

T2+2™ Market Overview
Metabolomics

August 4, 2009

Metabolomics is the "study of the small-molecule metabolites produced by the body." As a field, it is still relatively nascent, being newer than other "omics" sciences related to genes, proteins and biomarkers such as genomics, proteomics and transcriptomics. Thus far, metabolomics have most often been used in drug discovery, where it is used to study gene mutations and to observe physiological shifts that happen as a result of environmental changes or the use of pharmaceutical products. Currently, there are two primary types of metabolomics: metabolite profiling and metabolic profiling.

- Metabolite Profiling: Also known as "metabolic fingerprinting," metabolite
 profiling allows for the phenotypic characterization of an organism in a noninvasive manner.
- *Metabolic Profiling:* Once metabolites are found using spectroscopy, metabolic profiling can be used to study them, especially alterations in their concentration levels.³

While market sizes are hard to estimate, the following provides our insight into the global metabolomics market:

Market Niche Size			
Market Size in Dollars	Growth Rate	Base Year	Detailed Basis for Estimate
\$200 million	50%	2007	Our market size estimate is taken from a 2007 Outsourcing-Pharma.com article. The same article also quotes market research firm Business Insights as expecting a \$1billion market by the end of 2011. Using the 2007 estimate and the 2011 projection we calculated a compound annual growth rate (CAGR).
\$225 million	107%	2010	Agilent Technologies, in a 2007 press release touting their new metabolomics initiative, estimated that the metabolomics market had been \$38 million in 2002 and would reach \$225 million in 2010 and \$2 billion by 2012 ⁵ . The release did not give a current market size. Our growth estimate was made using the 2010 and 2012 projections.

While the two above market sizes are divergent, they have in common an extremely robust growth rate and future projections that are of the same order of magnitude. We

¹ "Metabolomics: The Next Omics Technology for the Diagnostics Industry." September, 2005. *Decision Resources, Inc.* Research and Markets web site. http://www.researchandmarkets.com/reports/314824 (August 4, 2009).

² "Advances in Metabolomics (Technical Insights)." March 30, 2008. Frost & Sullivan web site (subscription required). http://www.frost.com (accessed August 3, 2009).

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⁴ Reymond, Emilie. "Finnish CRO Dives into Metabolomics Sea." June 21, 2007. Outsourcing-Pharma web site. http://www.outsourcing-pharma.com/Clinical-Development/Finnish-CRO-dives-into-metabolomics-sea (accessed August 3, 2009).

⁵ "Agilent Technologies Launches Metabolomics Initiative with New Web Site and Customized METLIN Database." February 26, 2007. http://www.agilent.com/about/newsroom/presrel/2007/26feb-ca07009.html (accessed August 3, 2009).

believe that the differences are most likely attributable to the still-early stage of development of the metabolomics market.

Market size and growth rate are a function of the number of people in the market and the anticipated rate of buying. As markets transition between emerging, growth, shakeout, mature, and declining, the basis for competition and the number of competitors usually changes, along with the factors influencing adoption of innovation. The number of and growth rate for customers suggests how many units might be sold.⁶

Our Current View on the Phase of the Market		
Today Trend		
Growth	Growth	

Our research indicates that the field of metabolomics is in a growth phase. Its required techniques and technologies, such as gas chromatography, mass spectrometry and Raman spectroscopy, are all widely used. Furthermore, the human metabolome has only 2,500 molecules, a number far below the quantity of genes and proteins in the human body, enabling metabolomics to develop quickly and to take its place "alongside genomics, transcriptomics, proteomics, and other large-scale experimental platforms." Additionally, as noted in the market size section of this report, the metabolomics market is growing extremely rapidly, which is indicative of a market that has achieved a dominant design and reached "take-off."

Markets can also be described in terms of the basis for competition (best technological performance, best value or the price/performance tradeoff that best matches the endusers' preferences, lowest cost, or best availability or the ability to get the product quickly). This dimension helps to define the context in which a commercialization strategy must be developed.

Basis for Competition in the Arena		
Today	Trend	
Best Value	Best Value	

⁶ For a detailed discussion of the "innovativeness dimension," see Everett M. Rogers, *Diffusion of Innovations*, 4th ed. (New York: Free Press, 1995). For further readings related to market phases and innovation, see also James Utterback, *Mastering the Dynamics of Innovation* (Boston: Harvard Business School Press, 1996) and Vijay K. Jolly, *Commercializing New Technologies: Getting from Mind to Market* (Boston: Harvard Business School Press, 1997).

⁷ "Advances in Metabolomics (Technical Insights)." March 30, 2008. Frost & Sullivan web site (subscription required). http://www.frost.com (accessed August 3, 2009).

⁸ "Metabonomics Providing Clues to Discovery." March 1, 2005. Genetic Engineering & Biotechnology News. http://www.genengnews.com/articles/chitem.aspx?aid=938&chid=2 (accessed August 3, 2009). ⁹ Marx, Vivien. "Bracing for a Metabolomics Data Storm, Thermo, Genedata Partner on Informatics." October 3, 2008. *Bioinform*. Genome Web web site. http://www.genomeweb.com/informatics/bracing-metabolomics-data-storm-thermo-genedata-partner-informatics (accessed August 3, 2009).

One of the reasons for the rapid growth of the metabolomics market is its cost-effectiveness when compared to other methods of biomarker detection. Furthermore, we found evidence that a positive attribute of new tools developed for metabolomics research is cost-effectiveness. As the term "cost-effective" refers to the trade-off of price and performance, these findings indicate a market where competition occurs based on value.

In each market there may be stakeholders and companies with significant market share that will influence the introduction of your technology. Some organizations or companies that will likely influence the introduction of this technology are the following:

Examples of	Examples of Major Competitors in the Arena		
Competitor	Relevance	Web site	
Agilent Technologies	Manufacturer of both discovery and targeted metabolomics systems, as well as data analysis solutions. 12	http://www.metabolics-lab.com	
Thermo Fisher	Provider of software and research technologies for metabolomics. 13	http://www.thermo.com/com/cda/landingpage/0,,2430,00.html?ca=metabolomics	
Molecular Biometrics	Developer of proprietary biospectroscopy technology for metabolic profiling. Near-Infrared-Spectroscopy (NIR) is also incorporated into their	http://www.molecularbiometrics.com	

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¹⁰ Schnackenberg, Laura K. and Richard D. Beger. "Metabolomic biomarkers: their role in the critical path." *National Center for Toxicological Research*. U.S. Food & Drug Administration. http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/ArticlesandPresentations/ucm077544.htm (accessed August 3, 2009).

Barbas, C. et al. "Capillary electrophoresis as a metabolomic tool in antioxidant therapy studies." January 20, 2008. *Journal of Pharmaceutical and Biomedical Analysis*. ScienceDirect web site. http://www.sciencedirect.com/science? ob=ArticleURL& udi=B6TGX-4RMNYG2-3& user=10& rdoc=1& fmt=& orig=search& sort=d& docanchor=&view=c& acct=C000050221& ver sion=1& urlVersion=0& userid=10&md5=df00e372e2948d69f6fbba1558d29145 (accessed August 3, 2009)

¹² "Metabolomics." Agilent Technologies. http://www.metabolomics-lab.com/ (accessed August 3, 2009).

¹³ "Metabolomics Resource Center." Thermo Fisher web site. http://www.thermo.com/com/cda/landingpage/0,,2430,00.html?ca=metabolomics (accessed August 3, 2009).

	technology platform. ¹⁴	
Genedata	Developer of software and computer systems for life sciences research, including metabolomics. Their Expressionist software has been integrated into Thermo Fisher metabolomics systems. Developer of software and computer systems of life sciences. The science systems and computer systems of life software and computer systems. The science systems of life software and computer systems. Developer of software and computer systems of life sciences. The science systems of life software and computer systems. The science systems of life sciences are specifically as the science systems. The science structure is the science systems of life sciences and computer systems. The science structure is the science systems of life sciences and computer systems. The science structure is the science systems of life science systems of life sciences and computer systems. The science systems of life sciences are specifically systems of life sciences and computer systems. The science systems of life sciences are specifically systems of life systems of life systems of life systems of life systems. The science systems of life systems o	http://www.genedata.com
Metabolon	Metabolomics services provider that also uses their technology to turn discovered biomarkers into diagnostic tests for prostate cancer and diabetes. ¹⁷	http://www.metabolon.com
Metabometrix	Company spun out from research of metabolomics pioneers at Imperial College in the U.K. The company has several technologies for creating and analyzing metabolomic data. 18	http://www.metabometrix.com/homepage.php

 ^{14 &}quot;Technology." Molecular Biometrics web site.
 http://www.molecularbiometrics.com/instrumentation.html (accessed August 3, 2009).
 15 "About Genedata." Genedata web site. http://www.genedata.com/company/overview.html (accessed August 3, 2009).

¹⁶ Wilkinson, Dr. Matt. "Thermo Fisher and Genedata to accelerate metabolomics research." July 20, 2008. LabTechnologist web site. http://www.labtechnologist.com/Applications/Thermo-Fisher-and-Genedata-to-accelerate-metabolomics-research (accessed August 3, 2009).

17 Metabolon web site. http://www.metabolon.com/ (accessed August 3, 2009).

18 Metabometrix web site. http://www.metabometrix.com/homepage.php (accessed August 3, 2009).

Human	Japanese	http://humanmetabolome.com/comp.php
Metabolome	company	
Technologies	developing	
	innovative	
	technologies	
	using capillary	
	electrophoresis	
	mass	
	spectrometry.	
	Their target	
	markets are	
	drug discovery	
	and food	
	production. ¹⁹	

Stakeholder	Relevance	Networking Channels with Contact Information Contact Information
Metabolomics	Organization that	2510 Sam Noble Parkway
Society	promotes the use and	Ardmore, OK 73401
•	research of	Tel: 580-224-6604
	metabolomics. Has	
	500 members, and	http://129.128.185.121/metabolomics_society/contact_us.html
	sponsors an annual	
	international	
	conference, held this	
	year in Edmonton,	
	Alberta. ²⁰	
The Human	Funded by research	Connie Sobsey, Research Coordinator
Metabolome	organization Genome	PANAMP
Project	Canada, the Project's	404 Athabasca Hall
	goal is to catalogue	University of Alberta
	all of the metabolites	Tel: 780-248-1205
	in the human	
	metabolome. Also	http://www.metabolomics.ca
	runs the Human	
	Metabolome	
	Database at	
	http://www.hmdb.ca/.	
	21	
Drug	Professional	800 Enterprise Road, Suite 200
Information	association with over	Horsham, Pennsylvania 19044-3595
Association	18,000 members that	Tel: 215-442-6100
	seeks to facilitate	
	education and	http://www.diahome.org
	information sharing	
	regarding	
	pharmaceuticals,	
	with a focus of	

^{19 &}quot;Company Overview." Human Metabolome Technologies web site.

http://humanmetabolome.com/comp.php (accessed August 3, 2009).

20 Metabolomics Society web site. http://129.128.185.121/metabolomics_society/ (accessed August 3, 2009).

^{2009). &}lt;sup>21</sup> The Human Metabolome Project web site. http://www.metabolomics.ca/ (accessed August 3, 2009).

	discovery and development.	
Metabolomics	A new laboratory set	Vladimir Tolstikov, PhD
Core	up by the Genome	Tel: (530) 754-5357
Laboratory	Center of the	vtolstikov@ucdavis.edu
	University of	
	California-Davis that	http://metabolomics-core.ucdavis.edu/
	uses mass	
	spectrometry for	
	metabolomics	
	research. ²²	
U.S. Food &	The CPI is FDA's	Dr. Rachel Behrman, Director
Drug	agency-wide	Food and Drug Administration
Administration	initiative to develop	10903 New Hampshire Ave
(FDA) Critical	the fundamental	Silver Spring, MD 20993-0002
Path Initiative	research that	Tel: 888-463-6332
(CPI)	underpins the life-	
	cycle of drugs,	http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/
	including	<u>default.htm</u>
	discovery. ²³	

Entry barriers are obstacles that remove customer segments from the market for some period of time. They limit the size of the addressable market in general or the market share that can be captured. These barriers must be overcome or avoided to have a successful market entry. Our work to date suggests the following entry barriers may prevent customer segments from buying this type of technology for some period of time.

Market Entry Barriers		
Name of Barrier	Description/Why	
Computational Issues	Despite the rapid growth of metabolomics, there is still a great deal of work to be done before it can be considered a complete, mature field. As of 2006, over 60% of metabolites still had an unknown chemical nature, and the pathways and networks of the metabolism still required identification. However, in order to do this work, advanced bioinformatics computer systems and software are required, the current lack of which is likely restricting the applications of metabolomics. ²⁴	
Lack of Integration with Genomics and Proteomics	Although part of the same larger "omics" family of scientific fields, there is currently little direct connection between metabolomics and genomics and proteomics, which focus on genes and proteins, respectively. This means that metabolomics research occurs in something of a vacuum, making the interpretation of resulting data difficult. ²⁵	
Quantity of Data	Metabolomic techniques generate very large amounts of data—millions of datapoints per second over a ten-minute or longer analysis. As a result, it is	

²² Metabolomics Core Laboratory web site. http://metabolomics-core.ucdavis.edu/ (accessed August 4,

²³ "Critical Path Initiative." Food & Drug Administration web site. http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm (accessed August 4,

²⁴ Mendes, Pedro. "Metabolomics and the Challenges Ahead." 2006. *Briefings in Bioinformatics*. Oxford Journals web site. http://bib.oxfordjournals.org/cgi/content/full/7/2/127 (accessed August 4, 2009). ²⁵ "Advances in Metabolomics (Technical Insights)." March 30, 2008. Frost & Sullivan web site

⁽subscription required). http://www.frost.com (accessed August 3, 2009).

critical that these data be evaluated in a sophisticated manner and the meaningful
points separated from the meaningless ones. Thus far, companies have had great
difficulty developing techniques for identifying the important data. ²⁶

Although metabolomics is clearly making inroads very quickly, it is apparent that it is still in the early stages of its development. There is a great deal about the composition and behavior of many metabolites, as well as the overall metabolism, that scientists just don't know.²⁷ As a result, advanced systems that can capture and analyze metabolomic data appear to be crucial for the continued development of the market.

Market drivers are forces that strengthen or weaken the importance of end-user needs over time. Practice level drivers are micro-economic; they affect the end-user directly. They influence the selection of substitutable goods and thus affect market share. Arena level drivers affect the organizations and industrial sectors in which the end-users work. They influence the overall demand for goods like this technology and its substitutes. They affect when and how much of the total addressable market is actually going to be in the market and buying.

Market Drivers	
Name of Driver	Why Significant
Cost of Developing New Chemical Entities (NCEs)	NCEs are previously unknown candidate drug molecules that are critical to the development of novel pharmaceutical products. ²⁸ They are extremely expensive to develop, with the average NCE costing \$1 billion to develop and only one-infive resulting in a marketable drug. Furthermore, NCEs can take eight-to-ten years to receive FDA approval. As metabolic profiling can discover toxicity very early in the NCE development timeline, it has the potential to save drug companies a great deal of time and money. ²⁹ This will likely be a significant driver of metabolomics market growth.
Collaboration Between Stakeholders	In order to drive the growth of metabolomics, many players in the market have partnered to share resources and expertise. For example, Agilent Technologies and the National Jewish Medical and Research Center have partnered on R&D, as have Chenomx and Umetrics AB, in order to develop an advanced metabolomics data analysis platform. ³⁰ Such collaboration will likely serve as a market driver.
Applications Beyond Drug Discovery	While drug discovery has thus far been the primary application of metabolomics,

²⁶ Marx, Vivien. "Bracing for a Metabolomics Data Storm, Thermo, Genedata Partner on Informatics." October 3, 2008. *Bioinform*. Genome Web web site. http://www.genomeweb.com/informatics/bracing-metabolomics-data-storm-thermo-genedata-partner-informatics (accessed August 3, 2009).

²⁷ Ibid.

²⁸ "New Chemical Entity." GeneEd web site. http://www.geneed.com/website/catalog/glossary_search.php?id=2491&search_term=new%20chemical%2 0entity&select=TRUE (accessed August 4, 2009).

²⁹ Schnackenberg, Laura K. and Richard D. Beger. "Metabolomic biomarkers: their role in the critical path." *National Center for Toxicological Research*. U.S. Food & Drug Administration. http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/ArticlesandPresentations/ucm077544.htm (accessed August 3, 2009).

³⁰ "Advances in Metabolomics (Technical Insights)." March 30, 2008. Frost & Sullivan web site (subscription required). http://www.frost.com (accessed August 3, 2009).

there are other applications where it could also fit well, such as agriculture and animal breeding, organ transplant monitoring, and preterm birth prediction. ³¹ Additionally, the biomarkers found with metabolomics are being used to develop diagnostic tests by companies such as Metabolon (for prostate cancer and
diabetes). ³² Such additional applications are likely to increase the growth in the metabolomics market.

The combination of these drivers has made for a potent brew, as our research found that in the near- to mid-term metabolomics will be a "dynamic" market that is "set to boom."34

Here are some additional data and sources that can help you better understand the market.

Name	Description
Metabolics	Metabolics is the journal published by the Metabolomics Society.
	View it at the following URL: http://www.springer.com/life+sci/biochemistry+and+biophysics/journal/11306
Metabolomics.net	Metabolomics.net is a portal for information, events and news related to metabolomics.
	View it at the following URL: http://www.metabolomics.net

31 Ibid.
32 Metabolon web site. http://www.metabolon.com/ (accessed August 3, 2009).
33 "The Future of Metabolomics." Business Insights web site.

http://www.globalbusinessinsights.com/content/rbdd0010m.pdf (accessed August 4, 2009).

Reymond, Emilie. "Finnish CRO Dives into Metabolomics Sea." June 21, 2007. Outsourcing-Pharma web site. http://www.outsourcing-pharma.com/Clinical-Development/Finnish-CRO-dives-intometabolomics-sea (accessed August 3, 2009).