



HEARING TESTIMONY

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ON BEHALF OF THE
BIOTECHNOLOGY INDUSTRY ORGANIZATION

BEFORE THE SENATE COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

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Good morning, Senator Cardin. Thank you for holding this hearing today in Rockville. I am Joe Hernandez, President and Chief Executive Officer of Innovative Biosensors, Inc also known as IBI. I am appearing before this Committee on behalf of the Biotechnology Industry Organization (BIO). BIO represents more than 1,200 companies, academic institutions, state biotechnology centers and related organizations in all 50 states.

I am the founder of IBI, a venture-backed, Rockville-based biotechnology company developing and commercializing a rapid pathogen detection technology originally developed with DARPA funding at the Massachusetts Institute of Technology. The CANARY technology, as we call it, was born out of a need to develop more sensitive and rapid detection systems for the identification of biological weapons. The technology is revolutionary because it leverages the machinery in nature to give us an ultra rapid, ultra sensitive detection technology. We use the best biosensors available, which happen to be cells of the immune system, and then genetically manipulate them into a jelly fish gene that makes the cells glow in the presence of a particular and predefined pathogen. This allows for ultra-sensitive tests in a matter of seconds. It's akin to a canary in a coal mine. This technology was published in the preeminent scientific journal, *Science*.

We have deployed the technology in building protection and today we are proud of the fact that our technology protects important buildings essential to the operation of our government. This is a big achievement for a company of 20 employees and it is primarily a byproduct of the hard-working patriotic employees we have working for us.

We are also developing the technology to be used in the rapid detection of hospital acquired infections such as MRSA and Staph, which has important clinical applications.

As we develop the next-generation of biosensors and treatments for diseases that would have been considered unapproachable just a decade ago, it is incumbent on our system to find ways to

support these risky but transformational discoveries that could improve the lives of children and adults suffering from genetic disorders, infectious diseases, cancer, and autoimmune diseases, among others. We want to take advantage of the ground-breaking scientific discoveries in basic research that have been achieved in the last decade at the NIH, in academic centers, and in industry and translate them into tangible treatments as rapidly as possible to improve the lives for patients. This has personal and economic benefits, both to the individuals affected, the organizations and companies working on these initiatives, and our society in general.

Small biotechnology companies have high and intense capital needs (over \$1 billion) and an unusually long development time of 5-12 years. The impact of the current economic crisis on small biotechnology companies has been and continues to be severe. According to the latest available data,:

- 16% of the 394 public U.S. biotech companies that were active at the beginning of 2008 ended the year either in bankruptcy, restructuring, or suspended operations, or were acquired.
- Since January 2008, over 125 biotech companies have laid off more than 10,000 employees to save cash and over 35 companies have shelved promising development programs with positive clinical data. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis and diabetes.
- 40% of the currently active 330 public U.S. biotechs have less than 1 year of cash
- 23% of the currently active 330 public U.S. biotechs have less than 6 months of cash.

The total capital raised by the biotech industry in 2008 has seen a steep decline, down 55 percent compared to 2007. A recent study by BIO and Thompson Reuters found that the current economic crisis has forced over 80% of biotech investors to change their investment approaches. They can no longer afford the high risk that is characteristic of investment in biotech. In just the last seven months, at least 40 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV, cervical cancer, Multiple Sclerosis and diabetes. The decline of the biotech industry jeopardizes not only America's patient population, but also America's competitive edge in the 21st century global economy.

While these projects tend to be high-risk, they are also high-reward, both economically and socially. The total employment impact of the biosciences sector is 7.5 million U.S. jobs, taking into account the direct and indirect jobs created in the economy. These are high-paying jobs that are on average 68% higher than the average private-sector job.

It is imperative that we find better ways to treat chronic diseases. A 2007 study by the Milken Institute found that the U.S. could save about \$900 billion in indirect costs (lost productivity) by 2023 by reducing the rate of chronic disease through improved prevention and disease management. Innovative treatments are an important component of reaching this goal. Currently there are more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDs and arthritis. The importance of fostering innovation by small U.S. biotechnology companies has never been clearer.

BIO has urged NIH to include small biotechnology companies in American Recovery and Reinvestment Act (ARRA) funded grant programs. It is important that there are ARRA funding opportunities for small companies that will assist them in continuing their research and development programs over the next two years while the economy recovers.

The vast majority of NIH grants have historically been targeted toward hypothesis-driven basic research, not the development-oriented endeavors small biotechnology companies pursue. Other than the very successful and vital NIH Small Business Innovation Research Program (SBIR), almost all NIH research funds are awarded to non-business entities. For example, in 2006, NIH awarded 54,773 extramural grants, of which 79% were awarded to higher education institutions, 8% to research institutions and 8% to independent hospitals. Outside of the SBIR/STTR grant program, businesses (of all sizes and fields) received a total of 0.04% of the 2006 awards. Unfortunately, even within the SBIR program there exist barriers to funding of biotechnology research, primarily due to the exclusion of small companies that are venture-backed. Hopefully Congress will fix this problem as a part of the SBIR reauthorization process and the funding level of the NIH SBIR program will become even more important for our industry going forward.

The ARRA does not require that 2.5% of the extramural research funds allocated to NIH be directed to the SBIR program, as would normally be the case under existing law. Rather, ARRA exempted NIH from this requirement, meaning that there are fewer dollars in the NIH SBIR program than would have otherwise been the case. However, it is my hope that NIH will recognize the importance of providing ARRA funded grant opportunities for small biotechnology companies, so that work on developing cutting-edge treatments and therapies that would be beneficial to the American public can continue. BIO has written to NIH urging them to do so, as I imagine have other groups and companies in the life sciences arena.

While NIH's primary role has been - and should continue to be - funding basic research, today's economic environment argues for a much more aggressive effort to sustain the small biomedical companies which will ultimately commercialize the scientific breakthroughs made at NIH and NIH-assisted research universities. Making these ARRA grant funds available to small biotechnology companies and having an expedited review process would enable these small companies to continue work on promising drug development programs beneficial to the public health. This would serve to meet two of NIH's stated missions: 1) To foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health; and 2) To expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research.

I commend NIH for including small businesses as eligible entities for the Challenge and GO grants. Preliminary information indicates that there were an overwhelming number of applications for both of these programs. I would especially like to commend NIH for creating the Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program and the Small Business Catalyst Awards for Accelerating Innovative Research Program (SBCA-AIR). These two small business-focused

competitive grant programs are exactly what is called for to ensure the continued development of next-generation discoveries, treatments and therapies.

We urge NIH to consider creating more small business competitive ARRA-funded grant programs. As long as the financial markets are frozen, it will remain difficult for small biotechnology companies to secure capital to fund high-risk, long-term projects. Access to NIH's ARRA-funded grant programs would provide substantial assistance to small biotechnology businesses' research and development program over the next two years while the economy recovers and the capital crunch eases, thus providing long term benefits to public health and ensuring that a whole generation of America's life sciences companies and their research is not lost. Furthermore, providing economic recovery funds to small biotechnology companies would help ensure that economic development associated with investments in biomedical research is maximized.

BIO is and will remain a strong supporter of NIH. As the nation's premier research agency for the study of human health conditions, diagnostics, and treatments, a properly-funded NIH is vital to the ability of small biotechnology companies to improve technology and develop innovative treatments and cures.

Thank you for the opportunity to testify.