SANARIA

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Testimony of: Stephen L. Hoffman, MD – Chief Executive & Scientific Officer – Sanaria Inc.
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Chairman Rubio, Ranking Member Cardin, members of the Committee, thank you for the opportunity to discuss the importance of the SBIR and STTR Programs in supporting scientific excellence and technological innovation in the United States.

My company, Sanaria Inc., was founded in 2003 to commercialize the first FDA-licensed vaccine to prevent malaria, a disease of unfathomable impact for the U.S., especially our military, and worldwide. The company started at my kitchen table with an idea and a vision, and then transitioned thanks to a Phase I SBIR grant from NIH to a team of three personnel, including me, moving into an 800 square foot facility described in a *National Geographic* article on malaria, as "a dismal strip mall in Rockville, MD." We were told at the outset by more than 95% of our colleagues that it would be impossible to develop the technology to manufacture the vaccine we envisioned in compliance with FDA regulations. We have proven them all wrong.

Thanks to continuous innovation, in large part supported by SBIR grants, our 80 personnel work today at a unique, state of the art facility, where we manufacture our malaria products in compliance with FDA regulations, products that have been assessed in clinical trials in 7 African and 5 European countries, and at 5 clinical sites in the United States. We are now initiating production of what is called Phase 3 and commercialization compliant vaccine that will be assessed in clinical trials in the United States, Africa, Indonesia, and Europe in the next year. These clinical trials are intended to provide data to support a Biologics License Application to the FDA by late 2021 and commercialization in 2022.

My company would not be here today without the initial and continuing support of the SBIR program. SBIR grants are peer-reviewed and awarded to those with the most cutting-edge science and innovation. Because of the credibility of the SBIR program throughout the research and development world, for every dollar my company has been awarded by the SBIR program, we have been able to raise an additional $3.50 from other sources. This leveraging of SBIR funds has facilitated our raising approximately $300M in direct and indirect funding. The indirect funding has been primarily to support clinical trials worldwide.

In addition to the funds received from the SBIR program, funds have come from multiple sources. Three U.S. oil and gas companies and the country of Equatorial Guinea have committed approximately $85M to the effort. The Bill and Melinda Gates Foundation and the US Department of Defense, through the Army and Navy, have committed approximately $40M each to our program. Additional funds have come from governments or foundations in Tanzania, the Netherlands, Germany, and Switzerland.

Malaria is a complex and extremely difficult disease to combat. From 2015 to 2017, despite an annual international investment of greater than $4 billion, the 200 million cases and 500,000 deaths caused by malaria annually have not decreased. The U.S. is the largest contributor to

this international effort. The only way to halt this output of funds from our country to fight malaria is to eliminate the disease, and only vaccines have eliminated human infectious diseases. Because of the SBIR program, we are moving toward the first FDA licensure of a malaria vaccine, a vaccine to be used for elimination. We only manufacture the vaccine in the U.S., and because of the technical and scientific expertise and infrastructure we have developed and will need, we are already planning to build the next manufacturing facility in the U.S. to produce approximately 20 times more vaccine than our current facility. This facility and the additional facilities we will need will support the U.S. economy and jobs creation.

The average cost to develop and license a new vaccine or drug is $2 to $3 billion. Thanks to the innovativeness required by the SBIR program and our funders, and the lack of investment by the traditional equity and pharmaceutical industry sources of capital, we have had to be extremely efficient, and we expect to get over the finish line of FDA licensure at about 20% of this cost ($500 million). Once we do so and have an FDA-licensed vaccine, we are confident that the investment potential will dramatically increase.

The SBIR program is internationally unique and the envy of biotech and biopharmaceutical companies in Europe and other parts of the world. It provides funds that would ordinarily not be there for innovators to launch the R&D needed to get their programs off the ground. Its excellence is maintained, because it is a peer-reviewed, merit-based program that rewards scientific and technical excellence and innovation, and does not just spread funds to non-competitive companies as a form of corporate welfare. Once the SBIR program is renewed, or better yet made permanent, I recommend that you continue to provide the authority for individual agencies to have the flexibility of funding at different levels, including jumbo awards, and to eliminate any loopholes that allow companies that are not truly small businesses to participate in the program.

In closing, I want to thank this Committee for the continued support and renewal of the SBIR/STTR program, and encourage you to make it permanent so that companies like mine, and fellow innovators, have the confidence, assurance, and support to keep the United States at the absolute cutting edge of innovation in the world.