

Written Testimony for
The U.S. House of Representatives
Committee on Small Business

**“Legislative Initiatives to Strengthen and
Modernize the SBIR and STTR Programs”**

June 17, 2009
10:00am
2360 Rayburn House Office Building

Derek K. Rapp
Chief Executive Officer
Divergence, Inc.
893 North Warson Road
Saint Louis, MO 63141
www.Divergence.com

Madam Chairwoman and Committee Members:

Thank you for the opportunity to appear before the House of Representatives Committee on Small Business and to offer my testimony to address the initiatives to strengthen and modernize the SBIR and STTR programs. My name is Derek Rapp, and I am the CEO of Divergence, Inc., a biotechnology research company located in St. Louis, Missouri.

I am a strong proponent of the continued awarding of SBIR grants. Such grants have made and continue to make a fantastic difference for Divergence.

First, I will provide a bit of background. Divergence has 27 full time employees who are focused on discovering safe and effective products for plant protection, animal health, and human health. Divergence's expertise lies in disciplines such as genomics, bioinformatics, parasitology, and nematology. Divergence has discovered both chemicals and plant genes that have the potential to be commercialized in various markets. Most of the products arising from Divergence's research are focused on the identification, treatment, and prevention of parasitic infections caused by roundworms (also known as nematodes).

Parasitic nematodes cost growers an estimated \$7-9 billion in the U.S. each year, as much as \$100 billion each year worldwide. These losses come in the form of reduced crop yields caused by the weakening of crops as a result of damage done to the plants by parasites. Parasitic nematodes are also a major problem for animals and humans causing significant morbidity.

Life sciences companies often have a much longer product development cycle than a typical small business, as they must conduct the initial discovery research, perform several years of product safety testing, and wait for a multi-year approval process in order to bring products to market. For example, many different sources estimate that the average time for a new drug to reach the market from the time of its discovery is between 10 and 15 years. As a small business focused on research and development in the life sciences, Divergence has a business plan that allows for funding of research during the significant amount of time it takes to get a product to market. Divergence funds operations through private investments, third party licensing and research agreements, and grant funding. Divergence relies on all of these funding sources to maintain operations.

Divergence began operations in late 1999 and has raised roughly \$21 million in equity financing during its nearly ten years in business. Investors include a group of sophisticated angel investors along with two venture capital funds. Corporate relationships for licensing and research have added more than \$7 million in revenue. The final source of funding for the Company has come through grants, totaling nearly \$7.6 million since inception. In addition to SBIR grants, Divergence has benefited from significant funding from the National Corn Growers Association.

The relationship that NCGA and Divergence have had for the past several years has been extremely positive, and, we hope, will lead to new yield-increasing technologies reaching the market for corn growers in the coming years.

A significant portion of grant funding to Divergence (approximately \$5.5 million) has come in the form of SBIR grants through the National Science Foundation, the National Institutes of Health and the United States Department of Agriculture. Divergence has applied for 48 SBIR grants in total, and 25 of these applications have been funded. Of these 25 funded applications, 15 were Phase I grants, 8 were Phase II grants, and two were follow-on grants (one NSF Phase IIB grant and one NIH Manufacturing Assistance Program grant).

Such funding does come at a cost however. Writing and submitting an SBIR grant is a time-consuming and expensive proposition for a company. We estimate that our team typically spends 120 to 150 hours writing and assembling an application. That time translates to more than \$10,000 in salary. In addition, the time it takes to work on the application takes our scientists away from the bench, slowing the progress they are making on their research. This represents a significant commitment of time for a small business, especially when applying for a Phase I grant that may result in an \$80,000 award from USDA or \$100,000 from NIH or NSF.

A life sciences company such as Divergence faces many challenges. First, we have to identify a significant need that can be addressed. Second, we must be innovative, identifying a solution that is feasible, novel, and superior to all others throughout the world. It may seem arrogant or presumptuous to demand of ourselves the development of the world's premier product, but this is the necessary mindset in our markets which are global and which allow for the flow of intellectual property rights through collaborations with parties worldwide. Once we have discovered a strong product candidate, there remains extensive product development work to do, as well as toxicology and environmental testing. These efforts require tens of millions of dollars and many years before commercialization.

A shareholder takes significant financial risks in investing in a privately-owned life sciences company. As discussed, the timeline for product development is quite long, the demands for capital are high, and science poses many challenges. This is significant since in the case of a privately-held company, a shareholder has little opportunity for liquidity of his or her investment. Hence, less than half of such companies succeed, at least to the point of delivering significant returns to their investors. Any activities that a company can take to increase its chances for success and decrease shareholder dilution will help a company attract the necessary capital to succeed. The SBIR grants do exactly that.

SBIR grants play other important roles for small companies in addition to improving opportunities for financing. They provide a validation of the science. The fact that the granting

process includes peer review as a component of the program is quite significant. Investors, potential employees, collaborators and others respect this rigorous review process.

SBIR grants also provide an incentive and a source of pride to scientific employees. The work in such companies is long, difficult, and often frustrating. For every positive result, there may be several negative ones. Word of receipt of a grant provides a “shot in the arm” for a team.

I hope I have made the case for why SBIR grants matter so much to companies and their investors. However, I recognize that for you to believe that these grants are worth funding, you also need to know that they benefit the public more broadly. Importantly, for the application processes in which Divergence has been involved, there have been several questions for the applicant to answer regarding the impact of the work. We are asked about market size, competitive alternatives, currently available products, and commercial plans. Hence, the reviewers should be able to determine whether the project has social worth and whether it will lead to a product that has a good chance of reaching the market.

Additionally, there is general benefit to our economy to see innovation. Innovation is essential for the world to tackle major problems. Innovation is also essential for the U.S. economy to remain competitive with other countries around the world in the area of life sciences. Agriculture, and human healthcare, and veterinary medicine are global markets, and due to their attractiveness and social importance, many countries place a high priority on research into these markets. Small companies are an important source of innovation, and SBIR grants can enable such innovation here in the U.S. There are certain reasons why, arguably, small companies are especially innovative. Small companies often have higher tolerances for risk than larger companies, and smaller companies are not saddled with institutional momentum around existing projects that compete with new projects for resources. Hence, small companies are often more able to respond to changes in the technological and commercial landscapes. Of course, large companies can be and are a source of innovation also.

It is a time of great excitement and also of great responsibility for those of us in life sciences. Agriculture is under tremendous pressure to achieve improved yields and ensure the availability of crops for uses in food, feed, fiber, and fuel. Close to one billion people in the world are malnourished. Arable land has been decreasing at an annual rate of .3%, and global population has been increasing at an annual rate of 1.2%. Hence, the world needs annual productivity increases of 1.5% simply to hold even, not to mention providing additional food to the malnourished people of the world. The situation actually becomes even more challenging when we consider the fact that demand for agricultural output is actually increasing at a faster rate than general population trends. This is true for two main reasons. First, dietary habits are changing in certain regions, primarily Asia, toward increased protein consumption. This change requires additional crops to be grown for the feeding of the animals that will be the source of the protein.

Additionally, society increasingly is utilizing agricultural output for non-food applications – e.g., fuels and fibers. For example, in the United States, roughly a third of corn production will be used for ethanol in 2009. In all, global demand for agricultural outputs (food, feed, fuel) will double between 2000 and 2050. More efficient and safe agriculture must therefore be a high priority for U.S and international interests, and control of pests, including nematodes, is an important part of the equation.

I would like to address some specific items envisioned in the various currently proposed pieces of legislation associated with SBIR grants.

Sections 3 and 4 of the “SBIR and STTR Enhancement Act” are focused on enhancing a company’s activities as it moves from Phase I to Phase II in the granting process. I applaud this move. If a project is sound enough to have received Phase I funding and leads to solid data for a Phase II application, it probably should be funded. A company that is failing at this step, for whatever reason, is missing out on a key opportunity; therefore, so too is our country, since this suggests that Phase I dollars did not lead to downstream projects. I would encourage the agencies to consider what are the most helpful ways to assist companies attempting to receive a Phase II grant. Merely generating some market research data and reviewing the business plan will not be sufficient in many cases, especially when the review work is done by someone who lacks expertise in the specific markets for which the funded project is targeted. Suggestions on how to advance the science and sophisticated, market-savvy assistance with the commercialization plan would be helpful. Doing this work in ways that are not overly burdensome on the recipient companies would also be appreciated, as the current processes demand a great deal of time and energy from the companies.

Section 12 of this act provides for an increase in the sizes of Phase I and Phase II awards. I recognize that there are trade-offs associated with larger awards – more grants funded versus more impactful grants. I am supportive of the proposed increase. The larger amounts would allow for more research to be completed in the Phase I stage, thus allowing for more thorough results and providing for a better supported Phase II application. The higher amounts for Phase II grants would also allow for significant progress to be made toward commercialization. Small businesses often do not have the funds to spend on the research and testing needed to bring a product to market; the larger grants would certainly help. In addition, small businesses typically apply some of their own funds towards a funded research product in order to complete the research as the Phase I or Phase II funds are often insufficient to cover the costs. The increased amounts would allow a small business to fund more fully the research with grant dollars so that they can then utilize their own funds for costs which are unallowable in a grant such as patent expenses.

Section 13 deals explicitly with the idea of a company being eligible for multiple Phase II grants simultaneously. If projects for SBIR funding are legitimately separate from one another, funding them both should certainly be deemed appropriate.

Section 3 of the “Investing in Tomorrow’s Technology” Act relaxes the limitations on grant eligibility regarding venture capital firm ownership. Admittedly, this constraint has not posed problems for Divergence as our ownership profile has always been somewhat skewed toward individual investors as opposed to firms. Still, I acknowledge that a company that has multiple venture capital firms owning stakes in it should qualify for SBIR grant funding in many cases, and venture capital firms will respond favorably to their companies’ receipt of grants, just as any investors would. In Divergence’s case, the receipt of grant funds helped us reach the point of receiving venture capital investment. The relationship between grant money and venture capital is an important one.

I would like to make one additional point. For all of the good that the SBIR program does, it is important that all of us remember one thing that the program does not do, at least not in many cases. It does not take many products to the point of commercialization. The time period from the end of Phase II funding ends until commercialization of a product is almost always long. In the case of the life sciences industries, it is likely to last several years. As Congress contemplates funding for SBIR’s, I hope that consideration will be given to helping companies bridge the large gap between discovery research and product commercialization. It is essential that the SBIR’s continue to receive funding, so I am not trying to shift the focus from SBIR’s. However, for the full impact of the program to be realized, there has to be sufficient support even after Phase II.

In summary, Divergence and many other small businesses are working hard to provide solutions to many of the challenges the United States faces today. As I have discussed, the work is difficult, and there are many obstacles that such companies need to overcome. Our scientists and our businesses need the support of the SBIR program and its program managers. We feel very strongly that the SBIR/STTR program provides an enormous value to small businesses, and thus, we enthusiastically support its extension.

Thank you for giving me the opportunity to convey this information and provide my views to this committee. Also, thank you for your efforts on behalf of a major piece of the American economy – small companies conducting innovative research toward the discovery and development of valuable, novel products.

Derek K. Rapp
Chief Executive Officer
Divergence, Inc