The recent decline of venture financing is threatening innovation in the $300 billion global market for medical devices. Venture-backed start-up companies are a vital innovation engine for the medical device industry, creating disruptive products, opening new markets, and fueling growth for large companies via acquisition. However, regulatory and reimbursement pressures continue to tighten, and there is increased scrutiny on the economic value of new devices. Facing less working capital, companies will need to adapt their business and product development strategies to deliver healthcare value.

In the United States, venture financing reached record volume in 2007 and 2008, with $3.7 and $3.6 billion respectively, for medical device technology. However, with financial markets crashing in late 2008, VC funding dropped over 25% to $2.6 billion in 2009 and declined further to $2.4 billion in 2010. In Europe, venture financing suffered similarly, with approximately €700 million raised in 2007, only to drop nearly 30% to €500 million in 2008 and 2009. Remaining funding was largely directed at reinvestment for late-stage ventures, rather than new investment in early stage companies. IPOs were virtually non-existent for the past three years compared to previous years. Within US public companies, R&D expenditure increased slightly, but there was a decrease in 510(k) and PMA submissions for regulatory approval. Using these metrics, the medical device industry has seemingly become less capital-efficient in innovation.

While the traditional funding model is not quite broken, the pendulum has clearly shifted from the risk-takers to the risk-averse. But despite challenging financial times, there remains sizeable opportunity in the medium and long term for the ‘risk-savvy’. There are several strategies that companies can deploy to create innovative products that deliver healthcare value:

**PROACTIVE RISK MANAGEMENT**

The medical device industry has long focused on clinical, quality, and safety risk management, an inherent necessity when developing healthcare technology for patients. However, program risk management, when utilized appropriately, can transform the capital efficiency of product development.

Program risk management should be practiced early and often in new product development. An objective program assessment can help identify key commercial, clinical, program, and technical risks that may affect resourcing, budget, and schedule. Understanding risk enables development programs to be structured to mitigate the highest risks early, lest they manifest later with higher cost and longer schedule delays. Risk management also facilitates strategic decisions involving invest or kill decisions for portfolio management, improving capital efficiency. Companies that utilize a risk-based approach to product development are more likely to get to market faster, with less development cost, and with improved product quality.
DIVERSIFICATION

Large companies can manage investment risk by leveraging their size and relative stability to diversify their core offerings. Companies that can integrate their products with new services, knowledge bases, and infrastructure, will enable entire healthcare networks to be connected seamlessly. Complication rates can be reduced, patient throughput can be increased, and outcomes can be tracked more efficiently. Central to communicating, securing, organizing, and analyzing the terabytes of data will be wireless technology, decision-making algorithms, and intelligent design of user interfaces.

Global diversification also provides ample opportunity to spur innovation and growth. Healthcare for the “next billion” is a largely untapped market, but presents tremendous challenges on multiple fronts. In various emerging markets, regulatory oversight is weak, payment structure is often nascent, and IP protection concerns still remain. Average device cost must be reduced dramatically to be palatable.

PARTNERING

Medical device companies will increasingly rely on partners within the industry to foster innovation. At the highest level, a confluence of surgical, pharmaceutical, biotech and diagnostic industries is occurring. The integration of these technologies will enable better clinical outcomes with lower risk, but will require successful collaboration with partners. Companies that form lasting partnerships within and across industries will more likely develop innovative products that create healthcare value. Additionally, there can be advantages in partnering with external firms to accelerate product development innovation and lifecycles.

STREAMLINING RESEARCH AND DEVELOPMENT

With smaller budgets and greater market pressures, both large and small companies cannot risk taking on inefficient development programs. Establishing a robust yet streamlined approach to product development is central to maximizing innovation with limited capital. Clinical, commercial, and program goals must be well-defined prior to embarking on a development program. Product requirements need to be defined early in the process, including clinical and technical specifications and also user and commercial requirements.

The industry’s innovation engine needs reigniting. Clinicians traditionally catalyzed product ideas, with companies applying resources to transform the idea into a product. With changing market demands, this model of innovation needs refinement. Companies that can facilitate structured creativity sessions with key process stakeholders will more likely ensure end clinical, commercial and user needs are met. Throughout product development, creativity sessions should include staff from multiple functions, such as engineering, marketing, sales, regulatory, clinical, manufacturing and procurement departments. Equally important is innovating within the right bounds – ideas are of little value if they cannot achieve performance within pre-defined requirements.

REDEFINING INNOVATION

Innovation in the medical device industry will no longer be measured only by PMA and 510(k) submissions, IPOs, or revenue growth, but also by a measure of the value provided to the healthcare ecosystem. Defining and measuring healthcare value is a complex undertaking - the definition of healthcare value will differ based on stakeholder perspective. Patients, clinicians, device manufacturers, insurance companies, providers, hospitals, regulatory bodies and even local and national governments all play a role in the healthcare ecosystem. Large companies could re invent themselves as champions of healthcare value by proactively designing medical devices that aim to improve overall economic cost in conjunction with clinical outcomes. Additionally, the industry as a whole will need to collaborate in discussing, formalizing, and delivering healthcare value that meets the needs of stakeholders.

The rationalization of working capital is not necessarily bad for the medical device industry – it will catalyze a focus on delivering better healthcare value. Market pressures will drive companies to develop devices that have better outcomes, lower patient risk, get to market faster, and impose lower cost burdens on the healthcare ecosystem. Innovation will no longer hinge on developing new technology, but also on new product development strategies, new business models and rethinking healthcare economics. Risk-savvy companies will outpace the risk-averse, and will be better positioned to innovate in challenging financial times.

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