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Foundation Medicine

Hematologic Malignancy Panel Launches Ahead of Expectations; ASH Data Looks Encouraging - ALERT

Over the weekend, Foundation Medicine announced formal commercial launch of the hematologic malignancy panel (vs. prior expectations of an early 2014 launch), while also presenting initial clinical data at the American Society of Hematology Annual Meeting in New Orleans. In line with recent commentary from the company, the data looks encouraging and should bode well for ramp of the hematologic panel next year. That said, we see little to change the underlying investment thesis, as first mover advantage in the high-growth pan-cancer panel market coupled with FMI's operating leverage is balanced by uncertainty around reimbursement timing and competitive dynamics. Reiterate Neutral rating; please see our <u>initiation</u> for detail on our investment thesis, and ASHG <u>recap</u> for notes from our site visit to FMI's new facility in Cambridge.

- Hematologic malignancy panel launches slightly ahead of prior expectations. On Saturday, FMI announced official launch of the second commercial product, the FoundationOne hematologic malignancy panel, which comes slightly ahead of our expectations for an early 2014 launch. As a reminder, FoundationOne Heme uses NGS to assess specimens for 405 genes that are currently known to be somatically altered and unambiguous drivers of oncogenesis in hematologic malignancies, as well as several sarcomas and pediatric cancers. In addition to DNA sequencing, the test also employs RNA sequencing across 265 genes (and hence, has higher COGS than the solid tumor panel) to capture a broad range of gene fusions, a type of alteration found to be a common driver of such cancers.
- New clinical data presented at ASH looks promising. In conjunction with the launch announcement, FMI is also presenting initial clinical data on the hematologic malignancy panel at the ASH conference. In addition to several papers and presentations focused on use of FoundationOne Heme in specific hematologic malignancies, Dr. Ross Levine of Memorial Sloan-Kettering (co-developers of the test) is presenting data based on a study of 317 cancer samples (289 patients) that found that the test identified 885 alterations (including gene fusions with immediate clinical relevance) with a high degree of specificity and sensitivity, along with detection of clinically relevant and actionable mutations. The data (see figure 1) suggests that the FoundationOne Heme panel is able to detect somatic alterations in several hundred genes known to be deregulated in and therapeutic targets for a broad spectrum of hematologic malignancies. Dr. Levine's presentation titled "Identification of Actionable Genomic Alterations in Hematologic Malignancies by a Clinical Next Generation Sequencing-based Assay" starts at 7:15 a.m. CT on Monday, December 9th. A complete list of oral presentations and posters at ASH by FMI can be found here on their website.
- Early launch coupled with positive data and dedicated lab space should all bode well for 2014 ramp. In addition to the early launch and positive data out of ASH, we note that FMI has set aside dedicated lab space for hematologic sample processing at the new facility in Cambridge. Moreover, the new lab also has room to add another sequencing line, should incoming sample volumes ramp substantially over the coming quarters. Taken together (and combined with the strong clinical results), these data points should bode well for a successful ramp in FoundationOne Heme revenue over 2014 and beyond. As a reminder, we assume a U.S. addressable market of ~133K patients for the test in 2014 along with a ramp in penetration from 0.6% to ~12% over the next 5 years. Assuming an initial ASP of \$5,500 (with declines of 3-4% per year), suggests clinical revenue of ~\$2M in 2014 growing to ~\$58M over the same 5-year timeframe. Sales to pharmaceutical customers should generate an incremental \$1-2M

Neutral

FMI, FMI US Price: \$24.61

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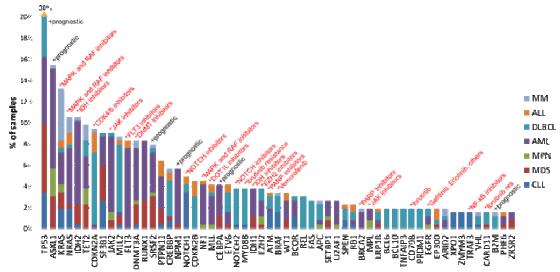
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in revenue per year. Cumulatively, FoundationOne Heme represents a modest \sim 7-8% of our 2014 total revenue forecast. We note that any international clinical revenue generated from the test would represent upside to our current estimates and do not expect a material contribution in 4Q13 given the timing of the launch.

• Maintain Neutral. While we are encouraged by the early launch of FoundationOne Heme and the positive clinical data presented at ASH, we see little to change the investment thesis at the moment. As such, we believe FMI's first mover advantage in the high-growth pan-cancer panel market coupled with its operating leverage is balanced by uncertainty around reimbursement timing and competitive dynamics.

Figure 1: FoundationOne Hematologic Malignancy Panel – Frequency of Detected Alterations



Source: Company reports, Levine et al.



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Foundation Medicine (FMI, FMI US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
21-Oct-13	N	33.99	38.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends. Initiated coverage Oct 21, 2013.

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