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Advanced Medical Technology Association

**HOUSE SMALL BUSINESS**

**SUBCOMMITTEE ON**

**INVESTIGATIONS AND OVERSIGHT**

**FEBRUARY 13, 2008**

**STATEMENT BY**

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**ON BEHALF OF**
**THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)**

We thank the Subcommittee for holding this important hearing today on the Small Business Innovation Research (SBIR) grant program and its role in advancing medical breakthroughs. My name is Jim Stefansic, co-founder and Chief Technology Officer for Pathfinder Therapeutics, Inc., a small medical device company located in Nashville, TN.

Pathfinder is a member of AdvaMed, the Advanced Medical Technology Association, which represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than $30 million per year. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the $86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of the public, in 2006 the industry employed 357,700 workers; paid $21.5 billion in salaries; and shipped $123 billion worth of products. Taking into account the national multiplier impacts, the industry created (direct plus indirect plus stimulated impacts): 1.96 million jobs; payrolls that totaled $93 billion; and $355 billion in shipments/sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Overview of Pathfinder Therapeutics, Inc.

Pathfinder Therapeutics, Inc. (PTI) is a surgical technology company that is focused on developing the world's first image-guided surgery systems for soft tissue applications. Image-guided surgery essentially describes the interactive use of images during a medical procedure and is often referred to as a "global positioning" system (GPS) for surgery. In an automobile GPS, the current position of a vehicle is accurately localized or "registered" onto an electronic roadmap located on the dashboard. As the automobile moves, its position is updated on this roadmap. The driver can use the GPS as a guide to determine where his or her vehicle has been and where it is headed. In image-guided surgery, the current surgical position is registered onto medical images that are used as a guide to conduct a therapeutic procedure.

PTI was incorporated in July 2004 through a partnership with Vanderbilt University, where the initial technology was developed by six current and former clinical and engineering faculty members, including myself. Note that the surgical guidance device was developed over a seven year period at Vanderbilt before the company was formed, so much of the technology risk associated with bringing a novel medical device to the market was eliminated. With support and

guidance from the technology transfer office at Vanderbilt, PTI was extremely fortunate to acquire a modest seed round investment to launch the company. Note that when PTI was formed, none of the founders had any small business experience. As I was the one founder finishing my part-time MBA at Belmont University and was inclined to work in industry, I left my position as a faculty member at Vanderbilt to run operations at the company. The other founders remained in their respective career academic positions.

In under four years, PTI has grown to eight employees and acquired $3.4MM in SBIR funds from the NIH / NCI. Our greatest achievement to date was being granted FDA clearance in late December, 2007 for our Linasys device, an image-guided liver surgical system that can be used to pinpoint and accurately resect or ablate tumors located deep within this organ. Given that tumor resection clearly provides the best chance of long-term survival for patients suffering from liver cancer, our device is of great benefit as it assists physicians performing these very difficult surgical procedures.

Although PTI has overcome much of the technology and regulatory risk associated with bringing a new medical device to market, many other challenges remain to ensure that our technology can improve the lives of those suffering from abdominal cancer. It is important to note that these risks would not have been conquered without both the SBIR grants and the modest seed round investment in PTI. Both of these funding sources are described in more detail below.

The Impact of SBIR for Pathfinder

Given that the expertise of the founders in successfully acquiring academic federal grant funding, we were encouraged by our seed round investors in the summer of 2004 to raise additional early-stage funds through the SBIR mechanism. With teamwork and considerable effort from all the founders, in early 2005 PTI was fortunate to land on our first attempt a fast-track SBIR grant from the National Cancer Institute (NCI) to develop a commercial software and hardware platform for a variety of image-guided therapeutic applications that target cancer. As the principal investigator on this grant, I have been able to focus part of my time and energy on taking the technology from the founders in the academic setting to commercialization without being concerned about salary support and other R&D resources for my engineering staff. The $1.5MM in grant funds have been primarily used to develop the SurgiSight image-guided therapy platform and will enable PTI to grow from one specific therapeutic area (liver surgery) to the broader field of surgical oncology (kidney and colorectal) to the broadest field of general surgery (vascular/soft tissue applications throughout the body). The key to unlocking this potential is the stability and versatility of our software platform and its ability to seamlessly interact with multiple hardware configurations. This versatility will enable Pathfinder to release products that are amenable to applications that employ either an open or minimally invasive surgical approach.

Although it took longer to acquire, PTI was fortunate in late 2006 to land a second fast-track SBIR grant from the NCI worth $1.9MM to conduct a 3-site clinical trial with our Linasys device and demonstrate its efficacy. To our knowledge, this will be the first formal clinical trial ever conducted by a company in the field of image-guided surgery. After considerable preparation, including the planning and actual replication of three Linasys systems, we are now set to launch the clinical trial at three premier cancer centers in the U.S. – Memorial Sloan Kettering, Univ. of Pittsburgh Medical Center, and Shands at the Univ. of Florida . The feedback we will acquire

from the thought-leader surgeons at these sites and data acquired will help us improve the quality of our device and successfully market our product for its now FDA-cleared indicated use.

The positive impact of the SBIR grants for PTI cannot be overstated. We would not have survived the critical and difficult stage of transferring the product from a research to a commercial environment without this funding. The costs can be staggering and are often not supported in full by early stage venture capital or angel funding because of the considerable technology risk and scientific unknowns.

To place their value in perspective, note that 7 of our 8 current employees are funded at least in part by the SBIR grants. Considerable R&D expenditures, in addition to some corporate overhead and other expenses, have been and continue to be covered with the direct, indirect, and profit components of this federal funding.

The Need for Venture Capital Funding

As stated previously, PTI secured an early stage seed round investment, which includes both angel and venture capital funding. Given the challenging environment for the acquisition of early stage funding for medical technology, this was a critical source of capital that PTI was fortunate to secure at the onset of incorporation.

Unless one has "been in the trenches" of a start-up medical device company, it is difficult to imagine all the time and financial resources that are required to initiate and maintain this type of business beyond product R&D. Note that many scientists who apply for and obtain NIH SBIR funding are starting their very first businesses. Although these individuals are intelligent and motivated, they usually do not have the experience or time to handle the "overhead" side of the business beyond R&D, including accounting, legal, quality/regulatory, and marketing & sales issues. They are so focused on handling the technology risk that all other risks are put on hold, sometimes indefinitely. To guarantee success, it is important for start-up medical device companies to consider these issues and more importantly their costs at the onset of launching their businesses. Unfortunately, most of their financial costs are not covered by SBIR grants.

With the help of our Board of Directors, PTI hired appropriate lawyers and accountants with experience launching and building medical device companies. This included lawyers skilled in the art of intellectual property prosecution. We also started a search for experienced management early in 2005. By January 2006, we hired our CEO & current President Paul MacDonald, a seasoned executive with industry-specific experience. We hired appropriate consultants to assist with regulatory issues related to FDA clearance. Finally, some limited resources were used to establish a FDA-compliant quality system.

As mentioned previously, the SBIR funding aids in reducing the technology risk associated with creating a sustainable medical device company. Unfortunately, there are many other types of risk that must be considered concurrently, including management (people) risk, regulatory risk, and market risk. Although Pathfinder only received a modest seed round investment from venture capital sources, we were at least able to consider these risks at the earliest stages of corporate development while taking advantage of the SBIR mechanism. This does not ensure that the

R&D efforts successfully executed with the SBIR money will lead to commercial and market success, but our chances are much greater.

The Impact of SBIR Eligibility Rules

A series of rulings from 2001 – 2003 by the Small Business Administration's Office of Hearings and Appeals resulted in the determination that small businesses that were majority-backed by venture capital investors were no longer eligible for SBIR grants. This interpretation of SBA regulations excludes many small medical technology companies from participating in the SBIR program – including many that have received SBIR grants in the past and are emblematic of the success of the program – even though these small businesses still have a tremendous need for assistance. It is at odds with the original intent of the SBIR program to assist small businesses with the enormous task of developing promising, early stage technologies so they can be brought to market for the benefit of patients. It also shrinks the competitive pool of SBIR applicants and hinders SBIR's goal of funding the most promising breakthroughs in medical technology to improve public health.

It is important to note that venture capitalists are becoming more and more risk averse. They are now investing in later stage companies in order to reduce their risk profile and put larger amounts of capital to work in companies that are already generating revenue or have completed human clinical trials. For Pathfinder, this trend has been very frustrating. Note that we have successfully navigated the technology and regulatory risks using a combination of both angel and institutional investors and SBIR funds, and even considered other risks as much as financially possible. However, in order to diversify appropriately, our current venture capital investors can only allocate a small portion of their funds to extremely high risk early stage medical device portfolio companies such as PTI. They are now looking for other venture capital firms to share in the risk moving forward and cannot fully support PTI's financial needs.

Unfortunately, new venture capital investors continue to wait on the sidelines for the risk to be even lower before they invest in PTI. For example, one key risk factor for these investors involves the size of the liver cancer market. Although liver cancer is one of a few cancers in the U.S. that is actually growing in rate and the NCI realizes that there is a need for new technology to combat this, the market is still very small compared to the large investor markets in orthopedics or cardiology. The investors are not convinced that their investment in PTI would provide an acceptable return given this market size. PTI has considered this and is prepared to launch the commercial liver surgery image-guided application first while continuing to focus on other higher volume image-guided surgical applications for colorectal or kidney cancer.

Of course, this strategy will still require additional R&D funding for both engineering and clinical costs. Because we continue to be provided with bridge financing by our seed round venture capital investors, PTI will very soon no longer be eligible for any additional SBIR funding given the change of our ownership structure. This is frustrating both to us and our seed round angel and venture capital investors who took a high amount of risk to bring our technology to its current stage and would appreciate future R&D funds to grow the company. PTI will continue to take advantage of current SBIR funding awarded to the company and work to lower the risk so new investors will consider our opportunity.

The Impact of New NIH & NCI SBIR Programs

Fortunately for SBIR companies, the NIH and NCI have recognized that companies need further resources beyond SBIR R&D funds to get their novel medical technologies to market. For example, PTI has recently benefited from the NIH SBIR Manufacturing Assistance Program (MAP). Assistance for developing a FDA and ISO quality facility at PTI will be provided by the Tennessee Manufacturing Extension Partnership (TMEP). In particular the Univ. of Tennessee Center for Industrial Services will provide PTI with 171 hours of consulting in the next 6 months that is paid for by the NIH. This assistance will not only ensure that we meet all necessary national and international regulations in the manufacturing of the Linasys device, but also improve the overall quality of our facility. Although this award is beneficial, it is very small compared to a Phase II SBIR grant and will not fill in all the gaps necessary to commercialize federally funded medical technology.

The NCI is also involved in new programs and is seeking to establish a financial bridge program to move SBIR companies through the "Valley of Death," or period in between the completion of significant technology milestones accomplished with SBIR funding and the FDA approval process. By providing funding beyond the end of the SBIR, the NCI seeks to share in the investment risk and incentivize venture capitalists to fund earlier stage projects. Note that Pathfinder has been able to somewhat navigate the "Valley of Death" through careful planning with venture capital support provided concurrently with the SBIR funding.

Legislation to Restore SBIR Eligibility for Small Businesses

These new programs at NIH are promising and will help assist small medical technology companies as they move from product development to commercialization. However, addressing the venture capital issue remains of utmost concern to Pathfinder and other small companies that rely on SBIR funding to develop new medical technologies for patients.

Mr. Chairman, we thank you for your leadership in the reauthorization of the SBIR program and for your strong support in restoring SBIR eligibility for small businesses like ours that also have venture capital investment. We also thank you, Congressman Graves, for your longstanding efforts and leadership to restore SBIR eligibility for the past several years. We also want to thank Chairwoman Velazquez for her leadership in moving SBIR reauthorization forward this year and for her support on the venture capital issue. And we also want to thank Congressman Chabot for his willingness to work with us to resolve this important issue. We look forward to working with all of you to ensure that small businesses will continue to drive medical innovation and develop promising new technologies for patients.

I want to thank the Subcommittee again for holding this important hearing. We look forward to working with you as SBIR reauthorization moves forward. I'll be happy to answer any questions you may have.