

Hope on the Horizon

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Is it possible to be a startup in today's marketplace or add value to a company while the market's down? Faced with investors still shell-shocked from failed clinical trials, the reality of long-term cash burn, and rampant speculation about the impact of healthcare reform, several biotech stock portfolios are at their lowest point in two years. Except for the embrace of generous corporate collaborators, a company's chances of getting the gleam back into investor's eyes is next to nil. Or is it? The trick is to creatively leverage the technology and resources presently available.

A starting point is the creative sourcing of funds and technological endorsements. Willing to take a chance in return for a future job and tax base, states and localities have been quietly promoting the traditionally private-sector business of risk capital. Programs offering seed capital—which brings high-risk innovation to the first stages of marketability—and further rounds of investment by “public” venture capital funds set the stage for a snowball effect of investor interest. Several states and cities invest public pension fund monies into venture funds, or in another trend, give huge capital tax breaks to R&D investors. One New York state venture capital program is the Corporation for Innovation and Development (CID). CID is funded directly by the state government and offers investments ranging from \$50,000 to \$250,000. Its success in the state is apparent, having been critical to the growth of Regeneron (Tarrytown, NY) and Progenics (Tarrytown, NY). The fact that Progenics—a spin-off from Columbia University (New York, NY)—obtained an endorsement from the state has apparently helped attract other private investors, allowing the company to remain privately owned even now as it begins clinical trials. The trick? CID uses the same kind of selection criteria that private investors use, and is highly selective in its investments, making its endorsement a credible stamp of approval.

The flip side of this is, of course, the need for the state and federal government to continue to innovate. Creating a sort of Federal Reserve Fund guarantee to cover investments in selected technologies could create a beachhead for initial investors. Alternatively, tax breaks encouraging companies to spin off a single technology as a separate stock-issuing company would allow investors more freedom to invest in particular technologies, rather than whole companies. On the federal level, new rules issued by the Small Business Administration (SBA, Washington, D.C.) in April 8, 1994 allow small business

investment corporations to apply state or local government money toward the amount that the SBA will match with federal funding. Using the new rules, New York City will give birth to a \$100 million venture fund dedicated to high-tech economic growth within the city's five boroughs. Certainly other cities could be encouraged to follow suit.

Companies today must also confront the question of clinical trials. Investors—and now regulators—demand clearer endpoints and better diagnostics during preclinical assessments. New methods for isolating chiral isomers in racemic drugs will lead to improved efficacy and fewer side effects. Also, with the advent of genomics, clinical trials can and must be refined as researchers isolate the specific genetic sequences linked to disease. Competitors racing to develop therapeutics for type II diabetes, for example, will soon be able to subdivide and classify this one disease into four or more new diseases according to the particular mutations linked to them.

Future clinical trials testing new drugs promise a higher degree of selectivity by including only those people with the specific genetic polymorphism for which a drug is targeted. Past clinical trials, some of which may have failed simply for lack of a precise disease definition, will no doubt be resurrected. Collaborative ties with a genomics company will probably prove to be a necessity. Hoffman-LaRoche's (Nutley, NJ) whopping \$70 million-plus collaboration with privately held Millennium Pharmaceuticals (Cambridge, MA) is indicative of this trend.

Another important consideration is the future of intellectual property rights and the creative, cross-disciplinary use of new laws. One to watch is the Biotechnology Patent Protection Act. Designed to correct for the Patent & Trademark Office's *In re Durden* (763 F2d 1406) decision, the act will not only offer protection to novel and unobvious biotech inventions made using a known process with a novel starting material, but will (unintentionally) also be quite applicable for use in patenting bioinformatics—the computerized information management systems designed to make the results of high-throughput DNA sequencing accessible and useful. With the majority of these systems based on neural networks, conventional computer patents offer only partial protection. However, the act is suitable for patenting a neural net's starting material:(public or novel) training sets of data; its unpatentable algorithmic process; and its novel product—the trained net.

The present slump in the industry should be looked upon as an opportunity to shore up the strengths a company already has. Adding value now, however incremental, will serve you well when the market rebounds. ///