SA biotech encounters more regulatory hurdles to U.S. market than in Europe

Having commercial success with its initial medical device in Europe, Bluegrass Vascular Technologies Inc. has had a far tougher time clearing the regulatory hurdles impeding its entry to the U.S. market.

San Antonio-based Bluegrass Vascular — seeking the U.S. Food and Drug Administration's approval to market its Surfacer System device, intended to facilitate greater central venous access — has had to adjust to the FDA's changing stance on what kind of product the company has.

Initially, the FDA deemed the Surfacer System a class II, or medium risk, device, which Bluegrass Vascular CEO Gabriele Niederauer said typically requires a company to demonstrate to the regulatory agency that its device is safe, effective and substantially equivalent to a "legally marketed device." However, after Bluegrass Vascular filed its appropriate application, the FDA changed its determination, saying the Surfacer System was not substantially equivalent to an approved device. So the company has had to switch gears and pursue U.S. commercialization through a de novo classification for novel devices.

"We essentially have to provide assurance [in the U.S.] of safety and effectiveness," Niederauer said, despite the fact that Bluegrass Vascular's product has been working safely for European patients. She said the company has compiled more than 200 reported cases substantiating its device's success in Europe.

"We've been on the market in Europe for almost three years, and we are getting great results there," she said. "In the U.S., it's taking much longer."

The company — which launched in 2011 and moved here in 2014 from Lexington, Kentucky — is not alone. Critics say roadblocks to commercialization in this country are stifling medical advancements and unnecessarily putting more people at risk as bioscience companies wait to get novel technologies to patients and providers.

Meanwhile, once the FDA approves the de novo classification for Bluegrass Vascular, it will smooth a regulatory path for others who follow.

FDA officials wouldn't say much about Bluegrass Vascular's situation, noting that the agency is limited in what it can share regarding companies and products awaiting approval.

The good news for Bluegrass Vascular is that it has been frugal with its resources during its long march to market. The company secured $5 million from Merit Medical Systems Inc. [Nasdaq: MMSI], which confirmed in December 2016 its investment in a Series B fundraising. For now, Niederauer said there is no need for another funding round.
“We have probably spent half of what other companies spend to get their product to where we are,” she said.

At the same time, other potential funders are noticing Bluegrass Vascular’s success outside the U.S.

“We have investors who continue to be very interested in us,” Niederauer said.

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