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Dan Leonard
(212) 277-6116
Dan.Leonard@Leerink.com

Justin Bowers, CFA
(212) 277-6066
Justin.Bowers@Leerink.com

Reason for report:
INDUSTRY UPDATE

HEALTHCARE EQUITY RESEARCH

LIFE SCIENCE TOOLS AND DIAGNOSTICS

BRCA in Balance; Validity of Medicare Rate Cut Would Pressure MYGN, FMI

S&P 500 Health Care Index: 638.72

Companies Highlighted:
FMI, MYGN

• **Bottom Line**: The final clinical lab fee schedule casts further doubt on the stability of breast cancer (BRCA) gene test pricing. If valid, the proposed cut to BRCA pricing would represent a material headwind to MYGN and also could further pressure reimbursement for FMI's FoundationOne test. We await further clarity, and continue to rate MYGN Market Perform while we rate FMI Outperform.

• **Payment for BRAC 1 & 2 testing deviates widely from September fee schedule**. CMS listed the national payment limit for BRCA1 / BRCA2 testing (CPT code 81211) at $1,438 in the final clinical laboratory fee schedule (CLFS) released late last week. This is 49% below the payment amount ($2,795) from the final 2013 gapfill fee schedule released on 9/30. While 0.75% of the decrease is identifiably due to statutory adjustments (e.g., consumer price index), the remaining, predominant delta in the rate is unidentifiable to us. We are surprised by the magnitude and timing of the rate change, if it is deemed final, since CMS implemented gapfill methodology to determine 2014 payment amounts. This implies that a majority of Medicare contractors revised their payment rates for 81211 downward after filing on 9/30, or CMS is exercising discretion separate from the gapfill methodology for this specific code. Alternatively, the reduced rate could have been a clerical error, which we discussed in our 10/1 note (MYGN Sell-off on BRCA Pricing Misplaced) when this occurred for the same code.

• **If real, the cut would pose a material headwind to MYGN.** The odds that this rate cut is a reality are certainly greater than zero and perhaps even 50/50. We'd find it curious that CMS would publish an erroneous rate for the same code on consecutive fee schedule updates, note that this pricing falls within the ~$1,000 – ~$2,500 range of competitive tests, and also note that MYGN itself has thus far been unable to offer clarity. While Medicare represents only ~10% of MYGN's sales, one would expect commercial plans to follow suit, which exposes ~85% of MYGN's revenue to substantial cuts sooner than expected. We currently model >$3,500 ASP for hereditary cancer testing (including BRCA) in FY2014E, and our thinking on fair value embedded in our $30 price target assumes hereditary cancer test pricing sustains at >$2,000 over the long term. The latter could still be true even if Medicare prices BRCA at ~$1,400, as MYGN migrates its business to myRisk. That said, we believe the pricing uncertainty great enough that we would not consider MYGN's sell-off a buying opportunity.

• **Headwind as well for most new entrants.** Pricing of $1,438 would also represent an incremental headwind for many new entrants in the BRCA testing market, including Ambry and DGX, both of whom charge >$2,000 for their competitive tests. In fact, the only two new entrants for whom this appears neutral to positive are Gene by Gene ($995 list) and Invitae ($1,500 list).

Please refer to pages 3 - 6 for Important Disclosures, Price Charts and Analyst Certification.

• **Any BRCA price cut would adversely affect those who use this code for stacking, including FMI.** If the $1,438 payment for code 81211 holds true, we would find this incrementally negative for FMI, which recognizes much of its clinical testing revenue based on stacked gene codes (clinical testing comprised ~50% of 3Q revenue). While FMI draws 0% of its revenue from Medicare (though 22% of its clinical test volume), Medicare nonetheless sets the tone for many commercial plans. While the importance of BRCA coding in FMI's reimbursement likely varies widely by case, we imagine the 81211 code is an important component for at least some portion of its reimbursement.

MYGN Valuation: Our price target of $30 represents an enterprise value (using projected levels of debt and cash) that is ~5.5x our FY2015 EBITDA estimate (ex options). We believe this steep discount to the peer multiple (~12x EV/FTM EBITDA) is appropriate in light of risks related to oncoming competition in MYGN's core BRCA gene testing business (~75% of revenue).

MYGN Risks to Valuation: Primary risks to our MYGN valuation include, but are not limited to: share loss in hereditary cancer testing, pricing pressure, pressures on healthcare utilization, and greater FDA oversight of lab developed tests (LDTs).

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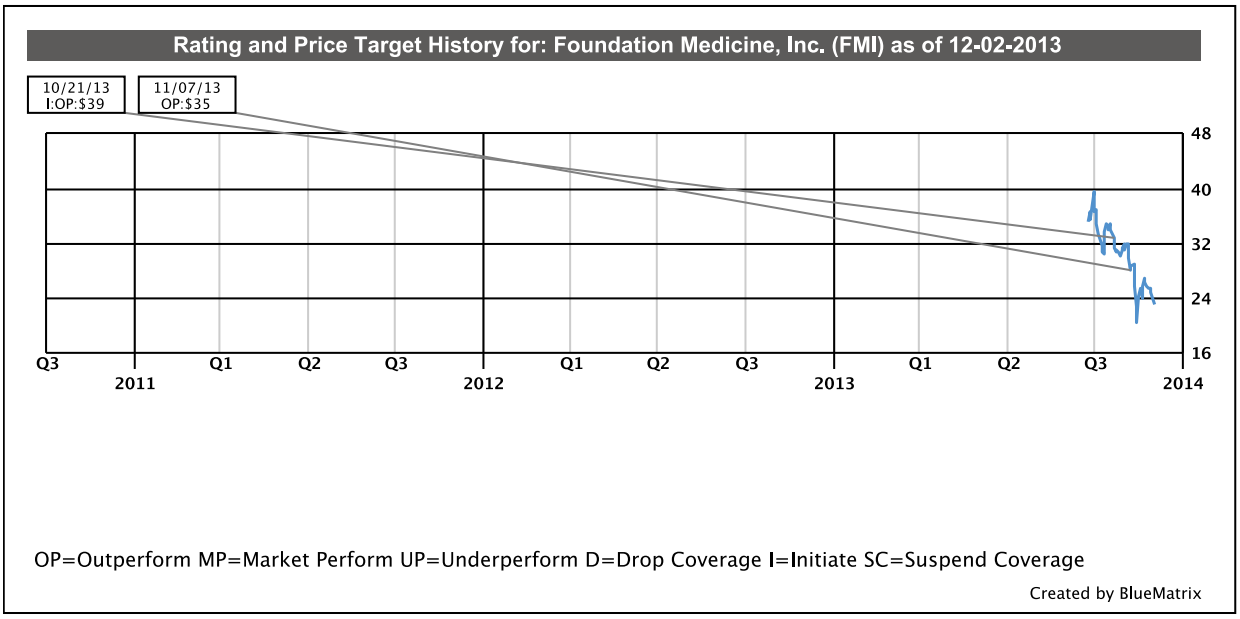
Disclosures Appendix

Analyst Certification

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.



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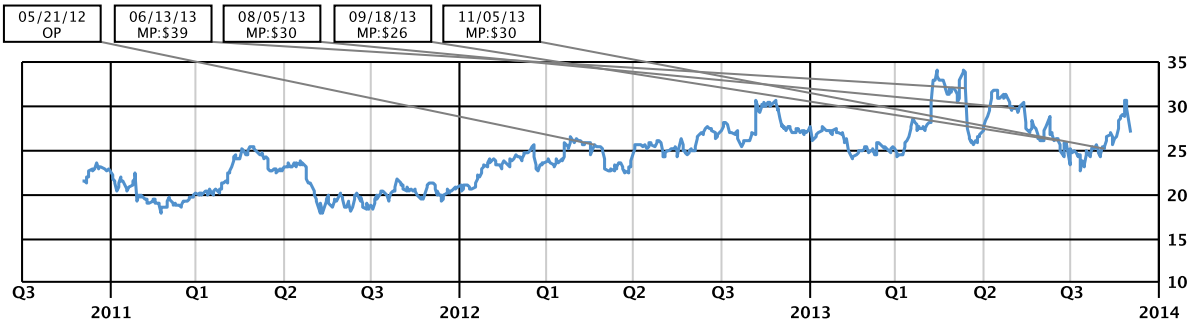
Rating and Price Target History for: Myriad Genetics (MYGN) as of 12-02-2013



Leerink Swann placed a Market Perform rating on MYGN on May 5, 2010. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

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Distribution of Ratings/Investment Banking Services (IB) as of 09/30/13				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

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In the past 12 months, the Firm has received compensation for providing investment banking services to Foundation Medicine, Inc.

Leerink Swann LLC makes a market in Foundation Medicine, Inc. and Myriad Genetics.

Leerink Swann LLC has acted as a co-manager for a public offering of Foundation Medicine, Inc. in the past 12 months.

Leerink Swann LLC Equity Research

Director of Equity Research	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	**Alice C. Avanian, CFA**	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	**John L. Sullivan, CFA**	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	**Howard Liang, Ph.D.**	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Marko Kozul, M.D.	(415) 905-7221	marko.kozul@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Jonathan Chang, Ph.D	(617) 918-4015	jonathan.chang@leerink.com
	Irene Lau	(415) 905-7256	irene.lau@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
Life Science Tools and Diagnostics	**Dan Leonard**	(212) 277-6116	dan.leonard@leerink.com
	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	**Seamus Fernandez**	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
Specialty Pharmaceuticals, Generics	**Jason M. Gerberry, JD**	(617) 918-4549	jason.gerberry@leerink.com
	Christopher W. Kuehnle, JD	(617) 918-4851	chris.kuehnle@leerink.com
Medical Devices, Cardiology & Orthopedics	**Danielle Antalffy**	(212) 277-6044	danielle.antalffy@leerink.com
	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Robert Marcus, CFA	(212) 277-6084	robert.marcus@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	**Ana Gupte, Ph.D.**	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology & Distribution	**David Larsen, CFA**	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	**Mary Ellen Eagan, CFA**	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164