TM Nutrition LLC

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Industry:Medical Food

Management:

Thea Marx, ND, Founder

Seeking to fill additional roles:

Clinical Trial Director Chief Commercial Officer

Advisory Board:

Martha D'Adamo, President, North American Pharmacal

Lori Butterfield, Marketing & Communications Specialist (WebMD, Cleveland Heart Lab, CNN, Discovery)

Scientific Advisory Board:

Patrick Fratellone, MD,
Cardiologist, Fratellone Medical
Associates; Professor of
Medicine(Cardiology),
University of Bridgeport

Eugene Zampieron, ND,
Profession of Medicine
(Rheumatology, Botanical
Medicine, Attending Physician),
University of Bridgeport

Number of Employees:1

Accounting / Tax:

TBD

Funding to Date: \$10,000

Founder: \$2,500

CT Next Level Mini: \$5,000 UB Community Grant: \$2,500

Financing Sought: \$500,000 For: Clinical trials \$75K, Commercialization \$425K

IP: Wilson Sonsini

Legal: TBD



Business Description / Company Background:

TM Nutrition LLC is a startup nutrient therapy company providing targeted pre- and post-surgical support for adult and pediatric populations. Dr. Marx, the founder, is a practicing Naturopathic Physician and nutrigenomic expert. After witnessing her patients suffer from surgical infections, she developed Vis presurgical.

Market Opportunity / Unmet Need:

Vis Pre-Surgical Support, a patented medical food administered prior to surgery, reduces the damage caused to the body by the surgical stress response and surgical site infections. Vis lowers the risk of infection related deaths, hospital re-admissions and overall cost of surgery. In the US alone, 48 million surgeries² are performed: 313 million worldwide³. Surgical site infections are the most prevalent and deadly post-surgery infection leading to an average of 6% of readmissions costing \$10 billion dollars and 400,000 extra hospital days each year. Once a surgical site infection occurs, the patient is 42% more likely to die following surgery. A diabetic's chance of death increases by *five* times⁴. Current protocol accepts surgical complications such as infections as known issues that are treated with antibiotics prior to surgery. Surgeons and hospital administrators need a way to affect a positive change in outcomes that augments current procedure and enhances positive outcomes including lowering surgical costs, reducing readmissions, improving hospital scorecards, and increasing survival. The annual global medical food market is estimated at \$21B and \$6B for the US and is growing at 5.2% annually.

Products / Services - Launched & Pipeline:

Our first product addresses the specific metabolic and biochemical needs of an adult surgery patient in stress response. Support of these processes with carefully calibrated nutrient therapy reduces the risk of a patient succumbing to infections, especially surgical site infections, urinary tract infections and pneumonia. Product mechanism of action promotes balance of blood sugar levels, an important driver in the infection process while supporting critical immune system requirements to prevent tissue degradation.

Competition/Competitive Advantage:

Hospitals are now recognizing the value of mitigating surgical stress with pre-surgical nutrition. A recent study¹ of 78 hospitals showed 87% had a protocol requiring a pre-surgery drink. One third used Gatorade. Market share is equally split between Abbott Ensure Pre-Surgery Clear, CF (PreOP) and Pepsico's Gatorade. Anecdotally outside of this study most hospital protocols use Gatorade. All three of these products create blood sugar spikes that decreases their efficacy and none are backed by clinical trials. *Vis Pre-Surgical* gets rid of the blood sugar spike and holds the blood sugar in balance. *Vis,* backed by clinical results, can provide enhanced, more effective results for post-surgical patients, surgeons, and health care administrators.

Traction and Progress:

Incorporated (Q1 2022); Vis Pre-surgery formula developed (Q2 2022); Palatable, taste tested samples available (Q2 2022); Provisional patent obtained (Q4 2022).

Future Plans and Milestones:

1st pilot study for safety and efficacy on abdominal surgical patients. (Q3 2023); PTC filing (Q4 2023); cohort study for general surgery (Q1 2024); test market launch (Q1 2024).

Financial Projections (Unaudited):

Vis will scale business in three steps - first to NY metro area hospitals, then to regions and states with highest surgeon populations immediately followed by nationwide rollout before going international. We plan to validate price point with pricing study, based on preliminary feedback we believe we can price it at \$19.

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	\$.9M	\$3.9M	\$15.7M	\$39.3M	\$59M
Gross Profit	\$.49M	\$2.3M	\$9.9M	\$27.6M	\$43.5
Gross Margin	53%	58%	63%	68%	74%

1-Singh, S.M., Liverpool, A., Romeiser, J.L. et al. A U.S. survey of pre-operative carbohydrate-containing beverage use in colorectal enhanced recovery after surgery (ERAS) programs. Perioper Med 10, 19 (2021) 2-https://stanfordhealthcare.org/medical-clinics/surgery-clinic/patient-resources/surgery-statistics.html accessed 4/2023 3-Meara J. Leather A, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. The Lancet Commissions | Volume 386, ISSUE 9993, P569-624, August 08, 2015. 4-O'Bricn WJ, Gupta K, Itani KMF. Association of Postoperative Infection With Risk of Long-term Infection and Mortality [published correction appears in JAMA Surg. 2020 Jan 1;155(1):94]. JAMA Surg. 2020.