

**Myriad Genetics, Inc. MYGN** |

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**We view Myriad as a powerful firm but are concerned about its competitive position in the long term.**by  
Morningstar  
AnalystsAuthors can be reached at [Analyst Feedback](#)[Morningstar's Editorial Policies](#)**Analyst Note**[Myriad Shares Slide Following Patent Litigation and Reimbursement Concerns](#)

by John Zecy, 12/03/2013

**Discuss**[See what other investors are saying about MYGN](#)**Analyst Note** 12/03/2013

Shares of Myriad Genetics fell in trading Monday after one of its patent litigation targets, Invitae Corporation, announced that it is countersuing Myriad. The case declares that certain Myriad patents relating to the BRCA1/2 and MUTYH genes are invalid and are not infringed upon by Invitae. Despite the case's uncertainty, the issue highlights the rigorous competition and legal environment and that Myriad will face as it defends its intellectual property against forthcoming advances in next-generation sequencing.

Uncertainty has also resurfaced regarding reimbursement for its BRACAnalysis from the Centers for Medicare & Medicaid Services as a recently announced rate fell considerably short of what the agency has previously paid. However, an announced reimbursement cut in September proved to be the result of a clerical error, and it is possible that this

stems from a similar issue.

**Investment Thesis** 05/09/2013

Myriad Genetics' predictive medicine business has demonstrated strength in discovering genes and their roles in various forms of disease, and we award the firm a narrow economic moat for its leadership position in this marketplace. However, we are cautious about the sustainability of Myriad's competitive advantages over the long term. Competition--particularly from next-generation sequencing--is intensifying, and we are uncertain whether Myriad will be able to keep ahead of the field and withstand severe margin and pricing pressure. New technologies can easily leapfrog existing systems, and we plan to watch closely as the diagnostic landscape rapidly evolves over the next several years.

Myriad has built its reputation on BRACAnalysis, a predictive test for mutations tied to an increased risk of hereditary breast and ovarian cancers. Introduced in the mid-1990s, BRACAnalysis helps patients with a family history of breast or ovarian cancer to determine if they carry genetic mutations that increase their risk of cancer, as well as those already diagnosed with cancer to tailor therapy and manage their disease. Armed with patent protection and a proprietary mutation database, Myriad has built an entrenched monopoly position in the United States and a dedicated customer following. Its internal salesforce has also been instrumental in driving product adoption and remains a key competitive asset in the high-touch diagnostics segment. Myriad has supplemented BRACAnalysis with a portfolio of eight other commercial offerings, including BART (11% of sales; detects large genomic rearrangements in BRCA1 and BRCA2), COLARIS and COLARIS AP (8% of sales; predictive medicine tests for hereditary colorectal and uterine cancer), and Prolaris (a prognostic test for prostate cancer). This stream of product introductions and a substantial pipeline have made Myriad a pioneer in the development of genetic testing and bode well for future growth amid robust demand.

Complementing Myriad's molecular diagnostic business is its companion diagnostics segment, the other major source of revenue generation (about 5% of sales). In 2011, Myriad acquired Rules-Based Medicine and now offers biomarker discovery

**Morningstar's Take** MYGN

Analyst		
<b>Price</b> 12-16-2013	<b>Fair Value Estimate</b>	<b>Uncertainty</b>
23.8 USD	31 USD	High
<b>Consider Buy</b>	<b>Consider Sell</b>	<b>Economic Moat</b>
18.6 USD	48.05 USD	Narrow
<b>Stewardship Rating</b>		
Standard		

**Bulls Say**

- Myriad operates highly complementary business segments with a keen focus on revolutionary molecular diagnostic tests. This narrowed approach enables the company to capitalize on tailored R&D and information cross-sharing across divisions, rather than adding complexity with ancillary end markets and product lines.
- Myriad should benefit in the long run from U.S. health-care reform, which will expand the number of insured Americans and boost testing volume.
- Now that it has spun off its pharmaceuticals segment, Myriad could garner a hefty takeover premium from larger, acquisition-hungry pharmaceutical or diagnostics firms.

**Bears Say**

- While Myriad has commercialized nine molecular diagnostics products, BRACAnalysis constitutes nearly 75% of total revenue, which puts pressure on the firm to boost sales of other products or risk tying its long-term fate to that of one product.
- The company maintains a healthy history of acquisitions in order to build out the product portfolio and expand into new markets. In some cases, Myriad may not be able to achieve all of its postmerger sales and cost synergy goals, which could result in lower operating margins and earnings growth.
- Myriad must innovate and protect its intellectual property portfolio in order to stay ahead of the blistering pace of technological advancement. The company's BRACAnalysis patents have been the target of litigation, and weaker patent protection on the firm's other marketed tests could make them vulnerable to competition. Furthermore, Myriad faces competition from larger companies with greater resources as well as from more specialized players.

**Competitors** MYGN

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Name	Price	% Chg	TTM Sales \$ mil
<b>Myriad Genetics, Inc.</b>	<b>\$23.80</b>	<b>-0.54</b>	<b>682</b>
Thermo Fisher Scientific Inc	\$101.86	0.51	12,883
Quest Diagnostics Inc	\$54.48	0.52	7,163
Agilent Technologies Inc	\$55.30	0.25	6,831
Laboratory Corporation of America Holdings	\$89.85	0.81	5,777
Life Technologies Corp	\$75.64	0.01	3,842

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and companion diagnostics services in several prominent disease areas, including neurological disorders, infectious diseases, and inflammatory diseases. Pairing diagnostic tests with cancer treatments is an emerging and fast-growing trend, and we expect Myriad will directly benefit from steps to tailor cancer therapy to a patient's genetic profile. While there have been several setbacks with PARP inhibitors at Sanofi SNY and AstraZeneca AZN, we think drugs from this class still have potential when targeted to BRCA mutants, adding to the rationale for testing. We expect to see this division become a meaningful revenue contributor over time as personalized medicine progresses toward a prominent component of clinical care.



While we view Myriad as a powerful player in the molecular diagnostics arena, we are somewhat concerned about its competitive positioning over the long term. In particular, we believe the flagship BRACAnalysis franchise faces an uncertain growth profile and significant pricing pressure due to uncertainties around reimbursement and intellectual property as well as impending competition. Specifically, the rapid transition of DNA sequencing from the research setting into widespread clinical applications is likely to revolutionize the molecular diagnostic landscape. Over time, as such technology is able to glean significantly more information at a fraction of the cost, we believe the market will evolve from limited mutation tests (e.g., BRACAnalysis) to comprehensive multigene panels and whole genome assessment. With fierce competition on the horizon and a possible paradigm shift in routine clinical testing/practice, we remain cautious about Myriad's ability to keep ahead of the field and withstand severe margin and pricing pressure. Simultaneously, we think it is too early to tell if the company's portfolio of emerging tests will prove successful enough to offset a maturing BRACAnalysis franchise and effectively diversify its revenue base. If Myriad is unable to adapt accordingly, forthcoming technologies may ultimately render its products obsolete.

#### **Economic Moat** 05/09/2013

In our opinion, Myriad's predictive medicine business forms the foundation of a narrow economic moat. The majority of total company revenue (74%) stems from BRACAnalysis, a predictive test for mutations tied to an increased risk of hereditary breast and ovarian cancers. The company has benefited from being the first mover in this arena, and with a substantial head start over rivals, it is establishing a devoted user base that should result in long-term, dependable revenue streams. Furthermore, Myriad's gene patents give it a monopoly position in the U.S. that could last until at least 2018, and the firm's access to a proprietary database of thousands of unique mutations should prevent others from achieving the same success for several years beyond patent expiration. In addition, success in this segment is fundamentally dependent on significant investments in R&D and regulatory approval, which help keep competitors at bay and also ensure pricing protection for Myriad's products. With nearly 200 patents and exclusive licenses under ownership, Myriad's broad and deep intellectual property suite provides significant barriers to entry and protects the firm against new and existing competitor encroachment.

Myriad has successfully launched several other products tied to cancer risk or cancer treatment decisions, which has broadened the menu and should help drive business in this high-growth market. The company has nine commercial molecular diagnostics on the market, including COLARIS and COLARIS AP, MELARIS, Prolaris, and BART. These innovative products, which are analyzed in the company's own reference labs, give Myriad control over the entire workflow and lower its cost structure, resulting in industry-leading margins.

We believe the company's core predictive medicine offering provides it with a narrow economic moat. Our model also forecasts returns on invested capital to consistently eclipse costs of capital over the coming years, quantitatively supporting our rating.

#### **Valuation** 05/13/2013

We are increasing our fair value estimate to \$31 per share from \$29 for three key

reasons: slightly more optimistic revenue assumptions for BART and BRACAnalysis over the next five years, a lower tax rate, and a modestly better long-term cost picture (specifically SG&A). For fiscal 2013, we continue to expect top-line growth to remain robust as physician office visits show stability, BRACAnalysis revenue demonstrates continued strength, new product introductions contribute more meaningfully to sales, and demand in the companion diagnostic services segment stays solid. Cost-containment efforts and operational improvements should further aid bottom-line results. Combined, this adds up to an estimated 21% revenue growth and 27% earnings growth in fiscal 2013.

Our longer-term outlook is less positive, however. In particular, we believe the BRACAnalysis franchise will face an uncertain growth profile and significant pricing pressure because of uncertainties around reimbursement, intellectual property protection, and impending competition. While we include a modest amount of revenue from new tests in our valuation, we are skeptical that the company's efforts here will prove successful enough to offset the maturing BRACAnalysis franchise and effectively diversify its revenue base. Taken together, we project a steady decline in revenue throughout our forecast period. Furthermore, following significant margin compression in fiscal 2012, we do not expect to see operational margin improvement during the next five years. We predict continued international expansion, enhanced research and development investments, and pricing headwinds will weigh on results. We estimate Myriad will increase annual revenue 10%-12% and earnings per share 9%-12% over the next two to five years.

Lastly, recent M&A activity in molecular diagnostics may provide an impetus for other companies to pursue similar deals. It could also help provide a floor for group multiples, particularly for companies trading at an enterprise value/EBITDA near or below the implied levels for takeover targets. While we have not incorporated a takeover premium into our fair value estimate and view the immediate possibility as somewhat unlikely, we consider Myriad a potentially attractive target for firms that want to build or expand their in-house molecular diagnostic platforms (for example, larger pharmaceutical or diagnostic companies).

#### **Risk** 05/09/2013

The diagnostics industry moves at breakneck speed, and Myriad operates in a fiercely competitive environment. If established corporations or new entrants introduce better products or develop stronger relationships with customers, Myriad may lose market share or its ability to extract price increases. The company also has significant exposure to regulatory risk, which could change and remain out of the firm's control. Furthermore, BRACAnalysis is still the key driver of profitability, and it remains unclear whether newer tests will prove successful enough to generate a basket of genetic tests and diversify the company's revenue base. Questions around intellectual property further represent a significant overhang. In addition, reimbursement pressure may continue to play a role in Myriad's future and could negatively affect top- and bottom-line results over the long term.

#### **Management** 05/09/2013

We assign the company standard marks for stewardship. Overall, we think Myriad has a strong record of generating shareholder value as it has risen to the top ranks of the molecular diagnostic field. Pfizer PFE veteran John Henderson was elected chairman in 2005. President and chief executive officer Peter Meldrum has been at the helm since 1991 and has a seat on the board. Meldrum introduced and expanded Myriad's BRACAnalysis business, spun off the pharmaceutical business to focus on the firm's core diagnostics products, and is now smartly leading the firm to diversify its portfolio and expand internationally. Myriad has made several small acquisitions of both firms and diagnostics tests in recent years, but it remains unclear whether this will reduce its reliance on BRACAnalysis revenue as the firm faces patent litigation and a rapidly changing sequencing industry. Strong cash flow generation has enabled the firm to begin to return cash to shareholders in the form of share repurchases, and the board is considering initiating dividend payments in the future.

**Overview****Profile:**

Myriad Genetics develops diagnostic products for use in predictive, personalized, and prognostic medicine. The company operates in two core segments: molecular diagnostic tests (95% of sales) and companion diagnostic services (5%). The United States accounts for the vast majority of the firm's revenue. Myriad spun off its pharmaceutical segment in 2009 and expanded its diagnostics business into Europe in 2012. The company is based in Salt Lake City, Utah.

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