Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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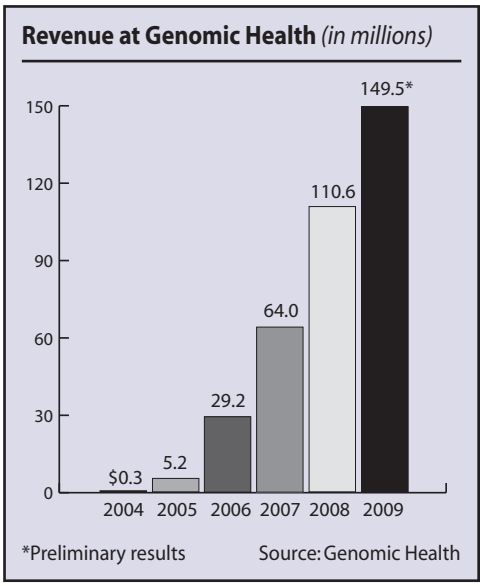
Genomic Health Revenue Climbs 35% in 2009

Genomic Health (Redwood City, Calif.) expects to realize 2009 revenue of $149.5 million. The company's preliminary total revenue for the year represents a 35 percent increase over the $110.6 million it reported in 2008. Meanwhile, clinical adoption of Genomic Health's flagship Oncotype DX breast cancer test grew by 24 percent in 2009, when the company's CLIA-certified laboratory performed 49,030 tests.



So, is there room for the $3,910 test to grow? "If you think about the breast cancer population, we've really only penetrated the U.S. population by about 30 percent," said Genomic Health President and CEO Kim Popovits on Jan. 11 at the J.P. Morgan Healthcare Conference in San Francisco. "And if you look at the worldwide opportunity, where we're now spending more of our time and resources, it's about 10 percent penetration there." For more on Genomic Health, see *Inside the Diagnostic Industry*, p. 5.

Quidel to Acquire Diagnostic Hybrids for $130M

Quidel (San Diego) is moving from the bedside to the bench. The point-of-care test maker has agreed to acquire privately held Diagnostic Hybrids (DHI; Athens, Ohio) for approximately $130 million in cash. The transaction is expected to close by the end of March.

Founded in 1983 as a spin-off of Ohio University, DHI manufactures and commercializes direct fluorescent in vitro diagnostic assays used in hospital and reference laboratories for conditions including viral respiratory infections, herpes, chlamydia, and thyroid diseases. The company, which had 2008 revenues of $38 million, has approximately 200 employees, including a direct sales force of eight that serves approximately 700 North American customers.

While DHI sells its products internationally through distributors, 97 percent of revenues come from domestic sales. "We see international expansion as one of several good growth opportunities," said John Radak, chief financial officer of Quidel, on a Jan. 11 conference call with investors and analysts.

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▲ **Quidel to Acquire Diagnostic Hybrids,** *from page 1*

On the product development side, the acquisition would diversify Quidel's flu-heavy diagnostic portfolio to include nonseasonal infectious diseases as well as autoimmune diseases. Additionally, both Quidel and DHI have begun investing in developing molecular diagnostic capability, and Quidel plans to coordinate and synchronize these efforts.

Quidel also plans to take advantage of DHI's expertise in antibody development and cell culture to improve the sensitivity of lateral flow products and the speed and ease of use of cell-based assays. "For example, DHI's strength in monoclonal antibody development can be leveraged in our QuickVue products to improve sensitivity of existing assays and increase the rate of new product introductions," said Douglas Bryant, president and CEO of Quidel.

Quidel plans to operate Diagnostic Hybrids as a subsidiary, and its current president and CEO, David Scholl, Ph.D., will remain president of Diagnostic Hybrids and become a senior vice president of Quidel.

Predictive Biosciences Buys CLIA-Certified Anatomic Pathology Lab

Predictive Biosciences (Lexington, Mass.) has acquired OncoDiagnostic Laboratory (Cleveland), a CLIA-certified anatomic pathology and molecular diagnostics lab serving urologists, gastroenterologists, dermatologists, gynecologists, and other subspecialty physicians. This strategic acquisition, for which financial details were not disclosed, provides Predictive with a fully integrated pathology laboratory through which the company will commercialize its proprietary noninvasive molecular cancer diagnostic assays beginning later this year.

Privately held ODL, which was founded in 1985 by a group of pathologists, will continue to operate from its Cleveland headquarters. The company has 40 employees, including a national sales force that is supported by company pathologists, laboratory staff, and customer service.

In addition to histopathology, immunohistochemistry, and cytopathology, ODL performs testing for a range of prognostic markers, including Bcl-2, p53, and HER-2/neu. The laboratory's menu of molecular diagnostic tests includes UroVysion, human papilloma virus, and chlamydia/gonorrhea.

Launched in 2006 and funded by a consortium of venture capital firms, Predictive Biosciences develops biomarker-based tests for cancer diagnosis. Its first tests are intended to monitor bladder cancer recurrence through the detection of proprietary urinary biomarkers, including matrix metalloproteinases and a disintegrin and metalloproteinases.

Acquiring ODL gives Predictive Biosciences a fully integrated pathology laboratory through which it can commercialize its assays. "We look forward to leveraging ODL's urology-focused sales organization to introduce our proprietary bladder cancer assay later this year," said Peter Klemm, Ph.D., president and chief executive officer of Predictive Biosciences.

ADA Issues Updated Recommendations for Diabetes Testing

New clinical guidelines issued by the American Diabetes Association (ADA) include the recommendation that the hemoglobin A1C test be used for diagnosing diabetes. The updated standards of care for diabetes screening, diagnosis, and prevention appear in a supplement to the January 2010 issue of *Diabetes Care*, the journal published by the ADA.

This marks the first time that the ADA has recommended the diagnostic use of A1C testing, which measures a person's average blood glucose level over the previous two to three months. The assay had suffered from lack of standardization, but today's highly standardized A1C assays produce results that can be uniformly and widely applied, notes the ADA.

The recommendations cite a 2009 report in which a committee of international experts recommended the use of the A1C test to diagnose diabetes with a threshold of greater than or equal to 6.5 percent and note that the ADA affirms that decision. "The diagnostic test should be performed using a method certified by the National Glycohemoglobin Standardization Program and standardized or traceable to the Diabetes Control and Complications Trial reference assay," noted the ADA. "Point-of-care A1C assays are not sufficiently accurate at this time to use for diagnostic purposes."

The ADA also recommends that the A1C test be used to identify people with "pre-diabetes," those at increased risk for developing the type 2 form of the disease, which frequently is not diagnosed until complications appear. The ADA estimates that approximately one-fourth of all people with diabetes in the United States may be undiagnosed.

"This recommendation will help in the battle against diabetes because the HbA1C test, unlike other tests, does not require individuals to fast ahead of time," said David Mongillo, vice president of policy and medical affairs for ACLA, which applauded the ADA decision to recommend A1C testing for diagnosis and screening. "We hope this increased convenience will allow more individuals to get tested and find out whether they are at risk."

Cepheid Receives FDA Emergency Use Authorization for H1N1 Flu Test

Cepheid has been granted emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Xpert Flu A Panel test. The test, which runs on Cepheid's GeneXpert System, identifies the 2009 H1N1 influenza virus in less than one hour. The FDA has authorized Cepheid's Xpert Flu A Panel to be used in laboratories certified under CLIA to perform "moderate complexity" (not waived) testing.

"Although PCR testing is now recognized as the new gold standard for detection of influenza virus infection, test availability for 2009 H1N1 has so far been limited to high-complexity laboratories and results are not typically available around the clock," said Cepheid CEO John Bishop. "Xpert Flu A Panel combines the convenience and ease-of-use of rapid testing with the performance of PCR."

Meanwhile, Cepheid is developing continue an expanded influenza panel product that it expects to able to test for Influenza A with strain identification for H1 seasonal and H3 seasonal influenza A subtypes, the 2009 H1N1 subtype, and Influenza B. The company plans to submit a separate 510(k) for that product later this year.

Philips and bioMerieux to Jointly Develop Point-of-Care Tests

This is a noteworthy move for Philips Healthcare, which has steered clear of in vitro diagnostics in favor of focusing on the diagnostic imaging and home health care markets.

Philips (Amsterdam) and bioMerieux (Marcy L'Etoile, France) have partnered to develop a line of point-of-care tests. The fully automated and handheld tests will be designed for use in critical care settings within hospitals. While the companies have not provided details on the specific applications of the immunoassay-based tests, they will likely focus on cardiac markers.

The alliance is a noteworthy move for Philips Healthcare, which has steered clear of in vitro diagnostics in favor of focusing on the diagnostic imaging and home health care markets. The company's clinical care systems division has already established a strong presence in critical care settings with its automated external defibrillators and electrocardiography products.

Meanwhile, despite its status as a major global player in clinical diagnostics, bioMerieux has yet to enter the point-of-care testing market, which the company estimates is growing at a rate of approximately 10 percent annually. Stephane Bancel, CEO of bioMerieux, sees the opportunity to enter this market by combining his company's VIDAS immunoassay platform technology with Phillips' engineering and technology expertise.

As part of the collaboration, bioMerieux will have access to Philips' proprietary Magnotech biosensor technology for hospital-based point-of-care testing applications. Products resulting from the partnership will be cobranded by both companies, with bioMerieux being the exclusive distributor worldwide. The collaboration is expected to reach its first milestone this year, and the companies plan to make products commercially available by 2013.

Abbott Receives CE Mark for Ovarian Cancer Test

Abbott Diagnostics (Abbott Park, Ill.) has received CE Mark (Conformite Europeene) certification for a blood test that can aid in the assessment of epithelial ovarian cancer. Developed with Fujirebio Diagnostics (Malvern, Pa.), the Architect human epididymis protein 4 (HE4) immunoassay runs on Abbott's automated Architect platform.

HE4, a relatively new biomarker, is the product of a gene that is overexpressed in patients with ovarian carcinoma. Several studies have shown that when combined with tests such as those for the widely used serum marker CA125, HE4 testing can help determine the risk of whether a pelvic mass is benign or malignant.

In 2008, the U.S. Food and Drug Administration cleared Fujirebio's HE4 enzyme immunoassay as an aid in monitoring recurrence or progressive disease in patients with epithelial cancer. In the Unted States, the test is performed exclusively by Quest Diagnostics (Madison, N.J.).

Genomic Health Looks to Replicate Its Oncotype DX Across Multiple Cancers, Continents

When asked to compare Genomic Health's business model to that of other diagnostics companies, President and CEO Kim Popovits doesn't have an easy answer. The proprietary research undertaken by the company is similar to that of the pharmaceutical industry, and at $3,910, its Oncotype DX breast cancer test is an outlier on clinical laboratory price lists. At the core of Genomic Health's intensive R&D program and "value-based pricing" is an approach that is centered on cancer patients. "When we looked at building the business and building the model, we wanted to go direct to oncologists," said Popovits, speaking at the J.P. Morgan Healthcare Conference on Jan. 11 in San Francisco. "We wanted to be working directly with patients, not going through intermediaries."

Genomic Health expects to perform 50,000 Oncotype DX breast cancer tests in 2010.

The direct-to-oncology approach, enhanced by the 20 sales representatives hired in 2009, is working. The company recently added Anthem Insurance Companies to its list of contracted payers and is forecasting 2009 revenue of $149.5 million, an increase of 35 percent over 2008.

The company has been savvy in steadily enhancing the clinical value of its 21-gene Oncotype DX test. Launched in 2004 as a test to predict breast cancer recurrence, it has been expanded to include information about a patient's likelihood to benefit from chemotherapy and quantitative genetic results. Popovits considers the expanded clinical utility of the test a significant competitive advantage. "As other assays come into the marketplace that can look at perhaps recurrence, they're not looking at chemotherapy benefit or the single-gene reporting that we have with Oncotype DX," she explained.

The test's ability to impact clinical decisions, a vital criterion for reimbursement, has been demonstrated in five clinical studies, including one published in the Jan. 11 online edition of the *Journal of Clinical Oncology*. The study found that Oncotype DX test results caused doctors to change their treatment recommendations in 31.5 percent of cases, while 27 percent of patients changed their treatment decisions. In most such cases, the change was to avoid chemotherapy. "This is the first study to show that results from this test simultaneously impact decisions by physicians as well as patients," said lead author Shelly Lo, M.D.

Now Genomic Health plans to replicate the success of its breast cancer test across multiple cancers, beginning with an Oncotype DX test for colon cancer. The test will follow the commercialization "recipe" of the breast cancer test, launching in the first quarter of 2010 as a test to predict cancer recurrence. "We'd like to then take this test and do the same thing that we do with breast cancer and start to answer more questions for colon cancer patients," said Popovits. "In 2013, our plan is to be able to answer questions around oxaliplatin [Eloxatin] use for both stage II and stage III patients, and then we also want to take a look at targeted therapies in the colon cancer area."

Another focus is boosting the company's international presence. Genomic Health has approximately 1,000 physician clients outside of the United States and processes samples from more than 50 countries through 10 distribution partners, but sees a much greater market opportunity. "The lab industry is not typically a global industry," says Popovits. "But we intend to make it one with Oncotype DX."

Seeing Strong Growth in Clinical Applications, Life Technologies Expands Molecular Diagnostics Franchise

Life Technologies (Carlsbad, Calif.), the company created by the 2008 roll-up of Invitrogen and Applied Biosystems, will report revenue of approximately $3.2 billion for 2009. The global biotechnology tools company is known for serving biological researchers but is seeing rapid growth in clinical applications of its systems, consumables, and services. This trend has been particularly apparent in molecular diagnostics, an area that Life Technologies recently indicated it will expand through the acquisition of quality controls company AcroMetrix (Benicia, Calif.).

"We see the fastest growth area as being in molecular."

"Increasingly, our technologies are finding their way into the clinical environment," said Gregory T. Lucier, chairman and CEO of Life Technologies, on Jan. 12 at the J.P. Morgan Healthcare Conference in San Francisco. "The fastest growing segment for us is where we're applying the biology beyond research."

The company's technologies are divided among three main categories. Approximately half of its revenue comes from its molecular biology business, with the remaining half split evenly between genetic analysis systems and cell analysis systems.

"We have about $400 million a year in commercial applications of these biological tools," said Lucier. "More and more, we're seeing our customers pull us into the clinical environment as these tools become ever more used for patient therapy."

As Life Technologies works to leverage its portfolio of research technologies in new markets, an important area of focus is molecular diagnostics. Today, approximately 10 percent of the company's revenue comes from diagnostics, through products and technology supplied to diagnostic providers. "We see the fastest growth area as being in molecular," said President and Chief Operating Officer Mark P. Stevenson, speaking at the same conference. He singled out oncology and some infectious disease applications as particularly important to the company.

One indication of Life Technologies' commitment to molecular diagnostics is its recent agreement to acquire Acrometrix, a provider of molecular and serological diagnostic quality control products to clinical laboratories, blood screening centers, and in vitro diagnostic manufacturers. Financial terms of the deal, announced Jan. 12, were not disclosed.

"We see the controls market moving from very large home-brew tests today to buying standardized reagents," said Lucier. "The acquisition [of Acrometrix] is a part of about $300 million a year that we do in basic tools and technologies

that are sold expressly to molecular diagnostic companies or laboratories. It's a great franchise for us, it's growing well, and we want to add to it."

The company's current portfolio of molecular diagnostic products includes assay components such as magnetic beads, fluorescent dyes, and specific antibodies, which can be custom designed for diagnostics manufacturers. Life Technologies also provides a chromogenic in situ hybridization (CISH) kit for HER2 screening of breast cancer patients, a system for automated HLA antibody screening, and molecular diagnostic instruments such as the CE-Marked 3500 Dx Series Genetic Analyzer and the 7500 Fast Dx Real-Time PCR instrument.

The 7500 Fast and 7500 Fast Dx instruments have received emergency use authorization from the U.S. Food and Drug Administration (FDA) for surveillance of the influenza A (H1N1) virus. The company is in talks with the FDA regarding 510(k) clearance for its 3500 instrument and expects to get the regulatory nod later this year. Meanwhile, Lucier noted that the instrument "is finding its way into molecular diagnostics labs for all sorts of DNA fragment analysis."

Looking ahead, Life Technologies plans to expand its molecular diagnostics business by developing more proprietary assays and instruments. "Increasingly, you'll see us move into the product side where we'll have both the platform and the content on these diagnostics," said Stevenson.

The company is working with Asuragen (Austin, Texas) to develop a BCR-ABL test, which can be used to monitor treatment response in chronic myelogenous leukemia patients. A collaboration with TrimGen (Sparks, Md.) intends to create sequencing-based assays for the research of KRAS and BRAF mutations.

The approximately $1 billion sequencing market is particularly significant for the company, a world leader in DNA forensics. Lucier sees a bright future for single-molecule sequencing, which allows users to conduct in-depth DNA analysis in hours as opposed to days.

"This is a remarkable technology that we think will further the movement of this science into the clinical realm," he said. "I can't tell you when and I can't tell you how much, but sequencing will become the basic medical protocol in cancer treatment over some time horizon into the future, and that's where we're taking our technology."

As sequencing becomes ever more efficient and affordable, the company sees a greater role for the technology in clinical diagnostics. "So rather than [test for] specific biomarkers, you're actually going to deeply resequence," explained Stevenson. "And that's the trial we're starting with a number of customers . . . using current short-run sequencing. A lot of short-run sequencing will go on, and that will be used ever more in a diagnostic setting, where we will interpret that as we interpret biomarkers."

Quest Diagnostics Introduces Lab-Developed Test for Colorectal Cancer

Abbott Molecular and ARUP Laboratories are developing their own versions of the test, which detects tumor-derived methylated DNA of the Septin9 gene.

Quest Diagnostics (Madison, N.J.) continues to expand its portfolio of cancer diagnostics. Four months after launching Vermillion's OVA1 test for ovarian cancer, the laboratory testing giant has introduced a molecular test that can aid in the detection of colorectal cancer. Quest's laboratory-developed ColoVantage test assesses the methylation status of the Septin9 gene, a biomarker associated with colorectal cancer.

Septin9 was identified by Berlin-based molecular diagnostics company Epigenomics, which granted Quest a nonexclusive license to the biomarker in February 2008. Abbott Molecular (Des Plaines, Ill.) has also licensed the biomarker, and on Jan. 4 announced that it had received CE Mark certification for RealTime mS9, an automated assay for detecting the Septin9 gene in plasma using Abbott's m2000 real-time PCR platform. Epigenomics is also partnering with ARUP Laboratories (Salt Lake City) and Sysmex (Kobe, Japan) on Septin9 tests.

In October 2009, Epigenomics launched its own Septin9 test, Epi proColon. With a cancer detection rate as high as 70 percent, the test has been found to significantly outperform guaiac fecal occult blood tests, the widely used stool tests that have a detection rate of between 30 percent and 40 percent. The CE-marked test is now offered by several molecular diagnostic laboratories in Europe. Epigenomics is marketing the test through direct sales in its home market of Germany, Austria, and Switzerland, and working with distributors to commercialize the test in other European markets.

Quest is the first commercial laboratory in the United States to offer a laboratory-developed Septin9 test, which the company will market as a supplement to colonoscopy and fecal occult blood tests. "Early detection rates [of colorectal cancer] are dismally low, largely because many patients find existing tests and procedures invasive or unpleasant," said Jon R. Cohen, M.D., senior vice president and chief medical officer at Quest, who noted that the ColoVantage test has yet to be validated as a screening test. "Rather, it may promote further evaluation in patients who have resisted testing in the past or as an adjunct to existing procedures."

Quest already offers a range of colorectal cancer diagnostics. The company's InSure fecal immunochemical test is a U.S. Food and Drug Administration-cleared fecal occult blood test for use in screening for sources of lower gastrointestinal bleeding, based on laboratory testing of a stool-based specimen. Quest also offers mutation testing to help predict if a patient with metastatic colorectal cancer will respond to certain therapies and genetic testing to aid in evaluating a patient's inherited predisposition to colorectal cancer.

Epigenomics has demonstrated in seven peer-reviewed studies involving approximately 3,000 specimens of patients with diagnosed colorectal cancer and of healthy control subjects that methylated Septin9 in blood plasma indicates an increased likelihood of colorectal cancer.

On Jan. 15, Epigenomics announced preliminary results of PRESEPT, a multicenter clinical study to evaluate the Septin9 biomarker's performance for colorectal can-

cer screening in individuals who have not been diagnosed with colorectal cancer. The initial analysis indicates that two of the three testing laboratories involved each achieved cancer detection rates of 62.5 percent, while a third laboratory reported a cancer detection rate of only 28 percent. According to Epigenomics, the steering team of the study "intends to conduct a failure investigation to identify the potential causes for the outlier results observed in the one of the laboratory before reporting final results of the study."

Genetic Variant Linked to Aggressive Form of Prostate Cancer

Researchers have identified an inherited genetic variant associated with aggressive prostate cancer that could one day be used to help distinguish between aggressive and slow-growing forms of the disease at an early stage. The findings were reported online on Jan. 11 in the Proceedings of the *National Academy of Sciences*.

Prostate cancer accounts for one-fourth of all cancer diagnoses in the United States. Although most men have a slow-growing form of prostate cancer, aggressive prostate cancers are currently the second-leading cause of cancer death in the United States, accounting for 27,000 deaths annually.

While multiple genetic variants are associated with the risk of developing prostate cancer, until now there have been no genetic factors associated with disease aggressiveness. "The current inability to accurately distinguish risk for life-threatening, aggressive prostate cancer from the overwhelming majority of slow-growing cases creates a treatment dilemma," said Jianfeng Xu, M.D., Ph.D., professor of epidemiology and cancer biology at Wake Forest University and lead author of the study.

The study involved the analysis of genetic information from 4,849 men with aggressive disease and 12,205 with slow-growing disease to determine if the men with aggressive disease had genetic variants in common. The analysis included participants in the Genetic Markers of Susceptibility study performed by the National Cancer Institute as well as additional study populations in the United States and Sweden.

The researchers identified a genetic variant (rs4054823) that was associated with a 25 percent higher risk of developing aggressive disease.

"A single variant with a moderate effect such as this is unlikely to be sufficient on its own at predicting risk," said Xu. "But its identification is significant because it indicates that variants predisposing men to aggressive disease exist in the genome."

As more variants associated with aggressive disease are identified, it is possible that doctors could test men to determine their risk of aggressive disease not only at the time of diagnosis, but early enough in their lives to target them for increased screening. Xu speculates that "a panel of variants could be an important part of developing a screening strategy that could reduce the number of men requiring screening, thereby reducing overdiagnosis, while also identifying men at risk for developing aggressive disease at a stage when the disease is potentially curable."

New Payers Sign On to McKesson's Molecular Dx Criteria Analysis System

New York-based MVP Health Care and Blue Cross of Idaho are the two latest payers using the InterQual Molecular Diagnostics Criteria system, from McKesson's Advanced Diagnostics Management Division (ADM), which uses reviews of evidence-based medicine to assess appropriateness and utilization patterns in making coverage decisions. This news comes as payers are taking a harder look at unnecessary molecular and genetic testing and are likely to demand more utilization and evidence data from labs before reimbursing for these tests.

InterQual's Web-based suite of services is designed to enable informed test selection, electronic routing, and automatic authorization against centralized rules for coverage and orders. Since the March 2009 introduction of the decision tree-based system, payers in New England, California, and the Midwest have adopted the system, said Matthew Zubiller, vice president of San Francisco-based McKesson's ADM division.

"The goal of these systems is to make it easy for the provider to know if they are ordering an appropriate test and allow the lab to ensure that their evidence is in line, which can be communicated to a payer who is making a coverage decision," said Zubiller. "We also want to work closely with the labs to understand what their evidence needs are so that they are incorporated into the system in an effective way and make sure we are getting the best data to the payers."

Medicare Spending Up, Even as National Health Spending Slows

Medicare spending continues to grow even as the growth in nation's total health tab slowed, in part due to the economic recession, according to the latest annual report on national health spending from the Office of the Actuary at the Centers for Medicare and Medicaid Services.

Medicare expenditures were up 8.6 percent in 2008 to a total of $469.2 billion, following growth of 7.1 percent in 2007. Fee-for-service (FFS) Medicare spending jumped 5.3 percent, compared with the growth rate of 3.8 percent in 2007, caused in part by accelerated spending for hospitals, the report said. Meanwhile, Medicare managed care spending rose 21.3 percent, similar to the 22.1 percent growth in 2007, as more beneficiaries switched from traditional FFS to Medicare Advantage plans.

The report also noted that national health spending grew 4.4 percent in 2008, to $2.3 trillion or $7,681 per person, the slowest rate of growth since the government began tracking expenditures in 1960. The rate was down from 6 percent in 2007, as spending slowed for nearly all health care goods and services, particularly for hospitals.

Still, health care spending continued to outpace overall national economic growth. As a share of the gross domestic product, health spending reached 16.2 percent in 2008, up 0.3 percentage points from 2007. With consumers less able to afford retail prescription drugs and clinical services, out-of-pocket spending grew 2.8 percent in 2008, far below the growth rate of 6 percent in 2007.

IVD Stocks Rose 31% in 2009 Led by Inverness, Clinical Data, Affy

The 16 stocks in the G-2 Diagnostic Stock Index climbed an unweighted average of 31 percent in 2009 versus respective gains of 44 percent and 23 percent for the Nasdaq and the S&P 500.

Rapid diagnostics and health management company **Inverness Medical Innovations** (Waltham, Mass.) was the best-performing stock in 2009 with a gain of 120 percent to $41.51 per share. Meanwhile, the company began the new year with ambitious plans for expanding its business. On Jan. 5, Inverness agreed to pay up to $255 million to acquire Epocal (Ottawa, Canada), the point-of-care blood diagnostics company with which it recently signed a five-year distribution deal. Inverness is also looking overseas. On Jan. 11, the company offered $286 million for a majority stake in Standard Diagnostics (Kyonggi-do, South Korea), which manufactures rapid test kits, enzyme-linked immunosorbent assay kits, and urine test strips.

Also performing strongly in 2009 was **Clinical Data** (Newton, Mass.), which climbed 105 percent to $18.26 per share. In April 2009, the biotechnology company sold its genomics services division, Cogenics, to Beckman Coulter for approximately $17 million as part of a plan to focus its resources on developing two late-stage drug candidates. Shortly thereafter it paid $10 million for Avalon Pharmaceuticals. Later in the year, Clinical Data expanded its Familion line of tests with the launch of a genetic test for dilated cardiomyopathy.

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The worst performing stock in 2009 was **Luminex** (Austin, Texas), which declined 30 percent to $14.93 per share. On Jan. 11, the company adjusted its 2009 full-year projected revenue guidance to between $119 million to $121 million from the most recent guidance of between $118 and $126 million. Look for an offshoot of the company, Rule-Based Medicine, to raise $90 million in an IPO this year. The company uses Luminex technology to perform biomarker-based multiplex testing in its CLIA-certified laboratory in Austin.

IVD Stock Review for 2009

Company (ticker)	Price 12/31/08	Price 12/31/09	52-Week % Change	Market Capitalization
Inverness Medical (IMA)	$18.91	$41.51	120%	3.60B
Clinical Data (CLDA)	8.90	18.26	105	479M
Affymetrix (AFFX)	2.99	5.84	95	390M
Abaxis (ABAX)	16.03	25.55	59	575M
Beckman Coulter (BEC)	43.94	65.44	49	4.74B
OraSure (OSUR)	3.68	5.08	38	235M
Nanosphere (NSPH)	4.76	6.44	35	174M
Bio-Rad (BIO)	75.31	96.46	28	2.79B
Becton Dickinson (BDX)	68.39	78.86	15	18.17B
Johnson & Johnson (JNJ)	59.83	64.41	8	179.48B
Quidel (QDEL)	13.07	13.78	5	462M
Abbott (ABT)	53.37	53.99	1	85.23B
Gen-Probe (GPRO)	42.84	42.92	0	2.20B
Meridian (VIVO)	25.47	21.55	-15	878M
Immucor (BLUD)	26.58	20.24	-24	1.42B
Luminex (LMNX)	21.36	14.93	-30	679M
Unweighted Average			31	

G-2 Insider

Learn how clinical laboratories can capitalize on molecular diagnostics. . . . "Putting MDx to the Test" is the theme of Washington G-2 Reports' fifth annual molecular diagnostics conference, which will take place April 14 to 16, 2010, at the Hyatt Regency Cambridge in Cambridge, Mass. A roster of experts will discuss how to best apply the emerging science, novel business models, and consumer demand of molecular diagnostics to grow your lab in the current regulatory and business environment. Scheduled sessions include:

- ❑ The Future of Molecular Diagnostics, a keynote address by Mara Aspinall, president and CEO of On-Q-ity;
- ❑ Building a Molecular Diagnostics Laboratory at National Jewish Health, a case study presented by Gary Smith, Ph.D., executive director of Advanced Diagnostic Laboratories at National Jewish Health;
- ❑ Molecular Diagnostics Gets Personal, a keynote address by George Church, Ph.D., professor of genetics and director of the Center for Computational Genetics at Harvard Medical School;
- ❑ Reimbursement for Molecular Diagnostics, presented by Rina Wolf, vice president of commercialization strategies, consulting, and industry affairs at XIFIN; and
- ❑ Genetic Counseling and the Clinical Laboratory, presented by Steven Keiles, vice president and director of genetic services at Ambry Genetics and president of the National Society of Genetic Counselors.

For full program details or to register, visit www.g2reports.com/molecular10 or call John Watkins at 800-401-5937 ext. 4710.

Company References

AACC 202-857-0717
Abbott 847-937-6100
Bayer Diagnostics 914-631-8000
Beckman Coulter 714-871-4848
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Biosite 858-455-4808
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