



Diagnostic Testing & Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Foundation Medicine Preparing for Launch of Next-Generation Cancer Test



Michael Pellini,
M.D., CEO,
Foundation
Medicine

Foundation Medicine (Cambridge, Mass.) is closing the year with huge success. The creator of a next-generation sequencing-based diagnostic test recently announced that it closed an expanded first round of financing totaling \$33.5 million. The company is using information garnered from its clinical trials and collaborations with four pharmaceutical companies to ready itself for its mid-2012 national launch of its comprehensive, pan-cancer diagnostic test. The lab-developed test (LDT) will aid oncologists in directing treatment decisions in newly diagnosed patients based on the analysis of more than 200 cancer-related genes. Foundation Medicine CEO Michael Pellini, M.D., who joined the company in May 2011, recently spoke with *DTTR* about the drivers behind the company's recent achievements as well as how the company is positioning itself for the evolution of next-generation sequencing technologies into clinical practice.

Foundation Medicine is nearing commercialization of a comprehensive diagnostic test. What differentiates Foundation Medicine's test?

In essence we apply next-generation sequencing to cancer diagnosis. We sequence approximately 200 clinically actionable genes, which is an important point. We are not arbitrarily sequencing the whole genome or exome. We focus on genes and pathways that have been shown to have some clinical application. We view this as the "sweet spot" between conventional hot spot testing that is most common today and whole genome/exome.

There is a lot of noise in the marketplace about whole-genome sequencing or applying broad-based next-generation sequencing to clinical diagnostics. But what most people do not understand is how challenging it is to actually apply this technology to cancer diagnostics. . . . When you couple the fact that cancer tends to be a very heterogeneous disease with the fact that many of the alterations that are clinically actionable are found at very low frequencies, the challenges of using this technology go up exponentially—especially doing this in FFPE [formalin-fixed paraffin-embedded], which adds to the challenge significantly. Foundation Medicine has spent the past year and half working through these challenges. We now have a clinical-grade test that applies next-generation sequencing to cancer diagnostics and are able to perform the test in an efficient way in terms of the type of sample and amount of tumor sample that we need as well as the cost of performing the test. Our lab has recently started accepting specimens from most

states. However, our broad commercialization efforts won't come until 2012.

While your test takes a comprehensive approach, are there subspecialties within oncology that will be targeted as part of the launch?

The test was developed as a pan-cancer test. While it makes sense medically going to the market with a pan-cancer test [as opposed to a targeted test], it might not be the best approach from a regulatory and/or reimbursement standpoint, so we are still working through some of these complexities. . . . In 12 months or so, a newly diagnosed patient with non-small cell lung carcinoma is probably going to have anywhere from 10 to 15 molecular assays performed on their biopsy. That fact may represent an enormous cost burden to the health care system and in most cases, there will just not be enough tissue to run all of those tests. Biopsies are too small and the expense is too great. So, from that scenario, lung cancer is an area ripe for a targeted approach using Foundation Medicine's test.

The test will launch next year as a lab-developed test. Do you have any plans to have it approved by the U.S. Food and Drug Administration (FDA)?

Foundation Medicine by the Numbers

Year Launched: 2010

Employees: 50

Financing: \$33.5M expanded Series A round

Partners: Four pharmaceutical collaborations

Test: Uses approximately 200 genes

Capacity: 250 samples per week, with doubling of capacity by mid-2012

As you stated, it will be launched as a laboratory-developed test, however, we certainly do want to work closely with the FDA on the regulatory path and we have already engaged the FDA in discussions. The good news is that the FDA appears to be very open to working with companies like Foundation Medicine on bringing next-generation sequencing through the regulatory process. I think they do understand that long-term this type of approach is very important for cancer care and it can also ultimately save the health care system a significant number of dollars if we approach it correctly.

How is Foundation Medicine readying for the national launch and what are the company's pricing and reimbursement plans?

We are receiving specimens right now from pharmaceutical companies, academic medical centers, and early users, but the national launch will be towards the middle of 2012. . . .

On the operations side, the laboratory is able to process a fair number of samples every week and turn results around in approximately 14 days. Having the broader launch in another six months or so allows us time to pressure test our processes and adequately ramp up the commercial side of the organization.

What is powerful about the test from a pricing standpoint is that for the price of running four, five, or six individual molecular assays, not only can you have the information on those four, five, or six markers, but you can also have complete information on 200 additional genes. . . . We are in the final stages of locking down the pricing, but it is safe to say it will be close to the aggregate price of testing for a half dozen molecular assays.

We have already initiated discussions with third-party payers and we have had our first conversation with CMS [the Centers for Medicare and Medicaid Services]

as well. Like with any new test, we do believe it will take time and appropriate clinical studies to convince payers this is the right approach long-term. We are a data- and market-driven organization and we ultimately will have a dozen or so clinical trials to support the commercialization of our test. The trials are being put in place to demonstrate the clinical utility of this test, as well as the health economics of this test.

Foundation Medicine recently announced its fourth pharmaceutical collaboration. How does Foundation Medicine's new partnership with Johnson & Johnson differ from the previously announced pharmaceutical deals?

There is a common thread to each of these collaborations. Our test is being used to better understand the molecular basis of their clinical trials' participants' cancer. The information may allow them to better stratify patients, to seek out better ways to identify responders and nonresponders, to identify why certain patients might have adverse reactions. It is all driving towards providing pharmaceutical companies with a tool to conduct clinical trials more quickly and efficiently.

Will companion diagnostic products likely emerge from these collaborations?

Yes. We are generating a significant amount of content and uncovering new information as we run samples through our laboratory. With that information we will pursue two avenues. One path will allow us to use this information to enhance the value of our comprehensive test, while the other path recognizes the benefit of having an IVD [in vitro diagnostic] strategy due to some of the potential reimbursement and regulatory challenges early on.

How will the clinical relevance of sequencing evolve in the next five years?

"Having the right complementary cancer biology skillset, as well as the IT infrastructure to sort through all of this data in a timely fashion, is something we still have to focus on as an industry. To allow for a clinically useful test, we have to simplify this complex information so that it is actionable."

*—Michael Pellini, M.D., CEO,
Foundation Medicine*

The advancement of [this] technology certainly means one thing, namely there will be more and more data out there that has to be managed. One of the rate-limiting steps from the broad-based application of this technology to cancer diagnostics is the number of well-trained clinically focused computational biologists is not yet sufficient to do this on a broad-scale basis. Having the right complementary cancer biology skillset, as well as the IT infrastructure to sort through all of this data in a timely fashion, is something we still have to focus on as an industry. To allow for a clinically useful test, we have to simplify


this complex information so that it is actionable. That is something Foundation Medicine already does well.

How will Foundation Medicine evolve in the next three to five years?

In some ways it is straightforward. Our aim is to have our comprehensive, fully informative genomic profile used up front in a high percentage of newly diagnosed cancer patients . . . not only throughout the United States but internationally. There are potentially profound medical and economic advantages of moving in this direction.

As we get insight into the additional genes, we do have the ability to add them to our test. Within the next year or two I would envision that maybe once or twice a

year we would come out with a new version of our test that expands the number of genes sequenced.

Longer term, the question of whole-exome sequencing and whole-genome sequencing certainly surfaces. We have already done the internal proof of concept for whole-exome sequencing and whole-genome sequencing, so it is not as much of a technical hurdle as it is really a question of whether all of that information is necessary. Is it clinically actionable? . . . I do think whole-genome sequencing will be used more broadly in cancer diagnostics. But still 90 percent of tests, even in five years, will be much more targeted than whole-genome sequencing. 

This article was originally published in G2 Intelligence's monthly newsletter, *Diagnostic Testing and Technology Report*, and is republished here with the express written permission of Kennedy Information, LLC. © 2011. It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact Jonathan Wentworth-Ping at G2 Intelligence's corporate licensing department, 973-718-4703, or e-mail jping@G2Intelligence.com. For more information about G2 Intelligence or to subscribe to any G2 Intelligence's publication, go to www.G2Intelligence.com.