COVER SHEET FOR PROPOSAL TO THE NATIONAL SCIENCE FOUNDATION

PROGRAM ANNOUNCEMENT/SOLICITATION NO./DUE DATE
NSF 18-592 12/04/2018

☐ Special Exception to Deadline Date Policy

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NSF PROPOSAL NUMBER

FOR CONSIDERATION BY NSF ORGANIZATION UNIT(S) (Indicate the most specific unit known, i.e. program, division, etc.)
IIP - STTR PHASE I

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SHOW PREVIOUS AWARD NO. IF THIS IS
☐ A RENEWAL
☐ AN ACCOMPLISHMENT-BASED RENEWAL

IS THIS PROPOSAL BEING SUBMITTED TO ANOTHER FEDERAL AGENCY? YES ☐ NO ☒ IF YES, LIST ACRONYM(S)

NAME OF ORGANIZATION TO WHICH AWARD SHOULD BE MADE
INFINITUM HEALTH, LLC

AWARDEE ORGANIZATION CODE (IF KNOWN)
7203578790

ADDRESS OF AWARDEE ORGANIZATION, INCLUDING 9 DIGIT ZIP CODE
INFINITUM HEALTH, LLC
10115 E BELL RD SUITE 107 NO 215
SCOTTSDALE,AZ 852602189 US

NAME OF PRIMARY PLACE OF PERF
INFINITUM HEALTH, LLC

ADDRESS OF PRIMARY PLACE OF PERF, INCLUDING 9 DIGIT ZIP CODE
INFINITUM HEALTH, LLC
3820 W Happy Valley Rd Ste 141 No 419,
Glendale,AZ 853103280 US

IS AWARDEE ORGANIZATION (Check All That Apply)
☒ SMALL BUSINESS
☒ FOR-PROFIT ORGANIZATION
☐ MINORITY BUSINESS
☐ WOMAN-OWNED BUSINESS

☐ IF THIS IS A PRELIMINARY PROPOSAL THEN CHECK HERE

TITLE OF PROPOSED PROJECT
Nutritional Supplement with Anticancer Properties

REQUESTED AMOUNT	PROPOSED DURATION (1-60 MONTHS)	REQUESTED STARTING DATE	SHOW RELATED PRELIMINARY PROPOSAL NO. IF APPLICABLE
$ 150,000	6 months	01/01/2019	

THIS PROPOSAL INCLUDES ANY OF THE ITEMS LISTED BELOW
☒ BEGINNING INVESTIGATOR
☐ DISCLOSURE OF LOBBYING ACTIVITIES
☐ PROPRIETARY & PRIVILEGED INFORMATION
☐ HISTORIC PLACES
☐ VERTEBRATE ANIMALS IACUC App. Date _____
PHS Animal Welfare Assurance Number _____
☒ TYPE OF PROPOSAL Research

☐ HUMAN SUBJECTS Human Subjects Assurance Number _____
Exemption Subsection _____ or IRB App. Date _____
☐ INTERNATIONAL ACTIVITIES: COUNTRY/COUNTRIES INVOLVED
_____
☒ COLLABORATIVE STATUS
Non-Collaborative

PI/PD DEPARTMENT

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CO-PI/PD				
CO-PI/PD				
CO-PI/PD				

CERTIFICATION PAGE

Certification for Authorized Organizational Representative (or Equivalent) or Individual Applicant

By electronically signing and submitting this proposal, the Authorized Organizational Representative (AOR) or Individual Applicant is: (1) certifying that statements made herein are true and complete to the best of his/her knowledge; and (2) agreeing to accept the obligation to comply with NSF award terms and conditions if an award is made as a result of this application. Further, the applicant is hereby providing certifications regarding conflict of interest (when applicable), drug-free workplace, debarment and suspension, lobbying activities (see below), nondiscrimination, flood hazard insurance (when applicable), responsible conduct of research, organizational support, Federal tax obligations, unpaid Federal tax liability, and criminal convictions as set forth in the NSF Proposal & Award Policies & Procedures Guide (PAPPG). Willful provision of false information in this application and its supporting documents or in reports required under an ensuing award is a criminal offense (U.S. Code, Title 18, Section 1001).

Certification Regarding Conflict of Interest

The AOR is required to complete certifications stating that the organization has implemented and is enforcing a written policy on conflicts of interest (COI), consistent with the provisions of PAPPG Chapter IX.A.; that, to the best of his/her knowledge, all financial disclosures required by the conflict of interest policy were made; and that conflicts of interest, if any, were, or prior to the organization's expenditure of any funds under the award, will be, satisfactorily managed, reduced or eliminated in accordance with the organization's conflict of interest policy. Conflicts that cannot be satisfactorily managed, reduced or eliminated and research that proceeds without the imposition of conditions or restrictions when a conflict of interest exists, must be disclosed to NSF via use of the Notifications and Requests Module in FastLane.

Drug Free Work Place Certification

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent), is providing the Drug Free Work Place Certification contained in Exhibit II-3 of the Proposal & Award Policies & Procedures Guide.

Debarment and Suspension Certification

(If answer "yes", please provide explanation.)

Is the organization or its principals presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency? Yes ☐ No ☐

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent) or Individual Applicant is providing the Debarment and Suspension Certification contained in Exhibit II-4 of the Proposal & Award Policies & Procedures Guide.

Certification Regarding Lobbying

This certification is required for an award of a Federal contract, grant, or cooperative agreement exceeding $100,000 and for an award of a Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding $150,000.

Certification for Contracts, Grants, Loans and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:
(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, ''Disclosure of Lobbying Activities,'' in accordance with its instructions.
(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Certification Regarding Nondiscrimination

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent) is providing the Certification Regarding Nondiscrimination contained in Exhibit II-6 of the Proposal & Award Policies & Procedures Guide.

Certification Regarding Flood Hazard Insurance

Two sections of the National Flood Insurance Act of 1968 (42 USC §4012a and §4106) bar Federal agencies from giving financial assistance for acquisition or construction purposes in any area identified by the Federal Emergency Management Agency (FEMA) as having special flood hazards unless the:
(1) community in which that area is located participates in the national flood insurance program; and
(2) building (and any related equipment) is covered by adequate flood insurance.

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent) or Individual Applicant located in FEMA-designated special flood hazard areas is certifying that adequate flood insurance has been or will be obtained in the following situations:
(1) for NSF grants for the construction of a building or facility, regardless of the dollar amount of the grant; and
(2) for other NSF grants when more than $25,000 has been budgeted in the proposal for repair, alteration or improvement (construction) of a building or facility.

Certification Regarding Responsible Conduct of Research (RCR)
(This certification is not applicable to proposals for conferences, symposia, and workshops.)

By electronically signing the Certification Pages, the Authorized Organizational Representative is certifying that, in accordance with the NSF Proposal & Award Policies & Procedures Guide, Chapter IX.B. , the institution has a plan in place to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students and postdoctoral researchers who will be supported by NSF to conduct research. The AOR shall require that the language of this certification be included in any award documents for all subawards at all tiers.

CERTIFICATION PAGE - CONTINUED

Certification Regarding Organizational Support

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent) is certifying that there is organizational support for the proposal as required by Section 526 of the America COMPETES Reauthorization Act of 2010. This support extends to the portion of the proposal developed to satisfy the Broader Impacts Review Criterion as well as the Intellectual Merit Review Criterion, and any additional review criteria specified in the solicitation. Organizational support will be made available, as described in the proposal, in order to address the broader impacts and intellectual merit activities to be undertaken.

Certification Regarding Federal Tax Obligations

When the proposal exceeds $5,000,000, the Authorized Organizational Representative (or equivalent) is required to complete the following certification regarding Federal tax obligations. By electronically signing the Certification pages, the Authorized Organizational Representative is certifying that, to the best of their knowledge and belief, the proposing organization:
(1) has filed all Federal tax returns required during the three years preceding this certification;
(2) has not been convicted of a criminal offense under the Internal Revenue Code of 1986; and
(3) has not, more than 90 days prior to this certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

Certification Regarding Unpaid Federal Tax Liability

When the proposing organization is a corporation, the Authorized Organizational Representative (or equivalent) is required to complete the following certification regarding Federal Tax Liability:

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent) is certifying that the corporation has no unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

Certification Regarding Criminal Convictions

When the proposing organization is a corporation, the Authorized Organizational Representative (or equivalent) is required to complete the following certification regarding Criminal Convictions:

By electronically signing the Certification Pages, the Authorized Organizational Representative (or equivalent) is certifying that the corporation has not been convicted of a felony criminal violation under any Federal law within the 24 months preceding the date on which the certification is signed.

Certification Dual Use Research of Concern

By electronically signing the certification pages, the Authorized Organizational Representative is certifying that the organization will be or is in compliance with all aspects of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

AUTHORIZED ORGANIZATIONAL REPRESENTATIVE	SIGNATURE	DATE
NAME		

TELEPHONE NUMBER	EMAIL ADDRESS	FAX NUMBER

Overview

Infinitum Health, LLC was founded to deliver a high quality integrative medicine products. In each product, you will find the most effective and efficient combination of extracts creating truly unique products at unique prices. Since the 1940s, about half of all drugs introduced are medicines derived from natural products. Evidently, 69% of anticancer drugs approved between the 1980 and 2002 are either natural products or developed based on knowledge gained from natural products[1]. We have created products with scientific evidence-based formulations supporting "health, forever, without limits™". These products have dramatic immunostimulating as well as anticancer properties. With our flagship product, Infinim® Immunity Multivitamin, we have received dramatic customer testimonials regarding its proposed anticancer activity.

Intellectual Merit

After receiving much of these anecdotal testimonials, we embarked on performing initial preclinical in vitro proof of concept anticancer studies. Our first study, performed by a Contract Research Organization (CRO), Natural Immune Systems, Inc, led by Gitte Jensen, PhD, used Infinimin® on four NIH approved cancer cell lines; A-172, glioblastoma, A-375, malignant melanoma, A-549, lung carcinoma and DU-145, prostate cancer cell lines. Using an MTT Bioassay to confirm cell viability, statistically significant reductions of cell viability were seen for all 4 cancer cell lines following treatment with Infinimin®. The decrease in Glioblastoma and Prostate Carcinoma cell viability following treatment with Infinimin® was dose-dependent and extended across a broad dose range[2]. We decided to perform another in vitro proof of concept study with a different lab and different cancer cell lines.

We performed a followup in vitro with Mayo Clinic Hospital, led by David Lott, MD, on nine different cancer cell lines. Seven of these are used heavily in mouse species;

C3H mouse – 6C3HED lymphosarcoma, SCC VII squamous cell carcinoma,
Balb/c mouse – BM185 leukemia, 4T1 mammary tumor, CT26 colon,
C57BL/6 mouse – MC38 colon carcinoma, B16 melanoma.

The final two are human cancer cell lines;
LN18 glioblastoma
MCF7 breast

Statistically significant reductions were seen in all nine cancer cell lines. We are currently in development of published research on this most recent in vitro study and have begun work in the in vivo model in mice, working with David Lott, MD, of Mayo Clinic Arizona.

Broader Impacts

Given these repeat results, our organization would like to apply for an STTR Grant to continue the research we have found to show significant anticancer activity in our formulation. With cancer diagnoses increasing worldwide by 15% each year, we feel we may have a natural cost-effective way to mitigate cancer prevalence worldwide[3]. We have invested $146,324 so far and are looking for an opportunity to scale up our research efforts to the preclinical mouse model, non-human primate model, phase II/III and eventually phase IV research to prove out our efficacy for our Infinimin® formulation.

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*Proposers may select any numbering mechanism for the proposal. The entire proposal however, must be paginated. Complete both columns only if the proposal is numbered consecutively.

Project Description

Elevator Pitch

Currently, worldwide cancer diagnosis increase year over year by 15%[3]. The patients who unfortunately become diagnosed with cancer are subjected to a dogma of surgery, chemotherapy and radiation therapy, for the most part, hasn't truly changed for over 30 years. The increase in cancers worldwide is a clear indicator of a failing system for cancer therapy. Our product, Infinimin® has been proven to be safe, effective and recently shown to have dramatic anticancer properties. Our product is cost effective and has an ability to given over-the-counter with physician supervision and guidance. Our innovative formulation is a patented blend of a base multivitamin panel, three seaweed species, three mushroom species, and a potent antioxidant fruit, acai berry. The blend, we feel uses specific extracts to interrupt multiple chemical pathways not only for cancer cell growth but also to stimulate the innate immunity of the patient. We chose these specific species for a set of complementing concentrations of extracts including fucoidans, β-glucans, antioxidant properties, and absorption strategies for what we hypothesize to be synergistic effect of one another. These extracts are available around the world and may have an immediate societal impact on those affected by cancer.

Broader Impacts

In 2018, an estimated 1,735,350 new cases of cancer will be diagnosed in the United States and 609,640 people will die from the disease. The most common cancers (listed in descending order according to estimated new cases in 2018) are breast cancer, lung and bronchus cancer, prostate cancer, colon and rectum cancer, melanoma of the skin, bladder cancer, non-Hodgkin lymphoma, kidney and renal pelvis cancer, endometrial cancer, leukemia, pancreatic cancer, thyroid cancer, and liver cancer. Worldwide, cancer is among the leading causes of death. In 2012, there were 14.1 million new cases and 8.2 million cancer-related deaths worldwide. Of the new cancer cases, 57% in 2012 occurred in less developed regions of the world that include Central America and parts of Africa and Asia while 65% of cancer deaths also occurred in these regions. The number of new cancer cases per year is expected to rise to 23.6 million by 2030[3]. Currently, these cancers are treated via a dogma of surgery, chemotherapy and radiation therapy. The competition in each of these markets is intensely fierce with high barriers to entry with regards to proving out the research and validating the evidence. Our product, however, has been marketed as a multivitamin as it is considered safe and has been on the market for 4 years without a single adverse event during our prototyping phase. The key competitors for the multivitamin market, a $102 Billion dollar market, are Centrum (Pfizer) and One-A-Day (Bayer), each with revenues of $300 and $400 million, respectively[4]. While both of these products make up 70% of the multivitamin market, neither of them purport to have anticancer properties. They currently are focused on daily health maintenance and gaps in nutrition. Our product would have a focus on daily health maintenance with our base multivitamin blend but also has a unique value proposition to aid in potentially preventing cancer and mitigation of cancer if the consumer has been diagnosed. As stated earlier, our commercialization approach was to bring to the multivitamin market our product and prototype the anticancer potential. We received dramatic customer feedback during this prototyping period and have begun the formal research to prove out the formulation and its capabilities. Going forward, we hope to keep the

traditional commercialization routes open that we have via health stores and online, but with proven research, open a new channel via the Physician and Oncologist recommendations. There has been research that promotes individual extracts of our product that complement traditional chemotherapy and we feel that Infinimin® may not need to be a complete replacement to the traditional dogma of cancer therapy but more on the order of an enhancement[5,6,7]. We feel that if we were able to prove out the efficacy of our product that we could enable physicians to safely add our product to their cancer therapy protocols. If we were able to secure the resources, we would spend our time proving out our research and begin the formal disclosure to the scientific community via Oncology Conferences and targeted speaking arrangements with Cancer Hospitals around the world. From these engagements, we would be able to answer questions from physicians and enhance their understanding of our product and how it can help their patients. If we are successful, we may be providing one of the most cost effective and efficient solutions for society for cancer treatment.

Our risks, however, are large. They are centered at disruption of an industry and culture change. If we are successful, there will be a large disruption of an industry that has survived due to not having a solution. There are Cancer Treatment Centers and Hospital systems focused only on cancer. If we are able to treat this problem more effectively and efficiently, this will disrupt a large part of our economy. A unique study subtly shows this in their effort to showcase one of the extracts in our study, fucoidan, and its ability to "synergistically" align with three other chemotherapy options, Paclitaxel, tamoxifen, and cisplatin[5]. In Figure 2 of this study, is a set of histogram graphs that show fucoidan alone and fucoidan added to one of the three known chemotherapeutic agents. What the authors don't speak to but the graphs clearly show, is that fucoidan alone, is as effective if not more effective than all three chemotherapeutic agents of Paclitaxel, Tamoxifen, and Cisplatin[5]. The high costs to develop a new drug like a chemotherapy create a large industry of work including human resources, facility, technical, and related resources. With all of these costs, the average cost to bring a new drug to market is $2.87 Billion dollars[8]. If this were multiplied against the three drugs used in the above study, we could be directly impacting an approximate $10 billion dollar industry, while indirectly impacting all other chemotherapy agents, pushing a Global Oncology/Cancer Drugs Market of $112 Billion dollars into a disruptive environment[9]. This disruption may not be taken lightly by current market leaders and resistance and attempts to block a new coming technology may become a reality.

If successful, not only would there be disruption to the market but the culture of western medicine may change. Historically, an innovation in the medical industry was performed by a physician or a highly esteemed researcher. Our innovation, while the inventor is highly educated with a MS in Biotechnology and an MBA, is not a physician nor a classical researcher. Our inventor and founder is an entrepreneur with a vision and desire to learn. This product was created from self-taught material publicly available via the National Library of Medicine (aka "PubMed"). What "Open Source Code" did for the high technology industry, essentially opening the door for lay users to copy/paste code and attempt to innovate in the tech space, "PubMed" is slowly doing for the medical space. With "Open Source Code," a very young, "uneducated" individual can create an industry disruptive application that can change the history of the technology it was in. For the biomedical space, "PubMed" is essentially "Open Source

Code" where a non-medically trained individual can self-learn by reading the research that is available and creating and testing new products to help the betterment of all. Western trained physicians and scientists that had to endure enormous time educating themselves via the traditional route may be extremely resistive to a product that was created by someone who didn't have to go through the rigorous education that they had.

Taking both the disruptive opportunity of a new product and the potential cultural resistance, our risks for our product are high, hence the need to truly vet out our research and prove what our product is capable of.

Intellectual Merit

Our resource need for formal commercialization is projected at ~$5 million. Our plan for formal commercialization is as follows. Our plan consists of four main phases;

Phase I: Prototyping and Proof of Concept

Phase II: Preclinical Efficacy and Evidence

Phase III: Clinical Efficacy and Evidence

Phase IV: New Commercialization Channel (removed from this application for proprietary reasons)

In phase one, we prototyped our safe and effective multivitamin formulation in the marketplace and performed one initial in vitro proof of concept study on four cancer cell lines; A-172, glioblastoma, A-375, malignant melanoma, A-549, lung carcinoma and DU-145, prostate cancer cell lines. Using an MTT Bioassay to confirm cell viability, statistically significant reductions of cell viability were seen for all 4 cancer cell lines following treatment with Infinimin®. The decrease in Glioblastoma and Prostate Carcinoma cell viability following treatment with Infinimin® was dose-dependent and extended across a broad dose range[2].

From this study, as well as dramatic anecdotal customer testimonials from the sale of our multivitamin in the marketplace[10], we proceeded into Phase II where we would move forward into repeat in vitro proof of concept studies, mouse model and non-human primate model studies to prove preclinical efficacy and further our evidence on our product's anticancer properties. We decided to perform another in vitro proof of concept study with a different lab and different cancer cell lines.

We performed a followup in vitro study with Mayo Clinic Hospital, led by David Lott, MD, on nine different cancer cell lines. Seven of these are used heavily in mouse species;

C3H mouse – 6C3HED lymphosarcoma, SCC VII squamous cell carcinoma,

Balb/c mouse – BM185 leukemia, 4T1 mammary tumor, CT26 colon,

C57BL/6 mouse – MC38 colon carcinoma, B16 melanoma.

The final two are human cancer cell lines;

LN18 glioblastoma

MCF7 breast

Our initial results with our Mayo Clinic contracted study show statistically significant reductions in all nine cancer cell lines in vitro.

In total, thirteen cancer cell lines of broad genetic and behavioral aspects, have been shown to be disrupted and apoptosis has been seen with our Infinimin® formulation.

We have formally moved into the mouse model test system with Mayo Clinic and have begun looking for additional resources to take us into the rest of the mouse model work and non-human primate work.

It is here, where we are requesting resources to continue our research. We require significantly larger funding to take to the preclinical stage as well as into the clinical stage. The Phase I STTR grant will help facilitate the rest of our "Phase II" process with our preclinical work; beginning with the mouse model studies and into our non-human primate research. The funding will also provide necessary monies to file additional patents, purchase raw materials for the study work, and pay the necessary operation costs during this phase. Our timeline for this funding would be early of 2019.

If successful in the animal model systems, we plan to move quickly into Clinical Phase II work for specific cancer cell lines to optimize cost of our study work. Depending on the success of the work, we will attempt to reapply for a NSF Phase II STTR Grant as well as pursue outside investment to help fund the expensive clinical trial work. Our timeline for this funding would be end of 2019, beginning of 2020.

If Phase II work is successful, our new commercialization approach will no longer only be over-the-counter via Online Stores such as Amazon, Whole Foods, and our own website. We will publish and present at significant conferences around the world to showcase our success and promote our product by physician and oncology practice recommendations to help their patients whom are diagnosed with cancer. We feel that we want our product to be at a price within reason for patients not just with good insurance but no insurance and managed by out of pocket expenses.

The Innovation

Infinimin®, is a unique integrative medicine multivitamin. It combines a full multivitamin panel with a patented blend of unique extracts from around the world creating a potent effective and efficient complement to an individual's diet. Inifinimin® has extracts that appear to promote dramatic immuno-stimulating, immune-modulating and anticancer properties as well as a base essential multivitamin panel for general health maintenance needs. The extracts in the patented

blend have over 1400 research articles illustrating their promising health benefits, individually, with no research or innovations combining them to optimize their effect.

We have a theory that our extracts are synergistically complementing one another and interrupting multiple cascading pathways for cancer cell growth, immune stimulation, immune modulation, and healthy cell survivability.

We have developed our formulation after four different prototype formulations and feel we now have the final formulation to take the public. With our launch of this product in the general marketplace, our theories seemed to be validated by anecdotal customer testimonials. We have 1 patent and have drafted 3 more in response to our future research that we are hopeful to be funded. We have performed one in vitro study by a Contract Lab as well as one followup in vitro study with Mayo Clinic and feel we have a strong evidence-based case for our product. The key technical challenges are being able to truly document the mechanisms of action.

Like with the discovery of penicillin, A. Fleming discovered penicillin (ironically from mushrooms) by accident and recognized the outcome for treatment of infections in 1928. Use began immediately in 1929 due to U.S. Great Depression and European economy collapse, causing large scale disease outbreaks. The actual mechanism of action wasn't known, the outcome of patients getter better was known. We are at the stage, we are seeing, anecdotally by our customer testimonials that they are getting better and are just getting started by proving out the research. For penicillin, it wasn't until 40 years later, in 1968, a formal mechanism of action was proven and understood, whereby penicillin, via β-lactam, break the 5-Glycine bridge of cell wall synthesis of bacteria[11].

This is our largest technical challenge, not entirely knowing our mechanism of action. In our technical portion, we have hypothesized some mechanisms of action but more research is needed.

The Company and Team

Our founder is Kevin Engholdt and our company is based in Scottsdale, Arizona. Our founder has a Masters in Biotechnology from the University of Wisconsin (GPA 3.5/4.0) and a Masters of Business Administration (MBA) from the University of Arizona (GPA 3.5/4.0). Our startup team consists of a medical advisor, sales and marketing advisor, regulatory consultant, and our sales rep. The team names are listed below with associated duties and roles:

David Lott, MD - Medical Advisor/Research Principal Investigator

Erik Merkow – Sales and Marketing Advisor

Steve Glaza – Regulatory Consultant

Whitney McLennan – Sales Rep (customer whom had tumors and ovarian cyst disease clear up from use of Infinimin®)10

Our vision for our company is to continue to create unique, evidence-based products that help facilitate a gap in our healthcare system. Over the next five years, we plan to rollout a new

product each year within a specific niche disease area and associated research programs to facilitate the evidence based approach. As with most biotechnology startups, our revenues over the past three years have been minimal as most of efforts are development of a brand, sales and marketing channels, and most importantly, the research around our products. Total revenues for the three years is $15,765. Our founder has invested his personal monies of $146,324 into the firm over the past three years and has yet to receive any outside investment from private or federal funding sources.

Technical Discussion and R&D Plan

Cancer is the leading cause of death worldwide. Cancer is a generic term for a large group of diseases that can affect any part of the body. Other terms used are malignant tumors and neoplasms. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries, which can then invade adjoining parts of the body and spread to other organs. This process is referred to as metastasis. Metastases are the major cause of death from cancer. Cancer is a leading cause of death worldwide. Cancer arises from one single cell. The transformation from a normal cell into a tumor cell is a multistage process, typically a progression from a pre-cancerous lesion to malignant tumors. These changes are the result of the interaction between a person's genetic factors and three categories of external agents, including:

- physical carcinogens, such as ultraviolet and ionizing radiation;
- chemical carcinogens, such as asbestos, components of tobacco smoke, aflatoxin (a food contaminant) and arsenic (a drinking water contaminant); and
- biological carcinogens, such as infections from certain viruses, bacteria or parasites.

Today, cancer is treated using three modes of treatment; surgery, chemotherapy, and/or radiation. Certain cancers and diagnoses require one or a combination of all three treatment types. All three types incur large costs to the healthcare system and the patient. All three types incur large risk to health and complications to the patient if they are unable to withstand treatment and/or make recovery through the treatment. These treatments today have been the standard treatment for over 40 years and have had minimal success in reducing the number of cancers across a population.

Recently, attention has been focused on using natural supplements to help prevent and reduce the onset of cancerous cells and maintain and stimulate immune response. Two specific extracts have received particular notice, fucoidan (from seaweed) and ß-glucans (from mushrooms). These two specific extracts, by themselves, have shown clinical evidence of reducing cancerous cells and immune balancing properties. Our product is largely focused on recognizing the combination of these two extracts (from six species; three seaweed and three mushroom) with an antioxidant fruit (acai berry) and ten essential multivitamins and minerals (vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D3, vitamin E, calcium, thiamin, riboflavin, niacin, folic acid, pantothenic acid) and their synergistic properties to prevent and/or reduce the onset of cancerous cells and maintain and stimulate immune response.

Vitamins B6, B12, C, E and Folic Acid are well known and documented to aid in heart health, vitamins A, C, and E for immunity and eye health, and finally, Thiamin, Riboflavin and Niacin to aid in converting food to fuel and maintain physical energy. Interestingly, recent research has shown that Vitamin C actually enhances the absorption and effectiveness of fucoidans and ß-glucans.[12, 13]

Antioxidants within fruit, vegetable or herb have gained increased clinical evidence as being a strong for overall cell structure and reducing toxicity from oxygen free radicals and oxidizers promoting cell longevity. Dietary antioxidants, such as in our product with acai berry (euterpe oleracea), are believed to be good external sources to counteract free radicals in the body. Free radicals are consistently formed as byproducts of aerobic metabolism in the human body. They are generally reactive oxygen or nitrogen species (ROS or RNS). The most common ROS and RNS in vivo are superoxide, hydroxyl radical, peroxyl radical, nitric oxide, and peroxy-nitrite. These ROS have been associated with many chronic and degenerative diseases including vascular diseases, diabetes, cancer, and overall aging. Acai berry (*Euterpe oleracea*) has been demonstrated to exhibit significantly high antioxidant capacity in vitro, especially for superoxide and peroxyl scavenging. It was found to have exceptional activity against superoxide in the superoxide scavenging (SOD) assay, the highest of any food reported to date against the peroxyl radical as measured by the oxygen radical absorbance capacity assay with fluorescein as the fluorescent probe (ORACFL)[14, 15].

The polysaccharide, ß-glucan, commonly found in mushrooms, is a very versatile metabolite due to its broad spectrum biological activity. Incredibly, a public health study in rural Japan in 1969 (and its 20 year followup study) showcased the original benefit if mushrooms on cancer. The studies showed a case study of a town with a mushroom factory for making Enoki (*Flammulina velutipes*) mushrooms. In this town (Nagano Prefecture), the factory had 80% of residents as employees and the factory would give away their "bruised" and often poor quality mushrooms that they wouldn't think anyone would buy to take home to their families as a gift for working there. Consequently, this town ate Enoki mushrooms at every meal. Amazingly, the public health researchers noticed that this prefecture in Japan had 90% reduced cancers than all other prefectures. They deduced the attribution of these mushrooms in the Japanese diet and this is where the research began for medicinal mushrooms and β-glucans[27,28]. These b-glucans consist of a backbone of glucose residues linked by β-(1 - 3)-glycosidic bonds, often with attached side-chain glucose residues joined by β-(1 - 6) linkages. Their mechanisms of action involve their being recognized as non-self molecules, where the immune system is stimulated by their presence. ß-glucans from various species of mushrooms have been studied due to these immunomodulatory effects which include mitogenicity and activation of immune effector cells, such as lymphocytes, macrophages, and natural killer cells, resulting in the production of cytokines, including interleukins (ILs), tumor necrosis factor (TNF)-a, and interferons. There is evidence indicating that b-D-glucans from medicinal mushrooms induce biological response by binding to membrane complement receptor type three (CR3, aMb2 integrin, or CD11b/CD18) on immune effector cells. The ligand–receptor complex is then internalized, intriguing a series of molecular events such as the activation of the nuclear factor NF-kB. These molecular events from immune modulation appear to have broad antitumor, chemotherapeutic synergy, antidiabetic, and antiviral properties[16,17,18,19,20,21,22].

Another polysaccharide, fucoidan, which contains substantial percentages of L-fucose and sulfate ester groups, are constituents of brown seaweed and some marine invertebrates. Fucoidans refers to sulfated fucans, that is, sulfated rich l-Fucopyranosyl (l-Fucp) polysaccharides. It is generally recognized that fucoidans are heteropolysaccharides made of l-Fucp (35–50%), (1→2)-, (1→3)- or (1→4)-linked, that can be sulfated or acetylated at various positions. The naturally higher content of sulfate groups in fucoidans is associated with a higher stimulatory activity on macrophage cells. Fucoidans isolated from different species have been extensively studied due to their varied biological activities, including antitumor, chemotherapeutic synergy, anticoagulant, antithrombotic, antivirus, immunomodulatory, anti-inflammatory, blood lipids reducing, antioxidant, activitiy against hepatopathy, uropathy and renalpathy, gastric protective effects and therapeutic potential in surgery[6,7,22,24,25,26]. Specific mechanism of actions are are still uknown, hence, the effort that we are engaging in.

The critical milestones, questions to be answered, and formal research and development timeline is summarized below.

Infinitum Health Strategic Plan Outline

Study Start	Aim 1	Aim 2	Topic	Product	Description	Costs
Jan-19	NA	NA	Raw Materials		Raw Materials Purchase	$10,000
Jan-19	Safety	Anti-cancer	Additional work within mouse model.	Infinimin Ultravitamin	Documentation that product does not fuel cancer cell growth, as an important safety aspect for people consuming the product.	$5,000
					Documentation of compromised cellular viability, proliferation, and mitochondrial function of a panel of cancer cell lines in vitro.	
Jan-19	Patent Application		Patent Development		Patent application with new evidence for formulation	$5,000

Feb-19	Anti Cancer	Immune Support		Infinimin Ultravitamin	To expand on completed pilot work to gain data of sufficient substance, repeatability, and standard to use for the writing of a manuscript for peer-review. (Cost for contracted consultant PI services from Mayo Clinic)	$18,000
Summary						**$38,000**
May-19	Anti Cancer	Immune Support		Infinimin Ultravitamin	Maintaining and expanding report documents as data accumulates, for presentation to potential investors under non-disclosure agreement.	12000
	Anti Cancer	Immune Support			Expanded Costs for mouse model studies contracted with Mayo Clinic	$38,000

Jul-19	Marketing			Infinimin Ultravitamin	Presentations at national conferences to obtain further evidence and build awareness of product	$7,500
Summary						**$57,500**
Jul-19	Immune Support	Anti-cancer		Infinimin®	Document long-term cumulative effects of product on immune function, with and without cancer. Mouse, Canine, Nonhuman primate studies. (Cost for contracted consultant PI services from Mayo Clinic)	$45,000
Aug-19	Marketing			Infinimin Ultravitamin	Presentations at national conferences to obtain further evidence and build awareness of product	$7,500.00
	Salary					$2,000
Summary						**$52,500**
Phase II STTR Grant						**$150,000**

Request Total						
Phase III	Anti Cancer	Immune Support		Infinimin Ultravitamin	Pilot studies on Phase II cancer patients to collect systematic documentation on effects (immune support during treatment as well as anticancer effect). Four studies performed on five different types of cancers, broadly showcasing the capabilities of Infinimin® (Cost for contracted consultant PI services from Mayo Clinic)	$4,000,000**

	Anti Cancer	Immune Support		Infinimin Ultravitamin	Writing of manuscript to continue to bring the data on immune support to the public domain, in support of product and company credibility.	$12,000.00**
	Anti Cancer	Immune Support		Infinimin Ultravitamin	Writing of manuscript to communicate pilot data on effects in cancer patients, in preparation for getting sufficient funds to run further cancer trials.	$12,000.00
	Marketing			Infinimin Ultravitamin	Presentations at national conferences to obtain further evidence and build awareness of product	$7,500.00
Phase III Summary Costs						**4,031,500**

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Biographic Sketch – Kevin Engholdt

Professional Preparation

Undergraduate Institution(s)

University of Wisconsin-Madison, Madison, WI,

Major: Biology, 2002

Graduate Institution(s)

University of Wisconsin-Madison, Madison, WI

MS: Biotechnology (cum laude), 2009

University of Arizona, Tucson, AZ

Masters of Business Administration (MBA) (cum laude), 2010

Appointments

None

Products

Centrum® Multivitamin

One-a-Day® Multivitamin

Synergistic Activities

This product, while labeled a multivitamin is bridging Western Medicine with Conventional Medicine, for the broader impact of the public health. An example of this already in the market is Centrum® Multivitamin. Centrum® has a base multivitamin panel but also has an extract from a flower called lutein, shown to have strong impact for eye health. We are taking this to a broader level, targeting oncology first, with our multivitamin and trying to bring to the public a more healthful daily maintenance multivitamin. While oncology is our first target niche, our product has antiviral, antidiabetic, and anticholesterol properties that we plan to develop research programs around.

Biographic Sketch – David Lott

Professional Preparation

Undergraduate Institution(s)

1999 BS - Exercise Science, Northern Arizona University

Graduate Institution(s)

2011 Fellow - Laryngeal Surgery and Professional Voice, Harvard Medical School, Massachusetts General Hospital

2010
Resident - Otolaryngology-Head and Neck Surgery; Chief Resident 2009-2010, Head & Neck Institute, Cleveland Clinic

2005
Internship - General Surgery, Department of General Surgery, Cleveland Clinic

2004
MD, Carver College of Medicine, University of Iowa

Appointments

Associate Professor – Mayo Clinic School of Medicine

Products

Centrum® Multivitamin

One-a-Day® Multivitamin

Synergistic Activities

This product, while labeled a multivitamin is bridging Western Medicine with Conventional Medicine, for the broader impact of the public health. An example of this already in the market is Centrum® Multivitamin. Centrum® has a base multivitamin panel but also has an extract from a flower called lutein, shown to have strong impact for eye health. We are taking this to a broader level, targeting oncology first, with our multivitamin and trying to bring to the public a more healthful daily maintenance

multivitamin. While oncology is our first target niche, our product has antiviral, antidiabetic, and anticholesterol properties that we plan to develop research programs around.

Data Not Available

SUMMARY PROPOSAL BUDGET

YEAR 1

FOR NSF USE ONLY		
PROPOSAL NO.	DURATION (months) Proposed	Granted
AWARD NO.		

ORGANIZATION: INFINITUM HEALTH, LLC

PRINCIPAL INVESTIGATOR / PROJECT DIRECTOR: Kevin Engholdt

A. SENIOR PERSONNEL: PI/PD, Co-PI's, Faculty and Other Senior Associates (List each separately with title, A.7. show number in brackets)	NSF Funded Person-months CAL	ACAD	SUMR	Funds Requested By proposer	Funds granted by NSF (if different)
1. Kevin Engholdt - Principal Inv	12.0			2,000	
2.					
3.					
4.					
5.					
6. ( ) OTHERS (LIST INDIVIDUALLY ON BUDGET JUSTIFICATION PAGE)	0.0			0	
7. (1) TOTAL SENIOR PERSONNEL (1 - 6)	12.0			2,000	
B. OTHER PERSONNEL (SHOW NUMBERS IN BRACKETS)					
1. (0) POST DOCTORAL SCHOLARS	0.0			0	
2. (0) OTHER PROFESSIONALS (TECHNICIAN, PROGRAMMER, ETC.)	0.0			0	
3. (0) GRADUATE STUDENTS				0	
4. (0) UNDERGRADUATE STUDENTS				0	
5. (0) SECRETARIAL - CLERICAL (IF CHARGED DIRECTLY)				0	
6. (0) OTHER				0	
TOTAL SALARIES AND WAGES (A + B)				2,000	
C. FRINGE BENEFITS (IF CHARGED AS DIRECT COSTS)				0	
TOTAL SALARIES, WAGES AND FRINGE BENEFITS (A + B + C)				2,000	
D. EQUIPMENT (LIST ITEM AND DOLLAR AMOUNT FOR EACH ITEM EXCEEDING $5,000.)					
TOTAL EQUIPMENT				0	
E. TRAVEL 1. DOMESTIC (INCL. U.S. POSSESSIONS)				15,000	
2. INTERNATIONAL				0	
F. PARTICIPANT SUPPORT COSTS					
1. STIPENDS $ 0					
2. TRAVEL 0					
3. SUBSISTENCE 0					
4. OTHER 0					
TOTAL NUMBER OF PARTICIPANTS (0) TOTAL PARTICIPANT COSTS				0	
G. OTHER DIRECT COSTS					
1. MATERIALS AND SUPPLIES				10,000	
2. PUBLICATION COSTS/DOCUMENTATION/DISSEMINATION				5,000	
3. CONSULTANT SERVICES				113,000	
4. COMPUTER SERVICES				0	
5. SUBAWARDS				0	
6. OTHER				5,000	
TOTAL OTHER DIRECT COSTS				133,000	
H. TOTAL DIRECT COSTS (A THROUGH G)				150,000	
I. INDIRECT COSTS (F&A)(SPECIFY RATE AND BASE)					
TOTAL INDIRECT COSTS (F&A)				0	
J. TOTAL DIRECT AND INDIRECT COSTS (H + I)				150,000	
K. SMALL BUSINESS FEE				0	
L. AMOUNT OF THIS REQUEST (J) OR (J MINUS K)				150,000	

M. COST SHARING PROPOSED LEVEL $ | AGREED LEVEL IF DIFFERENT $

PI/PD NAME: Kevin Engholdt

ORG. REP. NAME*

FOR NSF USE ONLY		
INDIRECT COST RATE VERIFICATION		
Date Checked	Date Of Rate Sheet	Initials - ORG

1 *ELECTRONIC SIGNATURES REQUIRED FOR REVISED BUDGET

SUMMARY PROPOSAL BUDGET

Cummulative

FOR NSF USE ONLY		
PROPOSAL NO.	DURATION (months) Proposed	Granted
AWARD NO.		

ORGANIZATION
INFINITUM HEALTH, LLC

PRINCIPAL INVESTIGATOR / PROJECT DIRECTOR
Kevin Engholdt

A. SENIOR PERSONNEL: PI/PD, Co-PI's, Faculty and Other Senior Associates (List each separately with title, A.7. show number in brackets)	NSF Funded Person-months CAL	ACAD	SUMR	Funds Requested By proposer	Funds granted by NSF (if different)
1. Kevin Engholdt - Principal Inv	12.0			2,000	
2.	0.0			0	
3.	0.0			0	
4.	0.0			0	
5.	0.0			0	
6. ( ) OTHERS (LIST INDIVIDUALLY ON BUDGET JUSTIFICATION PAGE)	0.0			0	
7. (1) TOTAL SENIOR PERSONNEL (1 - 6)	12.0			2,000	
B. OTHER PERSONNEL (SHOW NUMBERS IN BRACKETS)					
1. (0) POST DOCTORAL SCHOLARS	0.0			0	
2. (0) OTHER PROFESSIONALS (TECHNICIAN, PROGRAMMER, ETC.)	0.0			0	
3. (0) GRADUATE STUDENTS				0	
4. (0) UNDERGRADUATE STUDENTS				0	
5. (0) SECRETARIAL - CLERICAL (IF CHARGED DIRECTLY)				0	
6. (0) OTHER				0	
TOTAL SALARIES AND WAGES (A + B)				2,000	
C. FRINGE BENEFITS (IF CHARGED AS DIRECT COSTS)				0	
TOTAL SALARIES, WAGES AND FRINGE BENEFITS (A + B + C)				2,000	
D. EQUIPMENT (LIST ITEM AND DOLLAR AMOUNT FOR EACH ITEM EXCEEDING $5,000.)					
TOTAL EQUIPMENT				0	
E. TRAVEL 1. DOMESTIC (INCL. U.S. POSSESSIONS)				15,000	
2. INTERNATIONAL				0	
F. PARTICIPANT SUPPORT COSTS					
1. STIPENDS $ 0					
2. TRAVEL 0					
3. SUBSISTENCE 0					
4. OTHER 0					
TOTAL NUMBER OF PARTICIPANTS (0.0) TOTAL PARTICIPANT COSTS				0	
G. OTHER DIRECT COSTS					
1. MATERIALS AND SUPPLIES				10,000	
2. PUBLICATION COSTS/DOCUMENTATION/DISSEMINATION				5,000	
3. CONSULTANT SERVICES				113,000	
4. COMPUTER SERVICES				0	
5. SUBAWARDS				0	
6. OTHER				5,000	
TOTAL OTHER DIRECT COSTS				133,000	
H. TOTAL DIRECT COSTS (A THROUGH G)				150,000	
I. INDIRECT COSTS (F&A)(SPECIFY RATE AND BASE)					
TOTAL INDIRECT COSTS (F&A)				0	
J. TOTAL DIRECT AND INDIRECT COSTS (H + I)				150,000	
K. SMALL BUSINESS FEE					
L. AMOUNT OF THIS REQUEST (J) OR (J MINUS K)				150,000	

M. COST SHARING PROPOSED LEVEL $ | AGREED LEVEL IF DIFFERENT $

PI/PD NAME
Kevin Engholdt

ORG. REP. NAME*

FOR NSF USE ONLY		
INDIRECT COST RATE VERIFICATION		
Date Checked	Date Of Rate Sheet	Initials - ORG

C *ELECTRONIC SIGNATURES REQUIRED FOR REVISED BUDGET

Budget Justifications

Infinitum Health, LLC

Founder: Kevin Engholdt

Phase I STTR Application

Below is a description of requested budget and the justifications for each item requested.

A. Senior Personnel Months: 12 Funds Requested: $2000

Justification: This effort has been largely self-funded by the founder, Kevin Engholdt, using personal savings, investment accounts (401k, etc), and salary of consulting employment. The $2000 requested is largely to cover time spent working with the contract labs on prep, protocol development, review of data, and research strategy. For funding from the STTR Grant, goal would be that the majority of funding go directly to research related efforts.

E. Travel Funds Requested: $15,000

Justification: This effort is to cover all travel costs associated with marketing of the research at scientific conferences. This would cover air, hotel, rental car, conference registration and presentation fees, meals, and incidental expenses related to the marketing of the research via conferences with the plan to commercialize.

G. Other Direct Costs Funds Requested: $133,000

Materials: $10,000

Publication and Documentation: $5000

Consultant Services: $113,000

Other: $5000

Justification: This effort is the majority of the costs for the research program, broken down by line item. First, $10,000 requested for raw material purchase of extracts for formulation, certificate of analysis completion, and import fees from respective countries.

Second, publication an documentation costs of $5000 for preparation of manuscripts, submission to journals, membership to journals, and final proof and editing of research work.

Third, and most importantly, Consultant Services for $113,000. This is the cost of use for contract services of Principal Investigator – David Lott, MD, the use of Mayo Clinic Sponsored Research Labs, the laboratory team performing the preclinical studies, the animal husbandry costs, and related contract research costs.

Finally, we have an "Other" category for $5000 for a patent application process. This would be the cost of a patent attorney to draft our patent and apply with the U.S. Patent Office.

In total, this comes to $150,000, the total amount of a Phase I STTR Grant.

Current and Pending Support

$146,324 – Self Funding from founder, Kevin Engholdt

Current and Pending Support

None at this time, all funding provided by founder, Kevin Engholdt

Facilities, Equipment and Other Resources

This research effort will be conducted under the supervision of Principal Investigator, David Lott, MD, of Mayo Clinic. Laboratory and Facility use will be conducted at the Mayo Clinic Johnson Center for Research in Scottsdale, AZ. These facilities will be expensed under the "Consultant" budget expense line and are considered excellent in terms of research quality.

No Detailed Plan is needed at this time. Data management will be coordinated from the Mayo Clinic Sponsored Research Labs, led by David Lott, MD.

Data Not Available

Data Not Available

Table 1

1	Your Name:	Your Organizational Affiliation(s), last 12 mo	Last Active Date
	Engholdt	Infinitum Health, LLC	11/15/18

Table 2

2	Name:	Type of Relationship	Optional (email, Department)	Last Active Date
R				

Table 3

3	Advisor/Advisee Name:	Organizational Affiliation	Optional (email, Department)
G			
T			

Table 4

4	Name:	Organizational Affiliation	Optional (email, Department)	Last Active Date
A				
A				
C				

Table 5

5	Name:	Organizational Affiliation	Journal/Collection	Last Active Date
B				
E				

Table 1

1	Your Name:	Your Organizational Affiliation(s), last 12 mo	Last Active Date
	Engholdt	Infinitum Health, LLC	11/15/18

Table 2

2	Name:	Type of Relationship	Optional (email, Department)	Last Active Date
R				

Table 3

3	Advisor/Advisee Name:	Organizational Affiliation	Optional (email, Department)
G			
T			

Table 4

4	Name:	Organizational Affiliation	Optional (email, Department)	Last Active Date
A				
A				
C				

Table 5

5	Name:	Organizational Affiliation	Journal/Collection	Last Active Date
B				
E				

Data Not Available

Data Not Available