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# On-Q-ity Winds Down, But Other Circulating Tumor Cell Startups Push Ahead

*Brian Gormley* | *March 27, 2013*



Several venture-backed startups aim to convince oncologists that analyzing rare tumor cells in the bloodstream will help them identify the best treatment for specific cancers.

Cancers can spread when tumor cells dislodge and enter the blood. Through tools to capture and study these circulating tumor cells, or CTCs, companies aim to help physicians predict cancer's course and select treatments.

The push is part of a broader effort to use the growing understanding of tumor biology to personalize cancer medicine. Harnessing these findings, drug and diagnostics companies are introducing a widening array of tests and treatment options.

Amid this crush of information, developers of new, personalized-medicine diagnostics often struggle to drive their products into clinical practice and to secure widespread insurance coverage for them. One circulating tumor-cell startup, On-Q-ity Inc., is winding down, VentureWire has learned. The field's pioneering company, Immunicon Corp., filed for bankruptcy in 2008.

Many young companies are pushing ahead with strategies to overcome these problems, including venture-funded Epic Sciences Inc ., Fluxion Biosciences Inc. and ApoCell Inc. They aim to challenge Johnson & Johnson subsidiary Veridex LLC , whose CellSearch system is the only test cleared for clinical use. Some doctors use CellSearch to monitor patients with metastatic breast, prostate and colorectal cancer.

CellSearch remains the gold standard, and some doctors say it gives them an early view into how well a patient is responding to treatment. When CTC counts rise in spite of therapy, it's a sign the treatment isn't successful, said Howard Scher, chief of the genitourinary oncology service at the Sidney Kimmel Center for Prostate and Urologic Cancers.

In recent years several startups have sprung up to advance new ways to capture CTCs, which number one in every billion blood cells. On-Q-ity was one of them.

The company, formed through the merger of Cellective Dx Corp. and DNA Repair Co., raised a $21 million Series A financing in 2009 led by Mohr Davidow Ventures. While CellSearch relies heavily on a tumor marker called EpCAM, On-Q-ity 's technology enabled it to collect cells based on their size as well as the presence of various markers of interest, such as EpCAM. This enabled it to capture CTCs that might otherwise be missed, according to Walter Carney, its former chief scientific officer and acting president.

Settling on a business strategy proved difficult. Dr. Carney said he preferred to develop research and diagnostic instruments, but readying the technology for sale would have required an additional $10 million to $15 million, he said. Investors weren't keen to put that much more into a company that didn't have a product.

It decided instead to develop its own diagnostics with help from a partner or acquirer. To execute this plan it named former GlaxoSmithKline PLC executive Michael Stocum as its chief executive in November 2011. He initiated an investment-banking process and raised $5 million from Mohr Davidow, Atlas Venture and Physic Ventures .

Several parties expressed interest in On-Q-ity , which had begun studies in diseases such as metastatic prostate and head-and-neck cancer, Mr. Stocum said. Multiple concerns held up a deal.

On-Q-ity planned to sell laboratory-diagnostic services. Tests sold as a lab service don't need Food and Drug Administration approval today, but some worried that they might be regulated more extensively in the future. Reimbursement was also a concern. To win over insurers, diagnostics must be shown to have clinical utility, or the ability to help physicians make decisions that improve outcomes.

Corporations were wary of investing before the value of On-Q-ity 's approach was clearer. With the uncertainties "it becomes a decision any acquirer or partner is going to take significant time to think through," Mr. Stocum said.

Time ran out late last year. Employees of the Waltham, Mass., company learned of the board's decision to wind the business down shortly after Thanksgiving, Mr. Stocum said.

If On-Q-ity had launched its tests, it would have had to fight for attention at a time when research advances are rapidly adding to the body knowledge for oncologists to digest. CellSearch earned its first regulatory clearance, for metastatic breast cancer, in 2004. Yet many doctors aren't well-versed in CTC testing, said Nancy Dawson, a professor of medicine at Georgetown Lombardi Comprehensive Cancer Center.

"The biggest issue is the lack of awareness among oncologists. There's strong data to support their use, but many physicians are not aware of their utility from a prognostic standpoint as well as an indicator of disease response," Dr. Dawson said. "The information highway is so packed right now, sometimes it's hard to keep up with everything that's going on."

Young companies are devising plans to impress regulators, insurers and clinicians. Epic Sciences, which raised $13 million in October from Domain Associates and the venture arms of Pfizer Inc . and Roche Holding Ltd ., is developing companion diagnostics, or tests that identify the right patient for a new drug. Since a companion test rides along with the therapeutic as it moves through clinical trials and FDA approval, insurers usually see the diagnostic as medically necessary. And since the drug and diagnostic are meant to be used together, there's less concern about adoption.

"In the diagnostics space, [it's] always been a challenge to get payers to immediately come on board," said David Nelson, Epic's CEO. "The one exception is in the case of companion diagnostics. The reimbursement is much more rapid, market penetration is much more quick than a conventional independent diagnostic test."

Epic, of La Jolla, Calif., is executing its plan through deals with companies such as Celgene Corp . ApoCell , meanwhile, uses its CTC technology to help drug-makers determine if their medicines are working as expected and to look for molecular markers that predict how patients will respond to a therapy and whether resistance will develop, said CEO Darren Davis .

The Houston company, whose investors include Summit Partners , also is readying an instrument that it plans to introduce as a research tool next year. In 2016, ApoCell expects to launch this instrument as a diagnostic. Labs could then use the technology to capture CTCs that could be analyzed to help physicians to select a therapy based on the tumor's molecular profile, according to Dr. Davis.

Like **ApoCell** , **Fluxion Biosciences** , of South San Francisco, Calif., has chosen to be an instrument seller. Its cell-capturing technology is designed to sit at the front end of research and diagnostic applications, recovering enough CTCs to enable the types of downstream analysis that the lab wants to perform, according to Program Director Michael Schwartz .

http://www.on-q-ity.com

http://www.fluxionbio.com

http://www.epicsciences.com

http://www.apocell.com

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