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Medical Start-Ups Challenged by Health-Care Reform

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Brian L. Frank for The Wall Street Journal

NeuroPace's Frank Fischer, above, is concerned about a new medical-device tax. His company makes a device to detect abnormal brain activity.

Medical entrepreneurs who have survived the downturn now face a new challenge: expanding their business amid the uncertainty created by health-care reform.

Investment in medical start-ups has dwindled of late as companies have struggled to go public and deliver returns to venture capitalists. The Affordable Care Act, the health-care reform bill signed into law in 2010, would seem to be the salve these companies need. Starting in 2014, most Americans will have to carry health insurance or pay a penalty. This promises to create millions of new, paying customers for medical companies.

But other provisions worry entrepreneurs. A 2.3% excise tax will kick in on medical-device sales next year, with no exception for loss-making companies. This will make it harder for start-ups to raise capital to launch and expand, say some observers.

Compounding the problem is the uncertainty of the law's fate given the upcoming election. Mitt Romney has promised to repeal the health-care law, should he be elected, but his ability to do so would also depend on the parties controlling the Senate and the House.

One executive who is concerned about the impact of the tax on his company's ability to raise capital is Frank Fischer, chief executive of NeuroPace Inc., a firm seeking U.S. regulatory approval for an implantable device that detects abnormal brain activity that could result in a seizure. The device can then send electrical stimulation to a targeted area of the brain to prevent the seizure from happening.

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An implantable device for treating neurological disorders, like epilepsy, is made by NeuroPace.

NeuroPace took the No. 1 spot on The Wall Street Journal's 2012 Next Big Thing ranking of the top 10 venture-backed health-care start-ups, released Thursday, and was No. 8 in the broader top 50 start-up ranking, released in September. Both rankings are based on fundraising success, recent growth in the company's value and the track record of its founders and board members, and an editorial review by reporters and editors at Dow Jones VentureWire, a unit of Dow Jones & Co. Unlike The Wall Street Journal's recently released ranking of the top 50 venture-backed companies, however, the firms on the top-10 list are compared only against other companies in the health-care sector, to identify the sector's most promising players.

The Mountain View, Calif., company hopes to get FDA approval by mid-2013. In the meantime, the company just leased a new facility where it plans to manufacture the devices. Health-care reform could hurt the company, Mr. Fischer acknowledges, because the device tax may damp financial projections, potentially making the firm less attractive to investors at a time when it will need more financing to launch manufacturing operations and establish a sales and marketing team. "If we were trying to start the company today, I don't believe we'd be able to fund it," he said. "[With] the length of time the regulatory process has been taking over [the] last several years, and this additional issue of the tax on top of that, I believe many companies—if they weren't in the later stages of approval—wouldn't get the funding to get there."

Wall Street Journal reveals its third annual ranking of the top 50 start-ups in the U.S. backed by venture capitalists.

The tax is also forcing start-ups with marketed products to make difficult choices. Entellus Medical Inc., whose devices enable minimally invasive treatment of sinusitis, or inflammation of the tissue lining the sinuses, will consider various measures to offset the new expense, such as raising prices, making fewer new hires, or investing less in research and development, said CEO Brian Farley. The Plymouth, Minn., company has less than $30 million in revenue and isn't profitable yet, he said.

Start-ups already face a difficult climb, given that they often need 10 years and $100 million to develop and launch a medical device, said Mr. Farley, whose company has raised $92 million in venture capital since forming in 2006.

Another device maker, spinal-products company Spine Wave Inc., had expected to reach cash-flow breakeven next year but won't be able to now because of the tax, said Chief Financial Officer Terry Brennan. The Shelton, Conn., company, which has 110 employees, will continue to hire but not at the same rate that it otherwise would, he said. "We're a growth company, but we're not going to be able to continue to grow and invest the way we used to," Mr. Brennan said.

Of course, the excise tax in particular isn't a concern for all start-ups, only those in devices. Biotech start-ups aren't affected by it, for instance.

Investors say another worry is that insurers will clamp down on prices as the use of medical products expands along with the growth of the insured population. The mere possibility of pricing pressure is already driving some public-market investors away from health care and making it harder for young companies to go public, said James Thomas, a partner of Thomas McNerney & Partners. "The No. 1 impact so far has been fear and uncertainty in the capital markets," Mr. Thomas said. "That's bad across the board."

Some companies aim to improve their chances of passing muster with insurers by emphasizing their product's potential to lower costs. A drug that Acceleron Pharma Inc., is developing with partner Celgene Corp., CELG -1.87%for example, could help certain anemia patients and reduce the need for other therapies, according to the company, which took No. 6 on The Journal's top 10 list of venture-backed health-care start-ups.

Acceleron's Sotatercept works differently from an existing treatment, erythropoietin, and may help people with anemia that's not well managed today. Blood transfusions these patients now require are inconvenient and can lead to a buildup of iron that necessitates iron-removing therapy, said Chief Business Officer Steven Ertel. Since Sotatercept could reduce the reliance on transfusions and iron removal, Acceleron believes the drug will be well received in an increasingly cost-conscious market, according to Mr. Ertel.

In some cases, venture capitalists and entrepreneurs are also pursuing new opportunities that play to specific aspects of the Affordable Care Act. San Francisco-based Castlight Health Inc., No. 4 on The Journal's list, raised a $100 million funding round in May. It enables employees with employer-sponsored medical plans to gain access to information about cost and quality to help them make informed health-care decisions. Its comparison-shopping tool, available online and as a mobile application, offers individualized information for each employee about out-of-pocket health-care costs.

Though its core customers are corporations that offer the comparison technology to employees, Castlight says it is also evaluating how its tools can address the market of the millions of people who will join the insurance rolls and will need help making decisions.

Venture firm Polaris Venture Partners is investing in a wider range of medical companies as it searches for opportunities in the new health-care landscape. The firm is making a few more investments in health-care services, said General Partner Terry McGuire, backing start-ups such as Ella Health Inc., a provider of breast-cancer screening services that could benefit from aspects of the reform law encouraging the use of preventive health care. "We've become more diversified in our life-science investing than ever," Mr. McGuire said.

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