour is cut out of a patient there is small amounts of cancer cells that remain. It is up to the immune system to locate and kill these cells. Often the immune system fails to recognize the cancer cells, they multiply, and relapse occurs. INKmune primes NK cells to identify the cancer cells. Once identified, the NK cells do their thing and kill cancer cells.

There is ongoing exploratory work on the benefits of neutralizing soluble TNF in many areas of health.

Financials

InmuneBio raised \$25,000,000 in 2020 and have total current assets of close to \$24,000,000 on Dec 31, 2020. They burned \$8,900,000 in 2020. I expect their burn rate increases in 2021. So, we can assume they have at least two years of cash to finance plans. If trials don't pan out by then, it wasn't meant to be.

Disclosure and Summary

I am long and this is either a bust or a multi-bagger. There is little middle ground. The probability of success is low, as with all clinical stage biotech companies, but the payoff is enormous if successful. Does the drug work and pass upcoming trials? Time will tell. All we can say is that phase 1 trial results are encouraging and the total addressable market regarding Alzheimer's disease treatment is huge and lucrative and the total non-precision TNF inhibitor drug market is also huge and lucrative.