

**PA House Policy Committee Statement**  
**Joe Camaratta**  
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**Co-Founder and President, BioSignal Analytics**

Good morning Chairman Benninghoff, Chairman Sturla, and members of the Republican and Democratic House Policy Committees.

My name is Joe Camaratta, and I'm a medical technology executive who focuses on taking new technologies from concept to clinical adoption. I've been in the industry for 30 years with multi-national companies such as GE Healthcare, Siemens Healthcare and Becton Dickinson, and appreciate the role that medical technology startups play in improving our healthcare system. My comments this morning are focused on commercialization of new medical technologies discovered in an academic environment. I'd like to introduce 2 early stage medical technology companies that I am managing, and present how we leveraged area resources to start the companies and get initial funding. And then I would share some of the challenges that we face bringing our first products to market and building sustainable companies.

Eight years ago, I volunteered to support the QED Program here at the Science Center as a business advisor and member of the selection committee. [The QED Program helps academic researchers identify and retire business risk in the earliest stages of new technology development.] The program exposed me to a rich set of innovative ideas and technologies being developed at local universities and academic medical centers. Philadelphia has a well-deserved strong reputation in the life sciences, and I was surprised to see the number of faculty devoted to developing medical technologies to diagnosis, treat and manage diseases. I am currently leading 2 startup companies focused on commercialization of technologies discovered at Philadelphia-based universities. Quantitative Radiology Solutions is leveraging a technology invented at the University of Pennsylvania to help physicians use medical images to make better treatment decisions. The company was founded through the Penn Center for Innovation's UPstart program that matches academic faculty with local entrepreneurs to commercialize Penn's research. Quantitative Radiology Solutions was formed in 2013, and I joined in January 2015 to identify potential applications for the technology and initiate fundraising activities. We targeted a first application to improve patient outcomes in radiation therapy and were recently awarded Small Business Technology Transfer (STTR) grants from both the National Science Foundation and National Cancer Institute. These grants allow us to lease space here at the Science Center and hire our first 2 employees.

The second company is called BioSignal Analytics and it is developing a technology that analyzes brain scans to predict seizures and alert clinical personnel that a patient needs attention. Temple University faculty applied speech recognition technology (the kind used, for example, by Siri in your iPhone) and applied it to recognition of abnormal events in brain scans. Support from the Science Center's QED Program allowed the faculty members to conduct initial experiments on data collected from Temple University Hospital and generate results that demonstrated the feasibility of the approach. They leveraged these initial results to obtain an I-Corps grant from the National Science Foundation that prepares scientists to identify product opportunities resulting from their research.

Based on the results from their I-Corps program, we formed BioSignal Analytics in June 2015 as part of the Science Center's Phase 1 Ventures program. That program provided us with both financial resources and expertise to create a new company and develop our STTR submissions. In June of this year, BioSignal Analytics was awarded an STTR grant from the National Science Foundation to help ICU physicians perform real-time seizure detection on patients with brain injuries, and we hired our first employee to work on that grant.

Both companies benefited from the resources in the Philadelphia' innovation ecosystem to help us jumpstart our operations. I already mentioned that BioSignal Analytics benefited from the QED and Phase 1 Ventures programs here at the Science Center to generate initial results, form the company and apply for federal development grants. The Commercialization Acceleration Program at Wharton Small Business Development Center conducted market research on the behalf of Quantitative Radiology Solutions to determine initial customer segments and market adoption criteria for our technology. This research proposed and tested potential business models and identified pitfalls of existing solutions. Quantitative Radiology Solutions used the results of this research to develop the commercial opportunity sections for our STTR grant submissions. Working with the Wharton Small Business Development Center provided us new insights into how commercialize our technology, and an objective assessment of the market potential for that solution.

The Small Business Technology Transfer (STTR) program helps bridge the gap between basic research performed in a university or academic medical center, and commercialization of the innovation. It encourages close collaboration between non-profit research institutes and for-profit small businesses to establish technical merit and commercial potential. However, a startup is not a small business. Startups do not have on-going operations to help fund commercial and business development activities. And, unfortunately, the SBIR and STTR programs do not allow use of their grants for such activities. Steve Blank is a serial entrepreneur and Silicon Valley investor who helped the federal government develop the I-Corps program in use by the National Science Foundation and National Institutes of Health. Steve describes a startup as a "temporary organization designed to search for a repeatable and scalable business model." Finding that business model is key to creating a company that can grow revenues, create jobs and support the area infrastructure. Finding that business model requires activities such as attending conferences and tradeshow to further understand the problem and existing solutions, developing relationships with additional clinical collaborators to review your approach and test your product, and promote awareness of your company to strategic partners who can provide further investment and commercialization support. Additionally, many medical technology companies must adhere to FDA regulations to promote and sell a product in the United States, which introduces additional development costs and postpones market introduction. For example, Quantitative Radiology Solutions is aiming to engage 3 – 4 additional academic medical centers to test a prototype of our radiation therapy planning software, and identify organizations that can accelerate our development activities. We are looking to engage consultants to develop a Quality Management Systems and a 510(k) submission as required by the FDA. While such activities are vital to the development of the business, and our ability to achieve additional federal funding, the STTR program does not support them. Their focus is more on developing a technology, than a business.

The state of Pennsylvania could support further development of startups to commercialize university-based medical technologies through enhanced funding for programs that improve success rates for Phase I and Phase II grants. The success rates for a Phase I grant from NSF and NIH are about 20% and

16% respectively. A university startup starts with an idea based on research results and needs to identify applications for that idea and what problems it could solve. Programs such as QED at the Science Center and the Commercialization Acceleration Program at Wharton Small Business Development Center provide resources that help startups demonstrate technical feasibility and assess commercial opportunity, strengthening their STTR submission and increasing their chance of success. These programs are extremely competitive and program administrators need to pick from scores of qualified applicants because of budget limitations. Every year promising technologies go unfunded, resulting in lost funding and jobs.

Additionally, state grants that match SBIR and STTR funds and support developing a sustainable business would improve a company's ability to secure Phase II funding. This funding could assist companies in developing strategic partnerships and a regulatory framework to accelerate development and commercialization of their products. For Quantitative Radiology Solutions, such funding would support our efforts to engage additional clinical collaborators and development partners who could us develop a platform to conduct a prospective study with those partners.

In the past year, Quantitative Radiology Solutions and BioSignal Analytics have been able to bring a combined \$850,000 of federal grant money to the Philadelphia area to further develop our technology. If we are successful, we can bring an additional \$1.75M in STTR grant money to the area in 2017. This would not have been possible without support of programs such as QED, UPstart and Commercialization Acceleration. We often use the word "ecosystem" when talking about innovation. Universities, academic medical centers, entrepreneurs, service firms providing legal and accounting advice, organizations such as University City Science Center and Pennsylvania Bio, and the federal and state government play an important role in connecting and funding that ecosystem. Thank you for coming to Philadelphia today to hear our stories, and thank you for your continued support of our ecosystem.

