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IMPORTANT SOURCE OF MEDICAL TECHNOLOGY INNOVATION IS INCREASINGLY THREATENED

ONSET Ventures Partner Calls for Overhaul of Reimbursement Approvals Process

SANTA CLARA, CA - JUNE 9, 2004 - A key source of innovative and lifesaving medical treatments and technologies in recent decades has come from venture-capital-funded startup companies. And yet, a critical issue is increasingly threatening the health of this source, advised ONSET Ventures general partner Leslie Bottorff. At the heart of the issue, said Bottorff, is that FDA approval notwithstanding, new technologies or treatments are not fully commercially viable until the insurance carriers have agreed to reimburse patients and physicians for their use. And until patient reimbursement is approved, there is a high risk that the new technologies don't get prescribed or used enough for companies to generate sustainable revenues for the startup companies.

Speaking recently before a symposium of regulatory affairs executives from medical technology and biotech companies, Bottorff stated: "As you are well aware, private insurers and the federal government's Centers for Medicare & Medicaid Services (CMS) have continued to increase the hurdle for clinical efficacy proof, often to where it is now higher than the hurdle for proving a technology's safety and efficacy to the FDA. This is increasingly taking its toll on medical technology and biotech startup companies."

According to Bottorff, this "secondary" approvals process, which doesn't begin until *after* the FDA has approved a product for widespread, commercial use, generally adds years and many millions of dollars of expenditures by the startup company to an already protracted approval cycle. Typically, the company has to design and implement additional randomized clinical trials - beyond what the FDA requires - simply for the sake of the insurers. "Unlike the large, established companies that have the deep pockets and alternative sources of revenue to carry them through this period, the technology startup has limited capital and time to get to meaningful revenues," she said.

The consequences, said Bottorff, are twofold. "First, many startups underestimate the cost and duration of the secondary approvals process to the point where they run out of funds before receiving reimbursement approval. They have excellent clinical results during the FDA trials, but may never survive to convince the insurers," she reported. The result, she said, is that their innovative, new technology dies before it is born. "The years of work without either an emotional or a financial payoff are devastating to entrepreneurs like yourselves," she said, "and the rest of society is deprived of the potentially life-saving benefits of your innovations."

But it is the increasing risk to the investors that strikes a particular chord with Bottorff - herself a seasoned venture investor - and was a key point of her address. "The lack of predictability,

the time, and the extended costs lead to the second - and potentially more severe consequence of the reimbursement approvals process - a growing decrease in the willingness of the venture capital community to back this type of startup." Warned Bottorff, "If the reimbursement process is not improved and streamlined, then many great ideas with profound clinical benefits will simply not be funded in the future. The risks to the investor are simply too great."

Bottorff told her audience of regulatory affairs executives that their future lay in their own hands. "It is crucial that companies such as yours begin planning for this process even before they write their initial business plan. Achieving FDA approval is now only one step in a much longer process, and that thinking must be a part of every startup company's DNA." But more important, said Bottorff, is that each company acting individually, and the medical technology and biotech industry acting in concert, must aggressively work to restructure the entire process, such that reimbursement approval comes much earlier - perhaps even simultaneously with FDA approval.

"In your own company, you can start today to design clinical trials that will simultaneously produce the data needed for both the FDA and for the insurers. This will have a tremendous impact on reducing risk and uncertainty, and on speeding new therapies to physicians and their patients. But you also need to band together - through groups and industry associations - and become activists with the insurers." The industry has decades of experience in lobbying and working with the FDA to streamline their processes, maintained Bottorff, and it is now time to transform that experience and focus to the carriers.

"They know, as you do," she said, "that the reimbursement approvals process is currently chaos. It's time to implement long-lasting solutions, particularly solutions that consider the particular reimbursement approval needs of technology startups, and can accommodate their unique timing issues.

"This is a great challenge," she concluded, "but one that is absolutely necessary to for the health and survival of the innovative startup"

Bottorff was speaking to the Regulatory Affairs Society's West Coast Symposium, in Santa Clara, CA. She and her colleagues at ONSET Ventures have invested often in medical technology startups. Some of their most notable successes include Inhale Therapeutics (now NEKTAR), Conceptus, Spinal Concepts, and Embolic Protection, Inc.

About Onset Ventures

ONSET Ventures specializes in providing an ideal mix of start-up, follow-on, and intellectual capital to entrepreneurs and early-stage technology ventures, to help transform world-class ideas into sustainable and valuable businesses. The firm has backed nearly 100 companies since 1984 and now has more than \$500 million under management.

ONSET pioneered, and has refined over 20 years, a highly-optimized tool set for risk and capital management, and a *shirt-sleeves style* of active collaboration with entrepreneurs that leverages the firm's substantial operating experience. That collaboration frequently begins before the closing of any financing, and typically continues throughout the life of the venture. The combined process, which has become the hallmark of the firm, has resulted in ventures that have consistently met their operational

and financing milestones. In addition, it has resulted in a franchise that not only brings successful, serial entrepreneurs back to ONSET Ventures time and again, but also attracts investors who want the increasingly rare opportunity to participate in very early stage venture investing.

ONSET Ventures focuses exclusively on information and medical technology-based start-ups, and has a long history of successful ventures in each of these sectors.

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Additional background information is available at www.roeder-johnson.com.