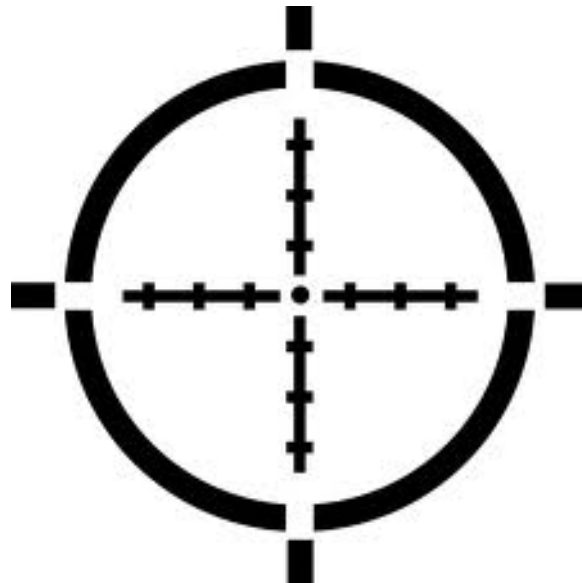


# Foundation Medicine Client Report

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## Executive Summary

Foundation Medicine operates as a molecular information company within the commercial medical and diagnostics laboratory industry. The company's goal is to use genomic information in order to provide cancer patients the most effective individualized cancer care. The company sells two clinical products, *FoundationOne* for solid tumors and *FoundationOne Heme* for blood and other cancers. Each product tests patients' cancer cells and identifies the particular genetic alterations present in their disease. Additionally, the company's genomic information platform then generates a concise report with associated FDA-approved targeted therapies for the alterations found, and recommends patients for on-going biopharmaceutical trials.

Foundation Medicine markets its products directly towards physicians, who in turn recommend the service to patients. It has actively fostered relationships with oncology thought leaders and published peer-reviewed reports in trying to validate its products. Currently, over 2,100 physicians across 25 countries have ordered tests from Foundation Medicine, representing relatively low market penetration. The company has also encountered some difficulties in collecting payments from third-party insurance payers and government health benefit programs such as Medicare and Medicaid.

As a result, the company has yet to post positive earnings and have incurred an accumulated deficit of \$89.8 million since its inception in 2009. To generate new revenue, the company plans on expanding its sales force to give Foundation Medicine the capability of marketing directly to community hospital centers or cancer care centers. Additionally, the company hopes to develop its online portal as a mobile application, and enhance its features to include physician collaboration and communication.

The DangerZone team has concluded that the Foundation Medicine needs to focus on increasing product acceptance rates and collecting revenues more quickly. Specifically the portal or mobile application could be improved to include physician-patient or patient-patient communication. Additionally, Foundation Medicine might look to grow its sales force, by recruiting recent medical school applicants or graduates. The company also needs to obtain a national coverage decision in order to establish a standard for collecting reimbursements.

# History

## Overview

Foundation Medicine, founded in 2009, describes itself as a molecular information company aimed at improving the methods with which cancer patients are treated. The company has developed a genomic information platform that generates actionable information from an individual patient's cancer cells, which allows physicians to implement optimal, FDA-approved treatment therapies and provide individualized cancer care. The company currently operates within three business segments: Clinical Products, Pharmaceutical Research and Development Collaborations, and Technology Products and Data Services. Foundation Medicine's proprietary platform can be utilized by physicians for direct treatment guidance, and by biopharmaceutical companies looking to improve their research.

The company launched its first clinical product, *FoundationOne*, in June 2012. *FoundationOne* is a genomic profile that expands treatment options for cancer patients with solid tumors. The product assesses 236 biologically relevant cancer genes with high sensitivity and specificity. After identifying the genomic alterations, the platform also produces a concise, actionable report for the physician, which provides information about FDA-approved therapies and on-going biopharmaceutical trials that the patient qualifies for. The company recently launched *FoundationOne Heme* in December 2013, which expanded the types of cancers profiled in *FoundationOne* to include blood cancers, hematologic malignancies and sarcomas, and pediatric cancers. The company also looks to develop partnerships with biopharmaceutical companies so that they can incorporate the most-cutting edge cancer research into its platform. Foundation Medicine only went public in late September 2013 and is still expanding its product lines and operations.

## Future Plans

In the future, Foundation Medicine is hoping to improve its Interactive Cancer Explorer, the portal by which the company currently delivers reports to physicians and patients. In 2014, the company would like this portal to also allow communication amongst physicians about their patients' treatment. By including treatment results on the portal, the company can expand its

dataset and incorporate the results into its platform. Additionally, the company hopes to expand its portal to a mobile application that physicians can use away from the computer.

Another focus for 2014 is expanding and improving the existing sales force. At the launch of *FoundationOne* in June 2012, the sales team consisted of only two individuals. Currently, the sales force has expanded to 26 members, and the company would like to continue growing a qualified sales team. It has been difficult for Foundation Medicine to find salespeople with the oncology experience and expertise necessary to effectively sell its products, which has slowed down the hiring process. The company hopes that expanding the sales force will allow Foundation Medicine to begin targeting entire community hospitals or cancer care centers for partnerships, rather than targeting specific physicians.

## Competitive Analysis (Five Forces Framework)

### Market Definition

Foundation Medicine competes within the commercial medical and diagnostics laboratory industry. The industry is comprised of approximately 8,000 companies that collect about \$47 billion in annual revenue, one third of which comes specifically from imaging laboratories. While it is important to understand this big picture, a narrower market definition is more useful for the following analysis.

Specifically, Foundation Medicine's comprehensive molecular information and genomic profiling platforms place it within a product market that encompasses existing mainstream diagnostic laboratories that offer single-marker or hotspot panel tests, academic research centers and NGS platform developers. They also compete with diagnostic testing kit manufacturers who sell capital equipment and reagents to local pathology laboratories for direct physician use. Despite enormous investments in research, as well as the introduction of new treatments, the global cancer burden is growing and remains a critical area of unmet need. As cancer is not a single disease, selecting the most effective treatment is evolving into a molecular-based paradigm. Foundation Medicine's two clinical products, *FoundationOne* and *FoundationOne Heme*, diagnose the genomic alterations in patient's cancer cells but also provide actionable information to physicians to use when recommending treatment.

The geographic scope of diagnostic laboratory competition is extensive, covering most of the United States; Foundation Medicine is also expanding their international sales strategy, partnering with leading distributors to sell to academic and medical centers. Large economies of scale exist in the operation of medical labs, as they can collect samples from large geographic areas (when smaller medical labs compete, their best strategy is specialization). Within the United States, required government licensing and certification imposes complex restrictions on the reach of laboratories across state lines. For example, in addition to meeting the federal Clinical Laboratory Improvement Amendments (CLIA) standards, several states require laboratories accepting specimens from out of state to be licensed in the state of specimen origin. Foundation Medicine holds the required licenses for these states.

## Overview

Force	Strategic Significance
Internal Rivalry	Moderate
Threat of New Entrants	Low
Substitutes and Complements	Low
Supplier Power	High
Buyer Power	Low

### Internal Rivalry

The medical laboratory segment is fairly concentrated and the 50 largest companies generate about 65% of revenue in the industry. Companies generally compete through product differentiation and brand loyalty, rather than price. This is due in part to the obscure billing and reimbursement structure of the medical industry at large, which renders prices and the terms of sales transactions difficult to observe. For these reasons, Foundation Medicine prioritizes establishing their products' added value and securing a network of key thought leaders, clinicians and researchers.

The industry is forecasted to grow at a rate of around 7% during the years 2014-2018. This projected growth will allow for companies to grow their businesses without having to compete directly for market share. This is particularly relevant for Foundation Medicine, as they claim to have the only commercialized comprehensive molecular information product available for the routine care of patients with cancer. This valuable first mover advantage means that the market share available for capture is expansive and growing - given biopharmaceutical advancement of treatments based on molecular diagnostics. If Foundation Medicine can solidify a quality reputation and a network of buyers that believe in their product as a standard of care, they will maintain a significant advantage over other laboratories attempting to enter the niche and grow even more quickly than the industry at large.

Some of the greatest competition experienced within the industry occurs downstream, inhibiting the distribution process. More specifically, many laboratories struggle with limited experience and resources within their sales and marketing departments. This is largely because of the stiff competition to attract and retain personnel with the required technical backgrounds necessary to sell to a large and diverse market of physicians. This process is even more challenging outside of

domestic markets. At this point in time, Foundation Medicine maintains its own sales force within the U.S., but contracts with distribution partners for international affairs.

## **Threat of New Entrants**

### *Government Policy*

Clinical laboratories must hold many federal and state licenses, certifications and permits to conduct business. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establishes quality standards in order to assure patients of the accuracy, reliability and timeliness of test results. Laboratories must also register diagnostic tests with The Centers for Medicare & Medicaid services - an especially important regulation required for billing both government and private third-party payers for reimbursement. Certified labs are subject to inspections and assessments of compliance at least every two years and often occur unannounced. Further, laboratories classified as "high complexity," such as *FoundationOne*, must adhere to even higher standards of practice. Such regulations represent not only a technologically complex barrier to entry but also a financial one, as CLIA is a user-fee funded program, meaning that certification and surveying costs are undertaken by the facility.

Laboratory Diagnostic Tests (LDT's) do not yet have to be registered with the FDA, but full validation of accuracy, precision, specificity, sensitivity and establishment of reference range is still required under CLIA regulation. However, in 2010 the FDA did state their intention to regulate LDTs, but they have yet to decide how. In 2013, they specified that they would soon implement a risk-based phased-in approach; the new requirement of getting FDA approval would be a long (several years), expensive and uncertain process. Even when FDA approval is obtained, the association often imposes many limitations on facilities.

Extra state requirements often specify minimum lab personnel qualifications, quality control, as well as facility and record maintenance procedures. As mentioned previously, additional state regulations can also restrict the geographic market boundaries, requiring state licensure from the states of specimen origin when samples are received from out of state. Foundation Medicine is CLIA certified, accredited by the College of American Pathologists, and licensed with specific states in order to facilitate their geographic reach.



It is also government regulation that laboratories properly dispose of medical, hazardous and biohazardous waste. Many companies, like Foundation Medicine, need to contract with outside vendors who have the necessary expertise and infrastructure to perform these disposal processes. Protective procedures must be in place to prevent exposure to blood-borne pathogens.

Lastly, medical and diagnostic laboratories are also subject to HIPAA and HITECH - laws that help ensure patients' information is kept secure and private. HIPAA details privacy and security regulations, as well as electronic transaction standards; such statutes also affect billing procedures. Fines and penalties are incurred for wrongful use or disclosure of protected health information. HITECH mandates health information security breach notification requirements.

#### *Brand Equity & Customer Loyalty*

Another barrier to entry within the market of diagnostic laboratories is the need to establish a well-known and respected presence amongst buyers. It is difficult and costly to convince the medical community of clinical utility and potential advantages that a new laboratory offers. Brand equity greatly impacts the willingness of physicians and patients to utilize new products. The necessity of establishing such relationships is also a barrier to securing reimbursement.

*FoundationOne* has a strong network of key thought leaders, clinicians and biopharmaceutical companies, but they must continue to complete clinical trials, publish scientific and medical results in peer reviewed journals, and to present their work at major scientific conferences if they wish to grow in the industry.

Once researchers and clinicians validate the platform of a laboratory's LDT's, they help drive and spread adoption, and play a keep role in establishing industry leadership. When a company can clearly demonstrate product value to clinicians, as *FoundationOne* believes it can, buyers are apt to show some brand loyalty, if not just for the ease of repeated transactions - given a laboratory can demonstrate reliability and consistency. Relationships between laboratories and biopharmaceutical companies, who contract in order to enhance their therapies, are similarly challenging to establish, but subject to the same loyalty dynamics once achieved.

### *Other Aspects of Entry*

Liquidity requirements within the industry pose a challenge for new companies as laboratories must cover sales and marketing, capital expenditures, working capital, debt service, general corporate expenses and the largest burden of the all, research and development. Innovation at *FoundationOne* is currently centered on perfecting their online platform, rendering research and development costs less of a concern. However, a need to expand capacity in order to meet building demand has the potential to strain the company through large increased capital costs. The uncertainty within the industry regarding projected reimbursement from third party payers can lead to serious liquidity problems if a company is unprepared. *FoundationOne* speculates that in a time of need they could sell common/preferred equity or convertible debt securities, and seek additional crediting facilities or debt financing; although they recognize the potential dilution to stockholders, and restrictions that third party funding may impose.

The success of medical and diagnostic laboratory companies also depends heavily upon proprietary technologies including methods and processes. As such, patents and trademark registrations are key. *FoundationOne* owns patents relating to genomic testing procedures, genomic discoveries, and genomic information delivery (as well as a pending U.S. and international portfolio). While established laboratories have an experience curve advantage and benefit from the potential of collecting royalties stemming from their existing patents, they must also fear and prepare for the retaliation of competitors who wish to claim patent infringement. Switching and sunk costs are also of great concern within the industry, as rapid changes in medical practices and technology could suddenly render the molecular information platform obsolete.

### **Substitutes and Complements**

Single-marker or hotspot panel tests are the only true substitutes that exist for Foundation Medicine's two products, *FoundationOne* and *FoundationOne Heme*. While extremely limited in diagnostic scope, these hotspot panel tests are distributed by mainstream diagnostic companies and have been used by physicians for years. Foundation Medicine claims that they have differentiation on their side, “having built the only molecular information platform that comprehensively assesses cancer tissue simultaneously for all four classes of genomic alterations

across all cancer-related genes with the sensitivity and specificity required for routine medical practice.”<sup>1</sup> Without comprehensive and single-marker molecular testing, clinical and researching oncologists lack important genomic information about each patient's individual cancer. This information gap renders clinicians unable to optimize treatments, and biopharmaceutical companies less able to target treatments. The fallback for medical and scientific professionals is to rely on intuition and a guess-and-check approach to treatment. These substitutes make the comprehensive molecular information products of Foundation Medicine all the more attractive.

Demand is linked to the number of people receiving medical care. More specifically, Foundation Medicine's demand is linked to the almost 2 million people diagnosed annually with cancer in the United States - 16 million worldwide. The diagnosis of cancer is almost always a complex and multidimensional process, requiring that clinical oncologists order multiple tests. Surgery, radiation and chemotherapy treatments are slowly giving way to more precise therapies that target cancers based on the specific genomic alterations that drive their growth. The more popular and effective these targeted treatments become, the higher the demand for molecular diagnostic testing will be. There are currently more than 40 approved targeted oncology therapies on the market, and more than 470 currently being tested in clinical trial stages. The simple fact that the array of therapeutic options is rapidly expanding also increases the need for comprehensive molecular information that is presented in a concise and actionable format - such as Foundation Medicine's Interactive Cancer Explorer Portal, a cornerstone of their current development.

### **Supplier Power**

Medical and diagnostic laboratories often rely on a limited number, and in some cases sole suppliers for lab instruments and materials. Replacements may be hard or even impossible to come by. This gives suppliers within the industry a substantial amount of power. If there were to be difficulties or delays in securing supplies (substances used in chemical reactions, reagents, sequencers, etc.), laboratory operations would endure costly interruptions.

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<sup>1</sup> Foundation Medicine, 2013 Annual Report

These limitations hold true for Foundation Medicine, as Illumina is its sole provider of sequencers, necessary maintenance and repair, as well as some reagents. Given that laboratories put their business and financial conditions, results of operations and general reputation on the line, contracts often layout detailed expectations. Foundation Medicine secured a 5-year contract in 2013 with Illumina, which requires them to make rolling forecasts of expected needs for reagents and other consumable inputs. Illumina is not allowed to unreasonably reject conforming purchase orders, and may at its discretion meet or deny additional purchase orders. Illumina benefits from low demand protection, as Foundation Medicine is obligated to purchase an amount of supplies equal to or greater than a percentage of their forecasted demand; there is also a fixed minimum in place. Contracts also stabilize transaction prices for a set period of time, and do not bind either company to exclusivity.

There is no guarantee that in the case of losing a supplier contract, that replacement sequencers and materials would meet quality control and performance requirements of a laboratory's standard operations. Foundation Medicine admits that there are very few supply alternatives. Additionally, the substitutes that are available would require greatly altering lab operations and procedures - a time consuming and very expensive undertaking. Further, such alterations would necessitate that both products, *FoundationOne* and *FoundationOne Heme*, would need to be revalidated and government approval and licensure re-secured.

Additionally, Foundation Medicine requires highly knowledgeable and skilled employees. The company's success depends on its ability to design to accurately test and diagnose individuals, to provide actionable information to physicians through its platform, and to convince these physicians that its services add clinical value. That means that the company needs knowledgeable personnel throughout all divisions of the company. The researchers need to be able understand and present complex information at conferences, the information technology department needs to be able to create a platform that physicians will find intuitive and useful, and the sales teams needs to understand the product in order to effectively sell it to physicians and hospitals. As a result, the company depends upon its employees and must have attractive compensation and benefit packages in order to attract and retain its personnel.

**Buyer Power**

Securing clients within the medical and diagnostic laboratory industry relies heavily on garnering the support of key thought leaders, and establishing the company's products as "a standard of care" in the eyes of leading clinicians. Biopharmaceutical companies are often some of the most profitable customers, using laboratory services to help perfect and innovate the therapies they suggest to clinicians in response to the results of diagnostic testing. Novartis for example, has provided Foundation medicine with more than 10% of their revenue in each of the preceding three years. Partnering with biopharmaceuticals allows molecular diagnostic testing laboratories to incorporate new genes under investigation into their platforms and products. However, contracts come with constraints, and it is not unusual for agreements to be terminated at will.

Buyer power is largely affected by the reimbursement of third party payers in any medical industry - diagnostic testing is no exception. It is key for laboratories to obtain a positive national coverage decision and favorable reimbursement rate from CMA early on. No matter how much product value is demonstrated, it is extremely difficult to persuade physicians and patients to order products that are not entirely, or at least substantially, covered by a third party payer. Currently, Foundation Medicine struggles with unstandardized reimbursement policies, and various regions are given coverage discretion. Further, the company has yet to receive any reimbursement for Medicare patients - this is due in large part to bureaucratic inefficiencies. For example, the company is still required to file claims using "miscellaneous codes," unnecessarily assigning all paperwork as lower priority and exacerbating an already time intensive process.

As the United States government continues to promote the containment of healthcare costs, coverage is becoming more limited, and the demand for pricing discounts and rebates is greatly increasing. The Affordable Care Act also mandated a 2% cut in Medicare payments for all services including clinical lab testing until 2023. It is becoming more and more difficult for medical facilities to obtain full reimbursement, or even enough to cover their costs. Foundation Medicine aims to demonstrate clinical utility, economic benefit and physician demand for their products, in hopes of eventually securing a positive national coverage decision. Without the stability of consistent third party coverage, it is difficult for companies to maintain a price level high enough to compensate for investment and product development - and collecting payment

directly from patients may be difficult, if not impossible. A laboratory can choose to share the burden of recovering reimbursement on behalf of patients if they choose to contract with providers, but this generally reduces margins.

Such limitations are especially difficult for companies to reconcile as forward integration is strictly prohibited within the industry. Firms are banned from practicing medicine, as well as employing or engaging physicians to practice medicine; this is often referred to as the prohibition against the corporate practice of medicine. Further, Anti-Kickback Statutes state that it is unlawful to knowingly and willfully offer, pay, solicit or receive remuneration for inducing, or in return for, the issuance of patient referrals.

## Financial Analysis

### Overview

Foundation Medicine's (NASDAQ: FMI) finances reflect a company still struggling to establish itself in the biotechnology industry. Although the company has grown, recording increased revenue and an increased adoption rate among physicians, Foundation Medicine remains unprofitable. The company conducted its Initial Public Offering (IPO) on September 25<sup>th</sup>, 2013 at \$18.00 but ended at \$31.50 that day, indicating either undervaluation or optimism. Foundation Medicine now trades at \$26.73, its stock underperforming compared to the S&P500 and peers. Increasing expenses and uncollected revenues are damaging to the company's financial health, but FMI remains hopeful of its strategy to expand, which would entail large-scale adoption of its molecular information platform.

### Industry Analysis and Competitor Comparison

	Foundation Medicine	Myriad Genetics	Genomic Health
Market Capitalization	739.43M	2.78B	826.66M
P/E	N/A	16.48	N/A
Current Ratio	8.46	6.74	4.86
EPS	-4.64	2.32	-0.42
Beta	N/A	0.96	0.41
EBITDA	-37.21M	300.47M	-5.51M
ROE	-45.88%	28.07%	-9.40%
Profit Margin	-148.13%	25.48%	-4.88%

As of April 10<sup>th</sup> 2014

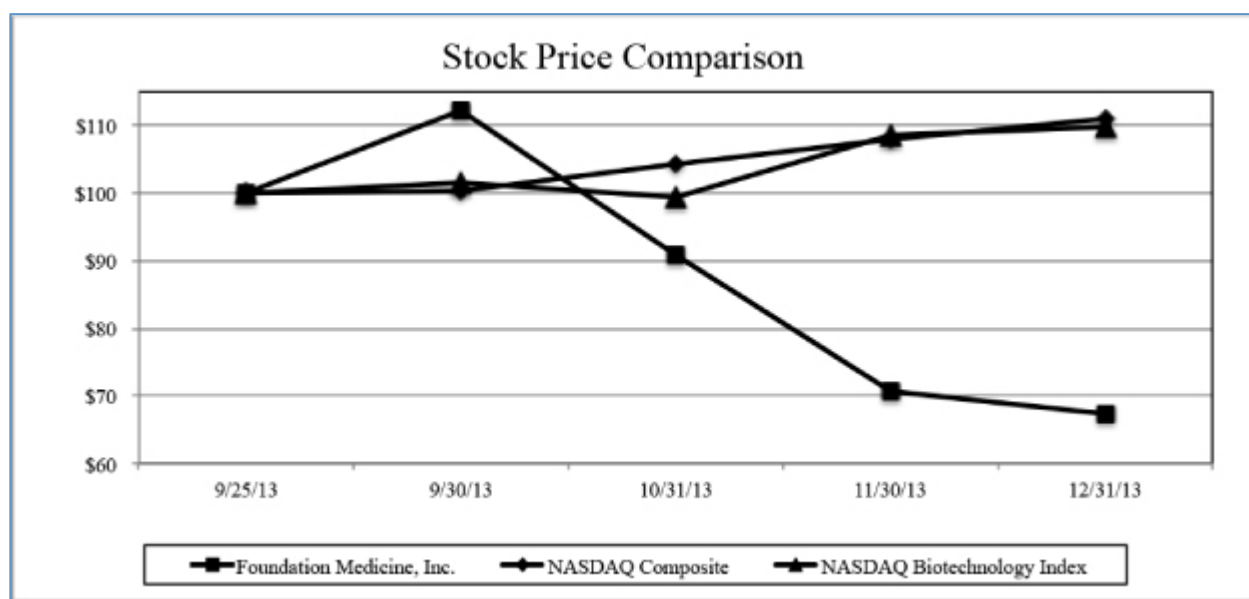
Foundation Medicine has two main competitors in the molecular information industry, Myriad Genetics and Genomic Health Inc. Myriad Genetics is a much larger company, conducting its IPO in 1995 and now with almost four times the market cap of FMI. Myriad Genetics has 1,325 employees. Genomic Health conducted its IPO in 2005, and now has a market cap of \$826.66M, similar to FMI, and 684 employees. FMI has a mere 186 employees.

The table above shows how competitive nature of the biotech industry. The general performance for the industry is poor, with the iShares Biotechnology Index down 6.1% this year, and some

analysts warning of a bubble that might soon burst.<sup>2</sup> FMI's ROE and profit margin figures are worrying, although its expansion strategy requires large initial costs for tests by ordering physicians and biopharmaceutical customers, laboratory personnel-related costs, new equipment purchases, and sales and marketing expenses, and R&D expenses. FMI's business model hinges on large-scale adoption of its molecular information platform and so these marketing and R&D expenses are necessary. FMI expects its revenue to increase over time as they expand their commercial efforts within and outside of the United States. In 2013, the company incurred a net loss of \$42.9 million, which increased its accumulated deficit to \$89.8 million.

We see mixed results when trying to compare FMI to its competitors. The bigger company seems to be shielded from the aforementioned biotech industry bubble. Myriad Genetics still produced an ROE of 28.07% and a profit margin of 25.48%, and it looks financially healthy. Genomic Health is similar in market cap to FMI but is older and has more employees. The company was not profitable in 2013, with an ROE of -9.40% and a -4.88% profit margin. This is slightly worrying since it could indicate that Genomic Health is still struggling to get its information platform adopted ten years after its IPO, and Foundation Medicine might face the same fate.

### Stock Performance



Source: Foundation Medicine Annual Report, 2013.

<sup>2</sup> Source: Business Insider, April 10<sup>th</sup> 2014.



As we can see, Foundation Medicine's stock has dropped compared to the NASDAQ composite and NASDAQ Biotechnology Index. This is an indication in the lack of confidence by investors and analysts alike, who have not seen tangible results from FMI since its IPO.



Source: Yahoo! Finance, accessed April 10<sup>th</sup> 2014.

Stock price has also dipped considerably between March and April, likely a result of the 180-day lockup period following its IPO on September 25<sup>th</sup>, 2013. The end of the lockup period allowed outstanding shares held by significant pre-IPO shareholders to be sold. There was a sudden flood of shares available for sale on the market (21.3 million shares added to 5.9 million shares currently), which led to a decrease in price that the company has not recovered from yet.

**Revenues and Expenses**

FMI's total revenue increased to \$28.9 million in 2013 from \$10.6 million in 2012, a 172% increase. This increase was due to increased revenue from tests reported for ordering physicians (\$14.8 million from \$2.6 million) and revenue from biopharmaceutical customers (\$14.2 million from \$8.0 million). FMI derives its revenue mainly from selling products enabled by their molecular information platform. Its profitability depends on adoption of the products and receiving payment as quickly as possible. Current adoption rates are increasing and will continue to do so, although this will invariably cause increases in marketing expenses. More pertinent is the expedition of payments.

FMI depends on the commercial third-party payers and government payers for revenue. FMI is not a participating provider with any commercial third-party payer and therefore does not have specific coverage decisions for its products with established payment rates. This means that coverage and payment is determined by third-party payers and government payers on a case-by-case basis. Additionally, FMI is not a participating provider in any state Medicaid program and therefore does not have coverage decisions under which its tests are covered by Medicaid. As for Medicare, FMI is a participating provider but does not have a coverage decision. Lastly, individual payments generally take a substantial amount of time to be collected. Therefore, there is a significant lag between selling the product and actually receiving payment. The cumulative number of tests that were billed to commercial third-party payers and reported for patients covered by Medicare but for which FMI has not recognized revenue was 3,200 and 2,481, respectively, as of December 31<sup>st</sup>, 2013. More instances like these will negatively impact FMI's revenue and earnings, and should be a cause of real concern for the company.

As touched upon earlier, expenses have also increased following aggressive expansion strategies. The cost of revenue increased from \$5.7 million to \$11.7 million dollars, driven by increasing test volumes from ordering physicians and biopharmaceutical customers. Sales and marketing expenses increased to \$12.3 million from \$3.5 million, primarily related to increases in personnel related costs to the tune of \$6.5 million and a \$1.7 million increase in consulting. General expenses have also increased from \$8.6 million to \$21.9 million, due largely to a \$5.0 million

increase in stock-based compensation, a \$2.6 million increase in rent and other facilities costs, and a \$2.6 million increase in personnel costs. R&D expenses increased to \$24.9 million from \$14.8 million, attributable mainly to a \$4.7 million increase in employee and contractor-related expenses and a \$2.2 million increase in technology investments. The nature of these costs appears to be unavoidable, especially given FMI's growth strategy. However FMI may want to focus on short-term cost decreases. In particular, a \$1.7 million consulting cost and a \$5.0 million stock-based compensation expense seem extravagant considering FMI's nascent status in the industry.

	Year Ended December 31,		Change	
	2013	2012	\$	%
<i>(in thousands, except percentages)</i>				
<b>Statement of Operations Data:</b>				
Revenue	\$ 28,990	\$ 10,645	\$ 18,345	172%
Costs and expenses				
Cost of revenue	11,659	5,681	5,978	105%
Selling and marketing	12,326	3,454	8,872	257%
General and administrative	21,865	8,644	13,221	153%
Research and development	24,901	14,777	10,124	69%
Total costs and expenses	70,751	32,556	38,195	117%
Loss from operations	(41,761)	(21,911)	(19,850)	(91%)
Interest expense, net	(235)	(421)	(186)	(44%)
Other expense, net	(948)	(61)	887	1,454%
Net loss	\$ (42,944)	\$ (22,393)	\$ (20,551)	(92%)

Source: Foundation Medicine Annual Report, 2013.

## SWOT Analysis

<b>Strengths</b> <ul style="list-style-type: none"> <li>- Superior testing products in <i>FoundationOne</i> and <i>FoundationOne Heme</i></li> <li>- Validation through oncology thought leaders and publications</li> <li>- First-mover advantage in creating a network effect</li> </ul>	<b>Weaknesses</b> <ul style="list-style-type: none"> <li>- Products have yet to achieve significant market acceptance</li> <li>- Limited experience, especially in sales and information technology</li> <li>- Difficulties in collecting reimbursements, specifically from Medicare and Medicaid</li> </ul>
<b>Opportunities</b> <ul style="list-style-type: none"> <li>- Develop mobile application to allow doctor-patient communication</li> <li>- Improve reimbursement collection practices by making products the standard of care</li> <li>- Expand operations with new tests, and expand target market</li> </ul>	<b>Threats</b> <ul style="list-style-type: none"> <li>- Molecular diagnostic industry changes rapidly so technology and products could become obsolete</li> <li>- Government regulatory changes could significantly affect operations</li> <li>- Breakthroughs in cancer diagnosis and treatment could render services useless</li> </ul>

### Strengths

#### Superior testing products in *FoundationOne* and *FoundationOne Heme*

Foundation Medicine has patented two clinical products, *FoundationOne* for solid tumors and *FoundationOne Heme* for blood-based cancers, hematologic malignancies and pediatric cancers. These products not only diagnose the cancer found in a patient's cancer cells, but they also take advantage of the company's comprehensive molecular information database to compile a report for the use of physicians. *FoundationOne* currently assesses 236 biologically relevant cancer genes with high sensitivity and specificity. Other existing hotspot tests on the market typically assess no more than ten genes. Thus *FoundationOne* appeals patients with small cancer tissue samples that cannot run repeated hotspot tests, or patients with rare or aggressive tumors that need information quickly. The product also identified at least one genomic alteration associated

with an FDA-approved targeted therapy for 82% of its clinical trials, suggesting that the product can provide very useful information to physician and patients.

Another strength of Foundation Medicine's clinical products is how they provide actionable information in a format readily utilized by physicians. The company's molecular information platform produces a summary report of the specific genetic alterations found in the patient's cancer genes, and then also suggests successful treatment for those specific alterations or sometimes recommends the patient for on-going biopharmaceutical trials that they qualify for. These reports are extremely intuitive and easy to read (see below for sample summary report). Additionally, the results are delivered within 14 to 17 days for *FoundationOne* and within 28 days For *FoundationOne Heme*, which is very timely. Turnaround time could even decrease as the company expands its laboratories and improves its information technology

FOUNDATIONONE™		Patient Name	Report Date	Diagnosis Breast Carcinoma
Date of Birth	Client	Specimen Received		
Gender	Physician	Specimen Site		
FMI Case #	Additional Recipient	Specimen Date		
Medical Record #	FMI Client #	Specimen Type		
Block ID	Pathologist			
<b>ABOUT THE TEST :</b>				
FoundationOne™ is a next-generation sequencing (NGS) based assay which identifies genomic alterations within hundreds of cancer-related genes.				
<b>PATIENT RESULTS</b>		<b>TUMOR TYPE : BREAST CARCINOMA</b>		
4 genomic alterations		Genomic Alterations Identified		
6 therapies associated with potential clinical benefit		ERBB2 amplification		
0 therapies associated with lack of response		PIK3CA F1047R		
50+ clinical trials		EGFR L858R		
		TP53 K132N		
<b>THERAPEUTIC IMPLICATIONS</b>				
Genomic Alterations Detected	FDA Approved Therapies (in patient's tumor type)	FDA Approved Therapies (in another tumor type)	Potential Clinical Trials	
ERBB2 amplification	Lapatinib	None	Yes	
PIK3CA F1047R	Trastuzumab	Temsirolimus	Yes	
EFGR L858R	None	Everolimus	Yes	
TP53	None	Erlotinib	Yes	
		Gefitinib	Yes	
		None		

Source: Foundation Medicine, 2013 Annual Report

## Validation through oncology thought leaders and publications

Foundation Medicine has also worked extremely hard to build relationships with oncology thought leaders in an effort to validate the platform and products. Foundations Medicine has created partnerships with the Memorial Sloan-Kettering Cancer Center, the Vanderbilt-Ingram

Cancer Center, the ION Network, the US Oncology Network, and numerous established researchers and clinicians in the field. The company also works to build relationships with biopharmaceutical partners to improve their research on oncology treatments. In addition to generating revenue, these partnerships also give Foundation Medicine access to the most cutting-edge research, which they can then incorporate into their products. Foundation Medicine currently has 18 such relationships with biopharmaceutical companies and is actively trying to build more.

The company has also validated its products through its research and clinical trials. In 2013 alone, Foundation Medicine published 30 peer-reviewed articles by various reputable scientific magazines. They also made over 50 poster presentations at major scientific conferences on their research, and spoke at 20 such meetings including the American Association of Cancer Research, Advances in Genome Biology and Technologies, and the American Society of Hematology. All of these efforts hope to increase the adoption of their products by gaining the validation of major thought leaders and opinion leaders.

### **First-mover advantage in creating a network effect**

Foundation Medicine also has a first-mover advantage because of the comprehensive oncology network they are attempting to create. The company believes that because it was the first comprehensive molecular information platform available for commercial sale, it has created a lock-in effect. For one, its information database contains the most samples, making the reports more reliable and leading to more business opportunities. Secondly, as the product becomes more accepted, a lock-in effect makes it harder for physicians to switch simply due to convenience, reliability, and standardization. Foundation Medicine wants its products to be the standard of molecular cancer diagnosis. In the future, Foundation Medicine hopes to strengthen its network by further developing the Interactive Cancer Explorer, its online portal. Currently the Interactive Cancer Explorer only delivers reports to physicians; however in 2014 the company hopes to expand the portal's features. Specifically, it hopes to add collection outcomes capabilities, which would allow physicians to communicate over the portal and share treatment results and advice. The company also hopes to improve the Interactive Cancer Explorer's mobile application. Further improvements will be discussed in the Opportunities section

## **Weaknesses**

### **Products have yet to achieve significant market acceptance**

Currently, more than 2,100 physicians across more than 25 countries have ordered *FoundationOne* tests. However, the Foundation Medicine has yet to achieve significant market acceptance overall. As a result has been focusing on expanding and improving its sales team. The company will have to convince the medical community that its products are useful and provide clinical value. Also, the company will need to make sure that insurance companies and government payers will reimburse payments for its products, otherwise physicians may be less likely to recommend them. By December 31<sup>st</sup>, 2013, the company has incurred an accumulated deficit of \$89.8 million, and it has yet to post any positive earnings. Until the company achieves broader acceptance, it is unlikely that this trend of net losses will change.

### **Limited experience, especially in sales and information technology**

Foundation Medicine primarily advertises itself as a molecular information company, with expertise in the highly complex field of genetics. However, in order to successfully market its products physicians and institutions, the company has had to delve into fields that lie outside their expertise – notably sales and information technology. Foundation Medicine’s success relies heavily on its personnel, and its business model requires that the company attract highly knowledgeable and skilled employees across all business divisions. It may seem somewhat obvious that the company needs talented scientists, researchers, and clinicians, however the business also requires salespeople and IT support with oncological or medical experience, which are harder to find.

So far, Foundation Medicine has had a difficult time building an experienced, oncology-focused sales force due to the complicated nature of the product. The company targets its sales at oncologists and pathologists in hospitals and cancer care centers. When the company launched *FoundationOne* in June 2012, its sales force consisted of only two individuals. Now however the sales force has grown to 26 professionals, with an average of 10 years of experience in clinical oncology sales. However, it has been difficult for Foundation Medicine to grow its sales force with qualified individuals, who can understand and market the products effectively. Hopefully, the network effect discussed above will make sales easier for the company, but until the

company receives more widespread acceptance, it will require an extremely knowledgeable and experienced sales force.

On the information technology front, the company is just now beginning to make improvements to its online portal, the Interactive Cancer Explorer. Currently, the portal only serves as a way for physicians to access their test results quickly online. However, enhancing the portal's functions will be a focus for the company in 2014, which indicates that it will need to bring in talented information technology personnel. The company hopes to expand its portal to allow for communication between physicians about cancer treatments, which could create a network for oncologists to communicate about on-going treatments. However, the portal could present other opportunities for expansion, which will be discussed in the Opportunities section.

#### **Difficulties in collecting reimbursements, specifically from Medicare and Medicaid**

There are essentially five sources that may potentially pay for Foundation Medicine's clinical testing products: (1) commercial third party payers such as health insurance companies; (2) government health benefit programs such as Medicare and Medicaid; (3) other healthcare providers such as hospitals or accountable care organizations; (4) international distributors; and (5) individual patients. Currently the price for *FoundationOne* is \$5,800 and the price for *FoundationOne Heme* is \$7,200, but actual payments are often less than list prices.

Foundation Medicine does not have any agreements with commercial third-party payers and so these payers pay based on Current Procedural Terminology (CPT) codes on a case-by-case basis. These CPT procedural codes though are constantly be reviewed and revised by the American Medical Association. As such, Foundation Medicine requests that physicians discuss with their patients the possibility that the patient will be responsible for covering some or all of the costs of the test if denied coverage, which makes the products a more difficult sell. However, the company will negotiate with individuals on price, and they offer a comprehensive patient assistance program to assist patients whose incomes are below a specified threshold. The company hopes to improve coverage decisions by validating its products with demonstrated clinical utility, support from the oncology community, publications in peer-reviewed journals, and increased demand for the products.



The company also struggles to collect from government health benefit programs. Only recently in late 2013 did Foundation Medicine become a participating provider in the Medicare program, but they still do not have a national coverage decision that determines if the tests are covered by Medicare. Therefore, contractors that administer the Medicare program have some discretion in determining coverage in their regions, and contractors determine reimbursement on a case-by-case basis. In November 2013, the company first began submitting claims to Medicare, although they have generated no revenue from this process. *FoundationOne* tests for patients covered by Medicare represented approximately 30% of total tests in 2013. Foundation Medicine is applying for a national coverage decision that would set a standard for the reimbursement of Medicare claims, although it has yet to be determined. Also it is worth noting that company has not registered for state Medicaid plans, but has now started that process. This is significant as the Medicaid program is expected to increase in the near future, as a result of the Affordable Care Act signed into law in March 2010.

## **Opportunities**

### **Developing mobile application to allow doctor-patient communication**

One big opportunity for Foundation Medicine would be developing its mobile application. Currently, the company does have an online portal called the Interactive Cancer Explorer, which primarily acts as a means for the company to deliver test results to physicians. However, the company has indicated that improving the portal will be a priority in 2014. Specifically, the company mentioned that it would like to allow physicians the ability to communicate through the portal to discuss treatment results and advice. For one, this improvement would allow the company to enhance its database, because it would have access to treatment results that could then be incorporated into the platform. Secondly, increasing physician communication via the Interactive Cancer Explorer would create a network for oncologists that could lead to a lock-in effect amongst users. This network effect could increase adoption rates and generate profits for the company.

The company would also like to enhance the Interactive Cancer Explorer's mobile application for physicians in 2014. The company might also look to develop their application for patient use

as well. The mobile application could serve as a support group or forum for patients to talk about their condition and their treatments. The application could also allow for physician-patient communication, where physicians could send appointment reminders or research articles to patients. These features, if done well, could create an online community for cancer patients along with physicians. Foundation Medicine has constantly sought to create a network effect by including all members of the oncology industry in its operations, however they have yet to include the patients themselves. A mobile application that allows them to view their test results, communicate with their doctors, and talk with other similar patients might create a powerful network and lead to greater market acceptance of *FoundationOne* and *FoundationOne Heme*.

### **Improve reimbursement collection practices by making products the standard of care**

Foundation Medicine needs to improve its reimbursement collection rates, because much of the company's revenues go uncollected, as discussed above. The company has indicated that it believes that the best way to improve reimbursement decisions from third-party and government payers is to demonstrate the economic and clinical value of its two clinical testing products. Eventually, it would be ideal for Foundation Medicine to receive a national coverage decision so that contractors would not have as much discretion in the reimbursement process. However, it is possible that the national coverage decision will be unfavorable if the products usefulness is not demonstrated. Thus, the company has focused on the performance and marketing of its products to demonstrate its value.

Foundation Medicine has stressed the high performance of its tests, and it has emphasized their sensitivity and specificity in the company's publications and presentations. *FoundationOne* identified actionable genomic information in 82% of clinical trials for example, so the product is very precise and valuable, especially for patients with rare or late-stage cancers. The company has focused much of its attention on marketing in recent quarters. They have expanded their sales force from 2 to 26 employees in just over a year. Also, Foundation Medicine has made a conscious effort to publish in peer-reviewed publications and present at major scientific conferences in order to increase adoption rates. They have also tried to establish relationships and endorsements from key members of the oncology community to validate their products.

The company hopes that these efforts will improve reimbursement decisions, but a national coverage decision would streamline and standardize the reimbursement collection process. The company only applied for Medicare reimbursements in November 2013 and is currently in the process of registering for Medicaid programs as well.

**Expand operations with new tests, and expand target market**

Foundation Medicine currently has two clinical products, *FoundationOne* and *FoundationOne Heme*, but it is looking to explore and develop new products in areas like epigenetics, with products that analyze circulating tumor cells and cell-free plasma DNA. By expanding its product base, the company could appeal to new segments of the cancer care market and take advantage of the economies of scale that large laboratories enjoy.

Foundation Medicine could also look to expand its target market and existing operations. Currently, the company's marketing efforts have been directed at patients who have aggressive diseases or uncommon tumors, who have little available tissue samples, or who have tested negatively under traditional hotspot tests. Foundation Medicine estimates that there are approximately one million patients who fit one of these descriptions out of the thirteen million cancer patients in the United States. The company also estimates that in the near future, its customers may include all patients who have metastatic disease, not limited to the challenging treatment categories described above, which would expand the market base by an additional 800,000 patients. Increasing the market base would increase demand to some extent.

At the moment, the company conducts all of its tests in a single laboratory in Cambridge, Massachusetts. If demand for the product does increase, it could make sense for the company to expand its operations and build other laboratories across the country. Although building and certifying laboratories can be costly, it may be necessary to meet increased demand and could potentially decrease the variable costs associated with conducting each test. However, expansion only makes sense if there exists sufficient demand.

## **Threats**

### **Molecular diagnostic industry changes rapidly so technology and products could become obsolete**

A significant threat to any biotech company is the rapid pace of change in these industries, which could render certain technology or products obsolete. Foundation Medicine admits, “our industry is characterized by rapid technological changes, frequent new product introductions and enhancements, and evolving industry standards, all of which could make our molecular information products obsolete.”<sup>3</sup> Thus the company will need to adapt quickly as practices and techniques within the industry change. Foundation Medicine hopes that its relationships with biopharmaceutical companies and oncology thought leaders will allow it to see the direction of the industry and adapt quickly to changes. Also, the company can update its software easily to incorporate advancements in cancer research. However, there still remains the risk that the equipment the company has invested in, its molecular information platform, and its clinical products could become entirely obsolete in the molecular diagnostic industry.

### **Government regulatory changes could significantly affect operations**

Government regulatory changes could seriously affect Foundation Medicine’s cost and revenue models and pose a significant risk to the company’s operations. Its business is highly regulated, from the way they conduct research in laboratories, to the way its products are priced, to the way it collects payments for its services.

Much of the regulatory risks have already been discussed in detail in previous sections, so only a few points will be highlighted here. The company’s laboratory operations are subject to Clinical Laboratory Improvement Amendments (CLIA) set by the federal government. Changes to CLIA can force Foundation Medicine to update its equipment and technology or even renovate its laboratories, which can be very costly. On a related note, health care reform has been a focus of recent administrations and policy-makers are extremely concerned about rising health care costs. It is possible, and even likely, that health care reform will change the way tests and procedures are priced. Finally, reimbursement regulations could affect the way that Foundation Medicine collects payment. While the number of people covered by health insurance plans may be

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<sup>3</sup> Foundation Medicine, 2013 Annual Report.

increasing, Foundation Medicine is still trying to obtain favorable national coverage decisions that will set the standard for how they collect reimbursements from government and third-party payers. However, unfavorable coverage decisions could make it extremely difficult for the company to sell to these patients, who would likely have to pay for the tests by themselves.

### **Breakthroughs in cancer diagnosis and treatment could render services useless**

Competition in the broader cancer care industry is extremely intense, as organizations across the world are working towards a cure for cancer. The National Cancer Institute alone has spent roughly \$5 billion in cancer research over the past six years, and other organizations are searching for cures as well. In 2012, more than 13 million people were suffering from cancer, and 1.6 million were newly diagnosed with the disease.<sup>4</sup> In 2020, it is estimated that there will be 16 million cancer patients<sup>5</sup> with an annual impact of approximately \$900 billion.<sup>6</sup> Because of the enormous impact that cancer continues to have in the world, it is unlikely that cancer research will slow in the future.

Therefore, Foundation Medicine might be concerned with how long it can sustain its competitive advantage. The company has never been profitable in the past and will require an increase in the implementation rates of its product before it generates any positive earnings, which could take a number of years. In the meantime, it is entirely possible that a breakthrough in cancer diagnosis and/or treatment could render the company's services useless. Depending on the nature of the breakthrough, cancer treatment might move away from the molecular trend that Foundation Medicine has followed. Although it is difficult to predict what such a breakthrough might look like beforehand, Foundation Medicine should not lose sight of the fact that billions of dollars are being spent in cancer research and radical changes could easily occur in such an industry and should look to accelerate its market acceptance.

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<sup>4</sup> American Cancer Society, *Cancer Treatment and Survivorship Facts & Figures 2012-2013*.

<sup>5</sup> World Health Organization, *Global Action Against Cancer*.

<sup>6</sup> American Cancer Society, *The Global Economic Cost of Cancer*.

## Strategic Recommendations

Because there exist so many threats to Foundation Medicine's competitive advantage, from within the industry, to the broader world of cancer research, to government regulations, it seems that the company needs to focus on generating profits as soon as possible. There are two main methods that the company could boost revenues: Improve Market Adoption Rates, and Collecting Revenues. Although the two approaches are interrelated, this report will offer strategic recommendations separately for both.

### **Improve Market Acceptance Rate**

For years, Foundation Medicine has been trying to improve its market adoption rate by validating its products with the endorsements of oncology thought leaders and publications and presentations about the success of its products. The company's most recent efforts to improving its adoption rate is the renovation of its online portal, the Interactive Cancer Explorer. In 2014, Foundation Medicine hopes to enhance the portal to allow for communication between physicians about the results of their cancer treatment. They also hope to develop a mobile application with the same capabilities.

While these are steps in the right direction, the company might also consider developing its portal and mobile application for patient use. The portal could serve as a way for patients to immediately view their test results and progress as they are treated. Additionally, the portal could allow for physician-patient communication, where the physicians could send appointment reminders to patients or send out publications about on-going cancer research. The patients could also ask questions to their physicians through the portal or mobile app – or better yet, the patients could start a question thread for all physicians to answer and comment on. Finally, the portal could be enhanced to allow for patient-patient communication potentially. All identification information would have to be either private or optionally given, but the portal could allow individuals in similar situations communicate and share their experiences. The portal could serve as a forum or support group for these interactions. Foundation Medicine has consciously tried to create a network effect, but thus far they have failed to include the patients in this network. By

allowing them access to various features on the portal, the company might attract new customers who are loyal to the product and might recommend them to others.

Another focus of Foundation Medicine has been expanding the sales team, though it has been difficult for the company to find qualified, knowledgeable salespeople. The company believes that growing the sales force will give them the ability to target entire community hospitals and community-based cancer centers that need a partner for comprehensive molecular information testing, rather than individual physicians. Currently, Foundation Medicine looks for sales professionals with backgrounds in oncology, pathology, therapeutics, and/or laboratory services, who have knowledge in the design and use of molecular information products. A younger sales force will not have the medical expertise that more experienced professionals will have, but they compensate for that weakness with a better grasp of how to utilize the platform, given a solid understanding of technology and a few weeks of training. If Foundation Medicine targeted recent medical school applicants or graduates for its sales force, these salespeople would have enough medical and technological knowledge to effectively pitch the product to customers. Perhaps the younger sales team would only sell directly to physicians, but that would at least free up time and people on the experienced sales team to target bigger organizations like community hospitals.

Finally, it is still important that Foundation Medicine continues to seek relationships with leaders in the oncology community and to publish reports and presentations. The company needs to validate its products and prove their usefulness to physicians and clinicians. Not only will this validation increase demand for their products, but it could also lead to more favorable coverage decisions when it comes to reimbursements from government or third-party payers.

### **Collecting Revenues**

Foundation Medicine has had difficulty collecting payment for many of the tests they have delivered, an area where the company definitely needs to improve. To gain coverage by third-party insurance companies, Foundation Medicine needs to make sure that they are up-to-date with all Current Procedural Terminology (CPT) codes and are aware of proposed changes to these codes. It is promising that the company has finally registered with Medicare and intends to register with Medicaid, but the company has yet to obtain any national coverage decision for

these organizations, meaning that contractors within different districts have some discretion about how to reimburse these tests on a case-by-case basis. Although applying for national coverage decisions may be risky, it would streamline and standardize the reimbursement process and give the company access to cash that they currently have to wait for. The risk of applying for national coverage decisions is that they could standardize the reimbursement process unfavorably. Thus the company will have to prove that its products provide clinical value, which connects to back to its marketing efforts discussed above.

Another way to collect untapped revenue would be to expand the target market beyond challenging treatment patients. Currently, Foundation Medicine targets patients with rare or aggressive diseases, or have tested negative under traditional hotspot tests. These patients are the most likely to benefit from a comprehensive test like *FoundationOne*, although it is significantly more costly. By expanding its target market to all patients with metastatic cancers, the company could almost double its potential customer base from one billion to 1.8 billion. While these patients may be less likely to purchase tests from Foundation Medicine, surely some portion of the additional market can afford the service. Also, there would be only marginal increases in marketing costs, as the company is pitching the same product to largely the same physicians. Foundation Medicine's goal is to make its products the standard for metastatic cancer diagnosis and treatment.