

SIMETRI

Improving the Small Business Innovation Research and Small Business Technology Transfer Programs

Testimony before the House Subcommittee on Contracting and Workforce of the Committee on Small Business and the Subcommittee on Research and Technology of the Committee on Science, Space, and Technology

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Good morning, Chairman Knight, Chairman Comstock, Ranking Member Murphy, Ranking Member Lipinski, and Members of the Committees. My name is Angela Albán Naranjo and I am the President and CEO of SIMETRI, a small women-owned, minority-owned business based in Winter Park, Florida and currently participating in the Small Business Innovation Research (SBIR) Program. Thank you for the opportunity to discuss the SBIR Program and Small Business Technology Transfer (STTR) programs pursued by SIMETRI, the role these programs play in allowing small businesses such as mine to develop innovative intellectual property that promotes more rapid technological innovation and economic growth in our communities. My remarks will focus on my personal experience as a small business owner involved in the SBIR and STTR programs. It is my opinion that the SBIR and STTR programs are ideally suited for creating opportunities for small businesses throughout our country to stimulate technological innovation and economic growth. These programs have afforded me the opportunity to grow our team and capabilities, have made us more competitive and allowed us the opportunity to achieve our mission statement: Improve medical outcomes through innovative training technology development.

I want to share our company's story and how participation in the SBIR program has fostered our growth and internal development, but first, I want you to understand how small our business truly is and how it started, so that you can witness how this program can transform lives and communities. I was born in Colombia and emigrated to the United States with my parents when I was five years old. I dreamt of becoming a physician, but while pursuing my undergraduate degree at Emory University, I realized that I wanted to make and break things, so I became an engineer. I came home to Central Florida, attended graduate school at the University of Central Florida and began working for a defense contractor as a Simulation Engineer. By the time I had my children,

I wanted the freedom and flexibility that came with being a small business owner, but most importantly, I aspired to become an honest and fair employer that inspired trust and innovation. I started my company in 2009 as a consultant and within a couple of years, we were awarded direct contracts with the U.S. Army developing new technologies and capabilities for medical training. By 2014, we were awarded our first Phase I SBIR contract. This contract marked a milestone for our company and allowed me to pursue more competitive research and development contracts. It enabled me to hire the right staff and develop foundational processes, methodologies, and technologies that prepared us for future work. Today, we employ twelve individuals, a family of dedicated workers drawn from different professional backgrounds whose culture and focus is built around the same goal: improving medical outcomes by developing innovative training technologies.

SIMETRI'S PARTICIPATION IN THE SBIR PROGRAM

The U.S. Army Research Laboratory Human Research and Engineering Directorate Advanced Training & Simulation Division (ARL-HRED ATSD) develops and matures affordable new technologies for simulation-based training. In support of these research and development efforts, ARL-HRED ATSD contracts with solution providers to develop technology, tools, and techniques for more effective medical training for Army personnel.

One such training gap is in the field of intraosseous (IO) infusion. Traumatic life-threatening injuries often require the immediate delivery of fluids and medications. The hazards of combat environments present new and heightened difficulties in delivering these lifesaving fluids and medications through intravenous (IV) access, especially during the treatment of critical injuries.

Medics, nurses, and physicians are highly trained in obtaining intravenous access, but when access is difficult or altogether impossible to achieve, alternative methods for administering fluids and medications are essential. IO infusion is a technique used to access blood vessels within the bone marrow, which is concealed in a rigid, structured bony wall. Unlike the body's peripheral veins, the IO space does not collapse when the patient is in shock (Communicore, 2006). Humeral Head IO (HHIO) infusion is the process of injecting fluids and medications directly into the marrow of the humerus to provide a non-collapsible entry point into the circulatory system. This technique is used in emergency situations to provide fluids and medication quickly, when IV access is not available or not feasible (Tobias & Ross, 2010) as depicted in Figure 1 (Teleflex, n.d.).

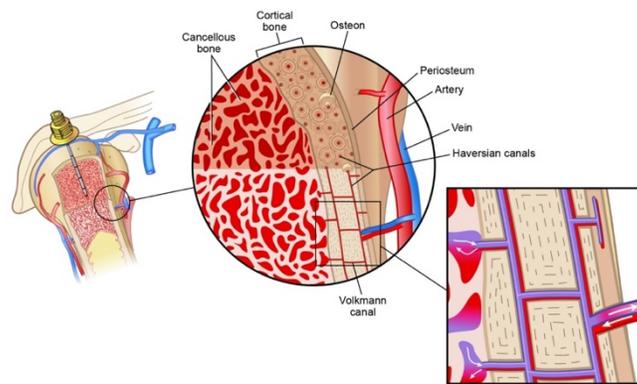


Figure 1. Rapid Infusion of Medicines and Fluids

Medications administered intraosseously reach the heart in less than thirty seconds, and the U.S. Army currently utilizes the EZ-IO Intraosseous Infusion System for HHIO insertions to deliver fluids in critical care situations. An insertion time by trained operators of as little as 20 to 40 seconds makes this technology particularly attractive for use on the battlefield to reduce casualties (Weiser et al., 2012; Carness et al., 2012; Sarkar & Philbeck, 2009). Even though the use of IO infusion was prevalent within the U.S. military during the Second World War, its use faded with the introduction of the plastic IV catheter. IO infusion re-emerged as a viable field alternative to

IV fluid introduction during the recent conflicts in Iraq and Afghanistan. As of 2010, the U.S. Committee on the Tactical Combat Casualty Care (TCCC) guidelines recommends using IO infusion in any resuscitation scenario in which IV access is not feasible (Weiser et al., 2012). Combat medics, flight medics, battalion surgeons and physician assistants deliver medical care from the time of injury through the battalion aid station, or brigade support medical company, until the injured soldier is delivered to surgical care. By making IO insertion training available to all soldiers, the Army can expect to see a reduction in casualties through the appropriate use of IO devices in the field.

This training imperative gave rise to the need for a low-cost, hands-on training system with sufficient fidelity to train soldiers effectively in the field use of IO devices for humeral head insertions, and provide them with “muscle memory” for this task. To meet this requirement, ARL-HRED ATSD created a Small Business Innovative Research (SBIR) Phase I Topic to develop a prototype, proof-of-concept device that demonstrates the feasibility of meeting the Army’s expectations for a HHIO Insertion Part Task Trainer (PTT). My company, SIMETRI, Inc., was awarded a Phase I SBIR contract in June 2014 and subsequently, a Phase II SBIR contract in May 2015 to develop a prototype PTT that teaches students to find the correct anatomical landmarks, to insert the IO needle at the correct location and proper angle, to verify proper insertion, and to prepare the catheter correctly to introduce fluids. Relying on Subject Matter Experts (SMEs) and ARL-HRED ATSD personnel, SIMETRI conducted the research, design, and validation of Phase I and Phase II HHIO PTT prototypes that addressed the specific learning objectives desired for Army medical training in proximal HHIO insertion. The prototype PTT developed during Phase I of the SBIR effort consisted of an arm only, with appropriate structures and characteristics. The

Phase II SBIR prototype consists of a torso with two arms that articulate, allowing the trainee to position the arms as they would prior to performing the procedure. The design process focused on durability, realism, reusability, and low lifecycle costs.

The Phase I research culminated with SIMETRI delivering a prototype single-arm humeral head HHIO PTT (Figure 2) which was well received by users. The prototype development focused on providing an accurate simulation of the humeral head IO procedure, and was shown through usability testing to have been successful. Follow-on research continued to develop this proven technology into a commercially viable device, implementing additional features requested by end users while preserving the focus on affordability, durability, reliability, reduced lifecycle cost, and user-friendliness.



Figure 2. SIMETRI's Single-Arm HHIO PTT Delivered for the Phase I SBIR Contract.

Building on the successes achieved during the Phase I effort, the objectives of the Phase II SBIR effort were to improve the Phase I prototype PTT for real-world use in the field, and to incorporate the recommendations, findings, and new requirements elicited from military and civilian end users and Subject Matter Experts (SMEs) from the Phase I effort. Leveraging the lessons from the Phase I device, the Phase II PTT (Figure 3) was enhanced to provide appropriate feedback to student

actions, with adverse effects when common errors are committed as well as visible results to represent success, so that proficiency can be observed and judged. The PTT allows a trainee to locate the anatomical landmark (humeral head), firmly seat the catheter, observe blood on the stylet tip, note blood at the catheter hub, aspirate blood or marrow from the humeral head with a syringe, and introduce drugs or fluids flow, all while providing tactile and pressure cues that simulate the real-world scenario.

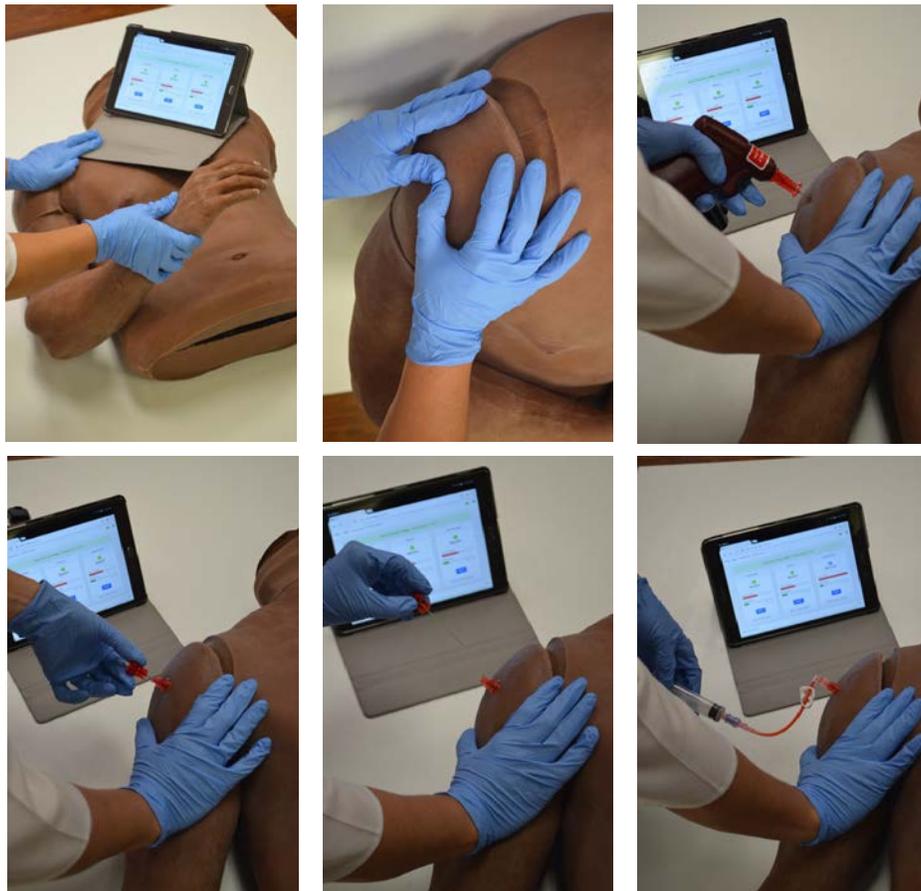


Figure 3. SIMETRI HHIO Part Task Trainer

During the Phase II SBIR effort, SIMETRI began utilizing 3D printing with additive materials such as high strength fiberglass and carbon fiber to reinforce components to strengths not typically seen in traditional 3D printing. The carbon fiber and fiberglass additives have provided sufficient

strength to these sub-assemblies to the point that they now replace traditional manufacturing techniques requiring machining of steel or aluminum. SIMETRI has replaced several of the Phase II PTT sub-assemblies with components that are now manufactured in house through additive 3D printing.

Use of 3D printing has now become a staple of any design and development effort that SIMETRI undertakes. 3D printing was used to advance the design of the Phase II PTT to achieve the accurate movement of the left and right arms, which in turn position the greater tubercle of the humeral head, achieving a major requirement in Phase II. These components were initially planned for machined aluminum but were quickly replaced with the additive 3D printing techniques when the cost of modifications and updates were factored in. Also, the rapid prototyping available through 3D printing allowed for the continuous improvement of the components with minimal cost impact to the final product. Use of 3D printing has also provided other opportunities and has been utilized to create support equipment used in the manufacturing process, molds for analyzing form, fit and function, and “positive” components that are then used to craft molds of reproducible/consumable components.

As part of the SBIR Program, SIMETRI recently submitted a proposal for a Second Phase II of the HHIO PTT that will build upon the results from the successful Phase I and Phase II efforts and culminate in an expanded and improved version of the Phase II prototype with additional capabilities, higher fidelity, greater user-friendliness, better reliability, and a specific design for commercialization. SIMETRI will leverage the lessons learned from the Phase I and Phase II efforts and continue to refine the HHIO PTT such that it can provide the best-available training

platform for the Army's medics, nurses and doctors, and be commercialized and transitioned to the civilian marketplace.

BARRIERS TO ENTRY INTO THE SBIR AND STTR PROGRAMS

Obtaining an SBIR or STTR award is very desirable to a small business because it presents an opportunity to develop technology while also growing a collaborative relationship with the federal government's representatives. In some cases, these awards afford small businesses an entry into working directly with the federal government while developing a technology that addresses an emerging need. At the same time, however, these awards are competitive, and every year there are more companies competing for a limited number of contracts. As a result, it is imperative that the small business familiarize itself with the problem space and the customer prior to the topics being officially released. Small business owners such as myself should also join with academic or other industry partners to ensure a competitive offering, since we typically do not have the depth of resources required to respond to some of the topics. Developing a network of partners is critical for a small business and we often find these partners in academia and industry. Although there are many opportunities for small businesses to develop these relationships, it is often a matter of time and resources. As a small business owner, we often have to prioritize our investments to maximize the return, and due to the highly competitive nature of these SBIR topics, the return is not immediate. In addition to securing the support of partners in academia and industry, we also secure support from the target industry for the technology being developed. Despite the fact that our company has successfully been awarded a Phase I and Phase II SBIR and soon a Second Phase II SBIR contract, we often submit proposals for new topics and are not selected as an awardee. We are cognizant of the value of these relationships and invest time and energy in cultivating the trust

required to convince partners to join our team. We also work with target industry partners to secure their interest and support as a part of our proposals. We focus our energy on pursuing topics in our market or adjacent markets to foster the confidence necessary for the Government customer to select our team. We work diligently throughout our local community to develop the relationships to grow our business to facilitate the commercialization of the proposed technologies. In our case, we are attempting to do the right thing to prepare our business for proposed work by fostering a corporate infrastructure that will position us for growth, but we are still not winning every proposal we submit because the stakes are high and the competition is often fierce. Some larger small businesses are leveraging internal investments in technology as a part of their proposed solution, thus lowering the risk for the Government during execution. Our company is not yet able to make these investments, but we intend to position ourselves to do so in the future.

WHAT DOES WORK

We only recently were notified that our Second Phase II contract would be awarded in the coming months. This additional funding will allow us to perfect a product that is completed but not necessarily optimized for commercialization and mass production. The SBIR and STTR programs are an excellent mechanism to rapidly innovate and prototype technologies, but they are not entirely sufficient to commercialize that technology into a long-term, sustainable product that can be accelerated into the final stages of R&D development in the period between discovery and commercialization. The scope and budget allocated to an initial SBIR Phase II effort are often based on estimates based on the nature of the technology and the complexity of the effort. There are often instances where those estimates are low. Under these circumstances, a Second Phase II effort should be considered to adequately mature the technology for transition and

commercialization. Such is the case with this Second Phase II award, as it will help mature the technology while developing the critical processes the federal government can leverage in the future.

Our company is very active throughout the Central Florida community to help build the network that we need to backfill areas of opportunity for growth. Fortunately, our community is focused on diversifying our economy through growth in the high-tech industry. Central Florida is known as the epicenter of Modeling, Simulation, and Training because the sector directly employs more than 30,000 Floridians with an average annual salary of over \$78,000, contributing more than \$6 billion to Florida's Regional GDP and more than \$11.6 billion in state sales (economic output) activity. "Team Orlando" Commands employ nearly 2,800 military & civilian personnel in the Research Park that are all dedicated to advanced R&D and acquisition of simulation and training devices and other technologies. The most recent economic impact study estimates that the Modeling, Simulation and Training sector brings 73,802 jobs to Florida's economy (Lasrado, 2016). The National Center for Simulation (NCS), based in Orlando, Florida, is comprised of 244 Member Companies/Educational Institutions/Not-for-profit Organizations/Individuals (practitioners & students). Of the membership, 50% (122) are working with the federal government. Of those 122 organizations, approximately 50% are small businesses that are agile, innovative and creating many new jobs in Central Florida.

Our community is also home to the nation's largest university. The University of Central Florida provides the backbone of the high-tech industry in Central Florida. Most of UCF's graduates establish long term residence in Central Florida and many launch new enterprises in a community

with an eye on future growth. Central Floridians are fortunate to be surrounded by community leaders and programs that foster our growth and shore up our ability to develop and sustain high tech enterprises.

As an example, I participated in the UCF Business Incubation Program (BIP). Founded with a focus on technology innovation companies, the BIP routinely supports client company participation in the SBIR/STTR programs. Support services provided include a full-time staff member focused on assisting companies with evaluating their potential for business, preparing to do business with the government, finding and pursuing government business opportunities of all types, offering regular SBIR/STTR proposal preparation workshops, and providing comprehensive business incubation support meeting the variety of needs associated with starting and growing their companies while providing cost-effective facilities. Between 2000 and 2016, thirty-four (34) client companies have successfully secured over 130 Phase I awards and 60 Phase II awards, cumulatively valued at \$63,800,000. At SIMETRI, we have received the BIP's assistance, and are grateful for what they have offered us and continue to offer us as a part of our network.

The Florida High Tech Corridor is an economic development initiative of the University of Central Florida, the University of South Florida and the University of Florida. Its mission is to grow high tech industry and innovation through partnerships that support research, marketing, workforce and entrepreneurship. A key program of the High Tech Corridor is the Matching Grants Research Program (MGRP) which fosters partnerships for applied research between high tech industry leaders and the three Corridor universities (UCF, USF, and UF). Every year, technology companies

bring their commercial challenges to expert faculty and leverage R&D budgets. An MGRP grant often helps in securing SBIR/ STTR grants for continued research and diversifies research funding for businesses in the 23-county region.

Since inception of the program in 1996, the High Tech Corridor has partnered with more than 360 companies on more than 1,400 research projects in sectors ranging from Agritechnology to Sustainable Energy. The more than \$65 million in funds that have been invested by the High Tech Corridor have been matched by corporate cash and in-kind investments of \$182 million, generating an additional \$900 million in quantifiable downstream impacts and resulting in a total project value of more than \$1 billion. Our company, SIMETRI, has been the recipient of several High Tech Corridor matching grants that afforded us the opportunity to include expert faculty on our team to amplify our ability to deliver the most innovative technology possible.

Based on the philosophy of Economic Gardening® — to grow existing businesses in a community, region or state — GrowFL, the Florida Economic Gardening Institute, is a critical component to the state's economic development strategy and Florida's entrepreneurial ecosystem. GrowFL was created in 2009 as an economic development program focused on helping scalable second-stage growth companies to prosper in the state of Florida. By providing strategies, resources and support to second-stage companies for next level growth through Strategic Research, Peer Learning and Leadership Development, GrowFL helps companies overcome obstacles to growth and leads them towards prosperity. GrowFL was the first nationally certified statewide Economic Gardening program by National Center for Economic Gardening through the Edward Lowe Foundation.

As of June 30, 2016, GrowFL assisted companies represent over 16,737 direct jobs across the State of Florida. In 2015, these companies had estimated regional sales of over \$3.4 billion and contributed regional GDP of over \$1.4 billion to the Florida economy. Between 2009 and 2015, a variety of state, local and private sector funding sources invested \$8.04 million in the GrowFL program. The activities of this program over the same period helped generate an estimated 10,942 net new direct, indirect and induced jobs. GrowFL has assisted more than 900 companies through their Strategic Research and CEO Roundtable programs and recognized 300 successful entrepreneurs through their annual awards program, Florida Companies to Watch. SIMETRI is currently participating in the GrowFL program as a means to prepare for the commercialization of the SBIR technology being developed.

The Department of Defense (DoD) has created the Velociter program to support rapid transition/commercialization of DoD SBIR/ STTR technology throughout the life cycle of the SBIR/STTR programs. The program provides a variety of services through a program roadmap designed to support awardees in achieving their business goals by offering training resources, business coaching, opportunity analysis, pitch preparation, and competition matchmaking. SIMETRI was recently granted admission into the program because we have an active DoD SBIR/STTR Phase II contract and desire assistance in commercialization and transition. The DoD Velociter Program does not replicate, but, rather, enhances government-wide small business assistance programs facilitating SBIR/STTR. The DoD Velociter Program is sponsored by the DoD Office of Small Business Programs, which administers the DoD SBIR/STTR Program. Although the DoD has various service branch specific transition and commercialization assistance programs, the Velociter Program offers a unique one-on-one coaching program customized to the

needs of each SBIR/STTR awardee providing subject matter expertise in acquisition, intellectual property (IP), accounting, marketing, and contracting. The coaches are business strategy consultants in areas such as marketing, intellectual property, and commercialization. The program strives to assist the awardee with a customize a roadmap to help them advance business goals toward transition and/or commercialization. This program is offered free of charge and purposed to assist small businesses achieve their SBIR/STTR Phase III goals.

The bottom line is that the SBIR/STTR program is embraced and fostered by the State of Florida and the Central Florida region where I reside and base my company. Our region is determined to diversify our economy through the growth of high-tech jobs and companies, therefore making the SBIR/STTR program an on-ramp for many entrepreneurs such as myself. I am fortunate to live in a region where I am encouraged, supported, and advised on how to grow our IP and our company into a sustainable proposition that will ensure the commercialization and transition of the technology developed under the SBIR contract we have been awarded.

At the same time, what has most ensured our success in the SBIR program has been the support and close collaboration with our Government customer at ARL-HRED ATSD. The Technology Manager that serves as my counterpart on the SBIR contract has provided us access to as much data and DoD SMEs to ensure the success of our project. This is an important and often overlooked attribute for the success of the program. Government employees should be encouraged and incentivized to invest the time required to ensure program success. We were afforded the opportunity to meet with stakeholders at the time we kicked off the project and continued to collaborate with them as a part of the development of the technology and usability studies. What

has worked for our team has been the access to Government personnel and resources that are relevant to the technology being developed in a timely fashion. Although the SBIR/STTR program is meant, among other things, to benefit the small business, it requires commitment from the Government team to provide access and much needed feedback as a part of the R&D process.

IMPACT OF THE SBIR AND STTR PROGRAMS AND WHAT STILL MERITS DEVELOPMENT

Since we are still into the early years of our SBIR journey, I would like to provide examples of two other companies that have been active SBIR and STTR program participants. Founded in 1995, Aptima, Inc. has been an active participant in the SBIR/STTR programs for the past 20 years. Examples of their success can be found in areas as diverse as pilot training, command and control, leadership instruction, user experience design, and cyber security. The common thread through all those areas: The human component. Aptima's focus has been on "human-centered engineering," in which methods and practice from the behavioral sciences is paired with cutting edge computer science (e.g., machine learning, artificial intelligence), software engineering, and military know how.

The goal of the SBIR/STTR programs is in part to support the growth of small businesses through commercialization and in part to provide the federal government with cutting edge technologies that help with the missions of various federal agencies through transition. Through successful collaboration with the United States Government and the Naval Air Warfare Center Training Systems Division (NAWCTSD) and their SBIR initiatives, Diamond Visionics developed and deployed new technology for the U.S. Navy P-3 and several other programs in support of our national defense. Diamond Visionics and the Genesis Family of software products have grown

through the technical innovation specifically sponsored through many SBIR awards. In total, they have received twenty-three (23) Phase I SBIR and fourteen (14) Phase II awards.

The dynamic construction engine in GenesisRTX is specifically designed to provide high-fidelity real-time visualization using GIS source data (including vector, model, imagery, classification, and elevation sources, including the United States Navy Portable Source Initiative (NPSI) by leveraging modern GPU architectures and multi-core processors commercially available on the market. The GenesisRTX technology eliminates the need for time-consuming and labor-intensive off-line database generation, while providing significantly higher fidelity than is typically possible using antiquated traditional approaches. The result is significant savings, while providing high-quality, high-performance 3D visualization constructed on-the-fly during run-time directly from the source data for a much lower cost and rapid turn-around times to support our nations warfighters.

Through successful collaboration with their U.S. Navy and U.S. Army counterparts, Diamond Visionics developed and deployed this new technology globally, which has allowed for modest revenue growth, local hiring and retention of their technical staff. In addition to full-time technical staff, Diamond Visionics have also employed nineteen (19) student internships over the years, seven (7) of which resulted in full-time employment with Diamond Visionics upon graduation from Binghamton University.

Aptima has worked hard to find success in both transition and commercialization. To support the commercialization goals of the SBIR/STTR programs, Aptima has developed a method of standing

up subsidiary businesses that take SBIR-developed technologies to new markets such as healthcare and educational technology. Similarly, Aptima has had made major efforts to transition technologies out of the SBIR programs and into operational use. Examples of this success includes the U.S. Air Force Distributed Common Ground System weapons System Trainer (DWST) and Confined Space Monitoring programs and the U.S. Navy P-8A program. For the P-8A effort, Aptima has added over \$6.3M to a Navy Phase II SBIR project with \$4.77M provided by from the Naval Air Warfare Center Training Systems Division (NAWCTSD) to enable diagnostic assessment and tracking of crew performance and readiness for P-8A aircrew.

The impact of the SBIR program on Aptima cannot be overstated. It is a main driver for growth and new innovation. The proof is in their recent projections for new hires; they anticipate 15% - 20% growth each year for the next three years, with much of that growth to occur in the Central Florida region. However, this growth could be even greater if there were more alignment between the SBIR topics and the larger acquisitions requirement process. Within the DoD, SBIR topics often describe technologies that are of interest to specific military agencies and offices but have not yet been incorporated into official requirements or the POM process. This becomes a challenge to the companies performing the SBIR activities because there may not be a ready contract for the new technologies to find continuing support after the Phase I and Phase II periods are over, even if there is agreement among military stakeholders that the technologies would be of significant benefit to our military service members.

Most companies with SBIR/STTR work often live under the threat of budget uncertainty and the Program Objective Memorandum (POM) process. There has been much written regarding how

Continuing Resolutions and the resulting unstable funding profiles affect force readiness. I would submit that this threat is especially felt by the small businesses performing this type of research. As small businesses, we cannot absorb the breaks in a program funding that often occur under these circumstances. It is nearly impossible to internally keep the project moving especially at the early stages of development

Additionally, there is often a disconnect between the SBIR/STTR pipeline of work and its maturation into the POM process. As the technology matures, Phase III funding decisions often require a fully-funded transition program represented in the POM. This practice fails to recognize the natural phasing of these efforts and often prevents relevant, innovative technologies from transitioning successfully. Currently there are no tangible incentives for the services' acquisition communities to transition technology as this often involves risk. In order to overcome this headwind, we have to change the way we view failure of some of these programs. We can choose to view the failures as the death knell of a program or as an opportunity to leverage all there is to learn and move forward to the next iteration.

CONCLUSION

In conclusion, I want to reiterate that not only as a participant, but as a taxpayer, I believe in the SBIR/STTR program. We are at a critical time in our Nation's history and it is now more imperative than ever to continue to be the World leader. A shift has occurred that puts at risk our ability to drive technological change and revolution. Progress is now determined by the new innovations we develop as much as by the ways in which we apply and how quickly we disseminate the advances. I hope that I have conveyed my personal experience with the SBIR and

STTR programs and how these experiences may represent other entrepreneurs in the high-tech sector. We find ourselves lagging as a nation in R&D when compared to other countries but we are also still as brilliant and agile as we have ever been. We have opportunities to expand and improve training, healthcare, communications, computation, cybersecurity and many other crucial technologies required to defend the freedoms we hold dear. This concludes my statement. Thank you for your attention and I look forward to answering any questions you may have.

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