

*February 5, 2016*

**Sector Analysis, Initiating Dawson James Sector Indices:  
Molecular Diagnostics**

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Molecular diagnostics as an enabling technology is going to play an increasing role in the execution of President Obama’s “Precision Medicine Initiative”. As such, we believe the innovators in these technologies merit being looked at as an unique subsector of the general clinical diagnostics field. The concept of analyzing specific molecular aspects of a disease, primarily through the use of genomics, is a unifying element among this universe, which includes companies whose products target infectious diseases, certain metabolic diseases/conditions, genetic diseases and cancer. Many of these companies are moving source testing material, traditionally tissue or cultured-based specimens read by pathologists, to the “Liquid Biopsy” approach which is more sensitive, more specific, reduces or eliminates the need for second or follow-on biopsies and thus, ultimately should contribute to overall healthcare cost savings.

**DAWSON JAMES MOLECULAR DIAGNOSTICS INDEX**



**Who’s in our Sub-Sector:** While many have defined the molecular diagnostics space in very broad terms, we have elected to include only those companies whose products generate specific information concerning the identification of disease or the state of disease. This would include monitoring diagnostics, prognostic

diagnostics, companion or “theranostics” and certain types of non-tissue based screening diagnostics. By design, we have not included tools or sequencing systems companies such as Illumina, the broad clinical diagnostic companies such as Abbott or service companies such as Quintiles or Lab Corp. We have included Myriad Genetics (MYGN/Not rated) as the “originator” of the group, despite its outsized market cap compared to the rest of the companies. Our index is a simple price-based index and MYGN volatility does not appear to materially impact the index value positively or negatively. It does however, appear to provide a measure of overall “stability” to the index.

As the accompanying Sector table demonstrates, this is an emerging sector that has not yet demonstrated traditional economic returns. We believe Liquid Biopsy technologies as a whole are on the cusp of a rapid market acceptance, but are held in check at the present, due to a number of regulatory and reimbursement challenges that investors largely ignored until the FDA announced in late 2014 that it would be changing the regulatory path for these products in concert with changes in reimbursement policy by CMS. In particular, the FDA and CMS joint effort intends to close many oversight “loopholes” identified by payors, and move virtually all diagnostics away from the loosely regulated Laboratory Developed Test (LDT)/CLIA pathway into the mainstream medical device regulatory system (Class I, Class II, Class III, depending upon complexity and risk) which requires both clinical validity and clinical utility benchmarks.

An example as to how this shift is affecting molecular diagnostics companies is found in a recent (January 13, 2016) announcement by Foundation Medicine (FMI/Not rated) to form a three-way collaboration with Horizon Healthcare Services in New Jersey and Clinical Outcomes Tracking and Analysis (COTA). The aim of this collaboration is to demonstrate, through the initiation of a prospective clinical trial, the benefit to the patient in terms of overall survival benefit and to payors in terms of cost savings, the clinical validity and utility of using FMI’s FoundationOne® comprehensive genomic profiling for patients with previously untreated metastatic non-small cell lung cancer (NSCLC). This trial will be run under the National Comprehensive Cancer Network guidelines that specifically recommend broad molecular profiling for NSCLC patients. We will be discussing the medical device vs LDT topic in some detail as part of “2016 themes”.

**A few comments on index performance.** We are establishing several subsector indices and have observed that among those we are specifically identifying such Comparative Biology & Vet Biotech, Immuno-Oncology and Rare/Orphan Diseases, the MDx Index has been, by far, the worst performing group in both absolute and relative terms. Among the companies in this group, the earliest “weak link” was T2Biosystems (TTOO/Not rated), which began to slide as early as June 2015. The group was decimated in mid to late August, led by steep declines in MDx Health (MDXH-Br/Not rated) and Foundation Medicine that coincided with both companies reporting reimbursement issues in their second quarter reports.

Additionally, despite relatively good performance from Myriad Genetics and unlike other biotech sectors that saw a small lift during the late fall before collapsing at yearend, this group has remained a mordant “flat-liner” with only two companies, Nanostring Technologies (NSTG/Not rated) and DiagnoCure (CUR-TSE/Not rated) showing some relative strength in the last few weeks. DiagnoCure’s strength is likely tied to its announcement in December of the asset purchase of its PCA3 test by Hologic, Inc (HOLX/Not rated) through its Gen-Probe Inc. subsidiary.

Based upon relative price action over the course of the last year, we believe MDx Health and Foundation Medicine are the group’s “signal securities”. Both companies will be reporting yearend results later this month on February 18<sup>th</sup> and February 23<sup>rd</sup>, respectively. With the level of base this group has established over the past several months, we would expect that if FMI and MDx Health report good results and have positive comments concerning regulatory and reimbursement issues, this group might to begin to finally show some life. *SG*

**DAWSON JAMES MOLECULAR DIAGNOSTICS SECTOR**

Ticker	Security Name	Price*	Intraday		Day Vol	YTD %Chg	Mkt Cap (\$MMs)	EPS FY1	PE FY1
			Chg	%Chg					
ECX-FRA	Epigenomics AG	4.52	-0.25	-5.30%	8,000	103.47%	89	-0.66	--
GHDX	Genomic Health, Inc.	29.03	-0.03	-0.10%	79,211	-17.53%	946	-1.02	--
CUR-TSE	DiagnoCure Inc.	0.14	0	3.57%	7,500	16.00%	6 --	--	--
SQNM	Sequenom, Inc.	1.64	0.07	4.46%	824,190	0.00%	186	-0.29	--
GBI-ASX	Genera Biosystems Limited	0.25	0	0.00%	0	-2.00%	24 --	--	--
NSTG	Nanostring Technologies, Inc.	13.78	-0.32	-2.27%	89,978	-6.32%	275	-1.74	--
MDXH-BRU	MDxHealth S.A.	3.85	0.02	0.50%	29,775	-6.55%	173	-0.27	--
BCART-BRU	Biocartis Group NV	11.98	-0.03	-0.21%	4,506	-9.35%	486	-1.5	--
VRML	Vermillion Inc	1.4	-0.15	-9.68%	18,223	-22.22%	81 --	--	--
ILIU	Interleukin Genetics, Inc.	0.07	0.02	39.72%	68,618	19.66%	9 --	--	--
VNRX	Volitionrx Limited	3.78	-0.07	-1.82%	2,231	-16.00%	71	-0.56	--
TTOO	T2 Biosystems, Inc.	9.44	0.58	6.55%	67,863	-13.71%	211	-2.23	--
ALEHT-PAR	Diaxonhit	0.4	0	0.00%	185,716	-16.67%	30	-0.09	--
GV-PAR	Genomic Vision SA	6.98	0.3	4.49%	5,347	-20.59%	30	-1.4	--
VCYT	Veracyte Inc	5.74	-0.04	-0.74%	32,293	-20.32%	160	-1.3	--
CGIX	Cancer Genetics, Inc.	2.51	-0.01	-0.40%	22,360	-23.94%	27	-1.94	--
TROV	Trovagene, Inc.	3.94	-0.05	-1.25%	306,854	-27.04%	119	-1.05	--
MTST	MetaStat, Inc.	3.55	0	0.00%	103	-24.87%	7 --	--	--
OPGN	OpGen, Inc.	1.54	0.03	2.18%	4,651	-18.79%	21 --	--	--
CDNA	CareDx, Inc.	4.65	0.09	1.97%	9,599	-27.34%	54	-1.12	--
FMI	Foundation Medicine, Inc.	15.31	0.32	2.16%	141,582	-27.28%	516	-2.72	--
ROSG	Rosetta Genomics Ltd	0.87	-0.01	-1.15%	81,105	-29.28%	16	-0.95	--
EXAS	Exact Sciences Corporation	6.61	0.17	2.56%	907,013	-28.44%	620	-1.77	--
TBIO	Transgenomic, Inc.	0.68	-0.04	-6.25%	57,473	-36.92%	15	-1.45	--
ALINT-PAR	IntegraGen SA	3.18	0	0.00%	33,524	-29.18%	16 --	--	--
<b>GBSN</b>	<b>Great Basin Scientific, Inc.**</b>	0.19	-0.01	-4.85%	5,929,093	-79.75%	15	-781.2	--
MYGN	Myriad Genetics, Inc.	36.11	-0.35	-0.96%	924,897	-16.33%	2,598	1.65	21.89

Source: FactSet

\*Prices as of 2/4/2016

\*\* Great Basin Scientific (GBSN/Rated Neutral)

### ***Risk Factors***

In addition to normal economic and market risk factors that impact most equities, and the common risks shared by the companies named in this sector and those in the biotechnology sector as a whole, we believe an investment in any of the Dawson James Molecular Diagnostic Sector companies involves the following risks:

- **Regulatory risks** – the companies in the DJ Molecular Diagnostics Sector are subject to regulatory review for their ongoing research and development activities and manufacturing operations with local, state and federal governmental agencies both in the US and Internationally.
- **Need to defend patents, trade secrets and other intellectual property** – Biotechnology companies rely heavily on intellectual property related to their technology and products. While larger companies may have adequate resources to defend their intellectual property, most of the smaller companies in the DJ Molecular Diagnostics Sector would be materially and negatively impacted by intellectual property infringement or the loss of one or more patents.
- **Historical lack of profitability** – To date this year and in past years, most of the companies in the DJ Molecular Diagnostics Sector have not operated on a profitable basis, and are not forecast to do so in the immediate future. Although companies typically have been able to raise funds from the capital markets, there can be no guarantee that any particular company will not be able raise additional operating capital in the future should losses continue.
- **Competitive Markets** – This universe of companies operate in a highly competitive marketplace, where speed to market, clinical results and other factors bear on a company's viability. There can be no assurance that any one company will be able to continue to market or later launch its products successfully in these competitive markets in the future.

Industry Update Notes provide current information we believe might be noteworthy to investors regarding the subject companies. Industry Update Notes are not intended to be complete research reports. More detailed information concerning the rated companies referenced in this Note, including the full reports, basis for price targets and other disclosures, may be found at: [http://dawsonjames.com/research\\_coverage](http://dawsonjames.com/research_coverage).

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- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	15	65%	10	67%
Market Perform (Neutral)	8	35%	6	75%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>23</b>	<b>100%</b>	<b>16</b>	<b>70%</b>

### **Analyst Certification:**

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