Hearing Testimony
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Chairman Altmire, Ranking Member Graves, and Members of the Committee:

Thank you for providing me the opportunity to testify before you today regarding the Small Business Innovation Research Program (SBIR). My name is Nicholas Franano. I am a physician, scientist, and founder of Proteon Therapeutics, an early stage biotechnology company with operations in Kansas City, Missouri and Waltham, Massachusetts. My familiarity with the SBIR program began in 2003 when Proteon Therapeutics first applied for an SBIR grant from the NIDDK. In 2004, Proteon was awarded a Phase I STTR grant from the NIDDK and in 2005 Proteon won a Phase I SBIR grant from the NHLBI. I have served as the principal investigator for both grants. In 2007, I went to the other side of the table and served as a member of a scientific review committee tasked with evaluating SBIR grants for the NIDDK, and so I have now seen the program both from the vantage point of applicant and reviewer.

In preparation for this testimony, I reviewed the excellent remarks by Douglas Doerfler, the CEO of Maxcyte, Inc, that were presented to the committee on January 29th. In my opinion, Doug's testimony provided an excellent summary of the strengths and weaknesses of the current SBIR program. His comments are almost entirely consistent with my personal experiences. Rather than remake the points Doug emphasized, I would like to relate my personal story and the story of the Company that I founded, as a way to provide additional depth to your understanding of the issues.

In 1993, I was a medical student at Washington University, St. Louis and had just completed the requirements for a master's degree program in biomedical research. While applying for a residency position in Radiology at Johns Hopkins University, I had the good fortune to meet Dr. Elias Zerhouni, who was then an associate professor. Elias wanted to bring more individuals to the Radiology Department at Hopkins who had a background and interest in research. As you may know from the size of his NIH budgets, Elias is a hard man to say no to. In 1997, after four years of medical training at Hopkins, Dr. Zerhouni asked me to apply for a physician research training grant from the NIH and devote half of my time to laboratory research for a period of two years. The grant paid 50% of my salary, freeing up the

time for research, an incentive that was necessary for the department to let me go into the lab.

When I sat down with Elias at the start of the project and asked him what he would like me to focus on, he gave a remarkable answer. Although I don't remember the specific words, his message was clear and memorable. Identify an important medical problem that interests you and that you could be passionate about, and then try to find a better way to treat it. It sounded so simple and straightforward, I thought. As an interventional radiologist, I had spent many hours unclogging vascular access sites for patients on hemodialysis and was interested in studying this problem. The difficulty begins when a patient's kidneys stop working. Without treatment, they will die within days. Fortunately, there are machines that can filter the blood of patients with kidney failure, allowing them to live. In order to get blood out of a person to filter through the machines and then give the cleaned blood back to the person, a surgeon must create a site in the body where blood can be removed and returned rapidly. Although these access sites are relatively straightforward to make, they don't last. The sites need to be repeatedly cleaned out and opened up, and eventually replaced. It is miserable for patients and expensive for Medicare to deal with this chronic problem, accounting for more than $1B in costs each year. During my time working as a physician at Hopkins, it occurred to me that the clogging occurs in a pretty short and predictable segment of blood vessel in the access site and the clogging is often a direct cause of the blood vessel being too small in diameter. During my time working as a researcher at Hopkins I invented a drug and methods that could be used at the time an access site was created that could enlarge the diameter of the key blood vessel segments and reduce the chance of clogging. Not surprisingly, Hopkins asked me file for a patent on the invention, which I did. The patent lawyers told me the University would almost certainly license this invention to a biotechnology or pharmaceutical company for development. After this, I left Baltimore in 2000 and went back home to Kansas City to start a family and a private medical practice. Life was good. In 2001, the Technology Transfer Office at Hopkins contacted me about the patent application. The Office had offered a license to the invention to a few companies but they had declined. My contact at the Technology Transfer Office indicated that the deadline for worldwide patent filings was coming up in the next few months and that without a licensee, Hopkins would likely abandon the patent rather than pay the additional fees. I implored them to keep investing in the technology. They responded by asking if I was interested in buying the patents from Hopkins and starting a biotechnology company myself.

I spent the next several weeks talking with individuals with biotechnology experience about whether I should do this. To my surprise, nearly all of the individuals I contacted recommended against it. First, they said it is really hard to find capital and talent for a biotech company in a place like Kansas City and that I would likely have to move to Boston or San Francisco to get a company started. Second, they worried that without formal business experience I would not be able to attract enough investors to be successful. Third, they said that even if I could get

past these two barriers, the odds that a pre-clinical drug candidate would make it to the market is very low, and that I could harm my medical career by spending a lot of time working on it.

One bright spot in this discussion, however, was learning about the SBIR program and understanding how the SBA could help support an early stage biotechnology company with a novel approach to an important unmet medical need. With that in mind, I got just enough courage to discuss the idea with my wife. To my surprise, she was cautiously supportive. I committed to continue working as a physician initially and see how the Company and technology came along. In the fall of 2001, Proteon Therapeutics was born. I attracted an experienced business partner and co-founder and quietly started moving money from my savings to the Company to generate additional data that we might use to attract investors. I set up an office in the basement of my house and started reading every research paper I could find on the topic. I worked nights and weekends, slept through parties, and missed a lot important events. Then in the fall of 2003, Proteon secured its first round of external capital, a total of $265K. We squeezed every last bit of progress out of each dollar and applied for an SBIR grant to help. We took no salary. Our first grant was rejected without review. We sent in a revised grant with more data and a new lead drug candidate (PRT-201) and got a borderline score. The program director Dr. Marva Moxey-Mims contacted me and indicated that if I formed a partnership with the University of Kansas and converted the grant into an STTR she might be able to get it funded. Within days, the grant was rewritten as an STTR and we got the $157,000. This allowed Proteon to hire our first real employee and helped build out a small laboratory at a local biotechnology incubator mostly with used equipment, some purchased off eBay. I went part-time as a physician in order to devote more time to the Company. That grant really made a difference for Proteon.

While raising subsequent rounds of capital from angel investors, it became clear to me that many of the individuals that we were talking with had difficulty assessing the technology and the likelihood for success. For a $50 – 100K investment, it did not make sense for them to spend too much time or money trying to figure this out either. In this setting, angel investors look for external signs to guide them. Being able to say that Proteon had submitted a grant application to a panel of experts at the NIH, had received a good score, and that the SBA had decided to fund the Company was a big help. I went so far as to show potential investors the actual grant reviews, which indicated that the problems were we addressing were big and important, and that the technology was novel and had a reasonable chance of making a difference. The partnership with the University of Kansas helped a lot as well, giving us access to some of the resources there. The grant and partnership was invaluable in attracting the additional capital that helped us through the "valley of death" that Doug described in his remarks.

In 2005 we were awarded a second SBIR grant by the NHLBI to study the use of our drug for patients with blocked arteries in their legs who are at risk for amputation. The work in both grants has ended successfully, and both drug development

programs continue to advance toward clinical testing. In the spring of 2006, Proteon was able to raise a $19M round of capital from a group of four venture capitalists from Boston, San Francisco, Durham, and Munich, Germany. It was the biggest biotech venture capital financing in Kansas City history. With that money, Proteon has continued the development of our lead drug candidate, which we expect will undergo testing in our first human clinical trials this year. In many regards, Proteon is an SBIR success story. Without those two grants, I think Proteon very well might have failed in 2005 and the development of our drug would have been halted. Given that, I would encourage the committee to renew the program and raise funding levels. I believe that the statement by the National Research Council that "U.S. technological performance is challenged less in the creation of new technologies than in their commercialization and adoption" is as true today as it was when they made it.

If this were a movie, the story would stop here, to make for a nice ending. However, there is another chapter. The Small Business Administration (SBA) Office of Hearings and Appeals (OHA) has ruled that once a company is owned more than 50% by venture capitalists, the employees of those venture capital companies and the employees of all of the other companies they have invested in count toward the 500 employee limit, effectively disenfranchising most biotechnology companies from the program, including a post-2006 Proteon. In my opinion, this will have a profoundly negative effect on the pace and quality of new technology development in the United States and will slow our economic growth. It will also slow the development of life saving medicines. As I sit here today, I have an idea for a new drug to treat aortic aneurysms, a life threatening condition where the main blood vessel coming from the heart bulges and is at risk for rupture, bleeding, and death. The problem is that Proteon's capital was raised to develop PRT-201, a necessary focus given that it may take an additional $50M or more to bring this drug to market. In prior years, I could have submitted an SBIR grant to start work on this new treatment and use the grant support to generate the data that could be used to get the project going internally. Today, however, this idea sits on the shelf, in limbo. Not moving forward, but not forgotten. Who knows if it will work? We will probably never know.

Sincerely,

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