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NEW MEDICARE, MEDICAID REIMBURSEMENT RULES PUT INCREASED PRESSURE ON VC-FUNDED MEDICAL START-UP COMPANIES

Innovative Products or Treatments Not Already Reimbursable Under New, Tighter CMS Rules Must Show Compelling Clinical Benefit, Tangible Cost Reduction, says ONSET's Kuhling

MENLO PARK CA, AUGUST 29, 2006 - The recent release by the Centers for Medicare and Medicaid Services (CMS) of its final FY07 rule substantially revising the Inpatient Prospective Payment System (IPPS) underscores the need for start-up medical companies - and the investors who underwrite them - to plan very carefully what markets and treatments they choose to invest in, says leading venture capital firm ONSET Ventures. Otherwise, they may face ending up with a product that is not reimbursable under the rules.

"The final 2007 CMS rule covering Medicare/Medicaid reimbursement for inpatient medical expenses, while a softer blow than some had expected, is a harbinger of increasingly tight reimbursement policies, particularly for new and innovative treatments," says ONSET partner Rob Kuhling. This means, he says, that start-up companies targeting medical devices and treatments must meet a higher standard than ever before, to ensure they can be funded, sell their products and survive. "Either the company needs to be sure that its category is already approved for reimbursement," says Kuhling, "or the breakthrough represented by the start-up must offer such compelling clinical benefits and cost reduction that the reimbursement process will be as smooth as possible."

Kuhling and his partners, who have invested in over 35 healthcare-oriented companies since ONSET's first fund, have been critically following the reimbursement issues for a number of years, and encourage other investors to do the same. "With the total cost of medical care under such scrutiny today, venture capitalists need to be very focused on whether a company under consideration will, in fact, actually be able to be paid for its developments when they finally come to market."

As Important as the FDA

According to Kuhling, the CMS now makes most of the earliest and most fundamental decisions about treatment reimbursement and often these decisions serve as guidelines for private insurers as well. Therefore, being on the right side of a CMS decision is key for a startup. Unfortunately, he says, predicting their decisions is extremely difficult, and adds a growing level of uncertainty for entrepreneurs and investors. "While the FDA [Food and Drug Administration] issues *medical* approvals based on demonstrable scientific and clinical facts, the CMS makes *business* decisions based upon quite complex, often political, and frequently irreconcilable issues. Developing a strategy to deal with this while a company is in its earliest stages is now as important as planning for the FDA trials," he says.

Because of this environment, ONSET provides the following guidance to its own portfolio companies and would-be portfolio companies:

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- Begin planning the reimbursement strategy at the earliest stages of company formation; it should be a fundamental part of the business plan.
- Consider the data requirements for supporting a reimbursement submission when formulating clinical trials. The data to support reimbursement may be significantly different than the clinical data.
- Seek out experts in reimbursement strategy; in addition to reimbursement being extremely complex, rules and winning strategies change frequently, making it essential to work with those who stay abreast of best practices.
- Focus on the economics of a procedure, not just its clinical outcome.

Reimbursement challenges notwithstanding, Kuhling and his partners remain bullish about medical start-ups. “There are considerable opportunities for new developments in established reimbursement areas, as well as novel areas where new reimbursement codes will have to be added by the CMS,” says Kuhling, “and we continue to invest in both types.” One such investment, Access Closure, has a novel vascular closure device that enjoys a mature reimbursement climate. Another, Neuronetics, treats drug refractory clinical depression with a non-invasive outpatient therapy. “Although new reimbursement codes will be needed for Neuronetics,” he comments, “the undeniable clinical benefit and cost reductions offered by their technology should expedite the process.”

Of ONSET’s more than thirty-five health-care investments over the years, five have been added just in the past six months.

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 over 100 companies since 1984 and now has more than \$700 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.