Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

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SIRS-Lab and Pfizer Join Forces to Fight Sepsis

Agreement Exemplifies Partnership Trend

Exemplifying the growing trend toward increased partnerships between diagnostics companies and pharmaceutical companies, SIRS-Lab GmbH (Jena, Germany) and Pfizer Pharma GmbH (Berlin, Germany) recently announced they will work together to fight sepsis. The deal marks an important move toward tandem development of companion products and an expansion in the development of these products outside of the field of oncology.

Together, they will initially focus on diagnosis and treatment of severe fungal blood-stream infections by evaluating the clinical impact of using molecular-based tests and pharmacoeconomics of such interventions. Financial terms of the deal were not disclosed. In a statement the companies said in patients with sepsis, traditional diagnostics can take days to receive results, often promoting the use of ineffective drugs, particularly in the case of antibiotic-resistant infections and fungal infections. Use of molecular diagnostics can rapidly identify microbes within hours, allowing for appropriate tailored therapies and improving patient outcomes. For more on companion diagnostic partnerships, see *Inside the Diagnostics Industry, p. 5.*

Diagnostics IPOs on the Rise, Expected to Continue

It could be a sign of general economic improvement or it could be validation of the increasing importance of diagnostics as scientific advances are beginning to turn the promises of personalized medicine into a reality. Either way, public capital markets are increasingly embracing diagnostics companies as the number of initial public offerings (IPOs) by diagnostics companies has begun to noticeably rise and is expected to continue over the next few years.

"It is a combination of factors—a pent up demand for liquidity events, an opening in the macroeconomic window, and favorable valuations based on recent acquisitions," says Keith Batchelder, CEO of Genomic Healthcare Strategies (Charlestown, Mass.). "And there is a maturation in the personal medicine space. People are really beginning to understand there is a business here and they are moving forward. It is useful to look at the IPO market as part of the evolution of a new space."

Continued on p. 2

Keith Batchelder

▲ **Diagnostics IPOs on the Rise,** *from page 1*

While personalized medicine is rapidly evolving, bringing the new technologies to market is an increasingly lengthy and costly process.

"Lots of companies need access to public markets for capital. It is a cheaper way to get it and smaller companies are often unable to secure debt financing," explains Brian Weinstein, an equity analyst for diagnostics products at William Blair & Co. (Chicago). "The FDA process is longer and the amount of cash needed is higher."

Weinstein adds that typically companies use proceeds from IPOs to fund clinical trials necessary to bring products forward into commercial space, rather than for general research and development. This was the case for recent IPOs of Sequenom and Pacific Biosciences.

In early December, molecular diagnostics developer Sequenom (San Diego) raised nearly $90.5 million in net proceeds from a total of 16.1 million shares at $6 per share in its IPO. The funds will be used to support ongoing testing and development of its trisomy-21 noninvasive, prenatal test, and possibly for acquisitions or investments in complementary businesses, Sequenom said in its prospectus for the offering.

In late October Pacific Biosciences (Menlo Park, Calif.) successfully raised $200 million through an offering of 12.5 million shares at $16 per share, the midpoint of its estimated range of $15 to $17. At the time, Pacific Biosciences, a developer of single-molecule, real-time sequencing technology, stated it intended to use proceeds from the offering in part to increase sales and marketing efforts in advance of its intended commercial launch of the PacBio RS system and to increase the scale of its manufacturing operations. Commercial production is expected to begin in 2011.

"Look for a domino effect. After one goes another company says, 'I will try too.'"

—Brian Weinstein

Successful IPOs Often Spur More IPO Attempts

"Look for a domino effect. After one goes another company says 'I will try too,'" predicts Weinstein. "Lots of small diagnostics companies are marching their way to an acquisition or an IPO. I don't see it slowing down. It will be a steady stream as long as from a macro perspective, market conditions are OK."

It appears as if 2011 will see a number of diagnostics IPOs. In December two companies, Fluidigm and BG Medicine, filed initial documents with the U.S. Securities and Exchange Commission (SEC) for their entries into public markets.

In early December Fluidigm (San Francisco) filed a preliminary prospectus for a proposed IPO worth up to $86.3 million. This marks a reviving of plans for an IPO the company scrapped in September 2008 due to poor economic conditions. The number of shares to be offered and the price range for the offering have not yet been determined, but the company said in its S-1 filing that it plans to trade on Nasdaq under the ticker symbol FLDM.

BG Medicine (Waltham, Mass.) disclosed in mid-December that it plans to raise around $67 million in its IPO from selling 4.75 million shares at an offering price of between $13 and $15. BG Medicine, a cardiovascular diagnostic test maker, abandoned an IPO attempt in 2007 on the Euronext Amsterdam Exchange. In an SEC filing, the company noted that it plans to apply more than half the funds raised by the offering to pay for the commercial launch of its lead product, the manual BGM Galectin-3 test for heart

failure that received U.S. Food and Drug Administration clearance in December.

While a strong management team and a clear path toward revenue and profitability are important to demonstrate during the pre-IPO road show, not all IPO attempts are successful. Complete Genomics' (Mountain View, Calif.) November IPO failed to meet the company's original expectations. Complete Genomics, a sequencing services provider, netted $47 million from selling 6 million shares at $9 per share, well below the company's initial target of $12 to $14 per share. In November, the multiplex molecular diagnostics firm Rules Based Medicine (Austin, Texas) withdrew its registration for an IPO citing unnamed, adverse market conditions.

"We see this in a longer time frame, two to three years, as accelerating," says Batchelder. "I'm optimistic this is the beginning of a trend. It may drop off after a big push and we let out some of the pent up demand, but it is accelerating in the future."

FDA Clears Quest's Simplexa Flu and RSV Test

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the Simplexa Flu A/B and RSV test on the 3M Integrated Cycler that is developed and manufactured by Focus Diagnostics, a subsidiary of Quest Diagnostics Inc. (Madison, N.J.). The test also received CE mark in the fall.

The test employs real-time reverse transcription polymerase chain reaction (PCR) to qualitatively detect RNA of the influenza A or B viruses or respiratory syncytial virus (RSV) in a patient's nasal or nasopharyngeal specimens. These viruses can cause serious respiratory illness but are difficult to clinically diagnose because their signs and symptoms often mirror infection caused by other respiratory viruses. The Centers for Disease Control and Prevention (CDC) estimates that between 75,000 and 125,000 children less than 1 year old are hospitalized each year due to RSV.

Quest's Simplexa test is the first molecular flu test cleared by the FDA that does not require confirmation of results using additional methods, such as virus culture. Additionally, following RNA extraction from a specimen the test takes only about an hour, with results expected to be reported in less than three hours following receipt of a specimen. While the test is currently designated for use in high-complexity laboratories, Focus Diagnostics said they are working with 3M to develop moderate-complexity versions of the test.

Genetic Results Enhance Prediction of Heart Attack Risk

Merging genetic scores with traditional heart attack risk models may refine clinical risk assessments and lead to improved clinical care, particularly for those patients rated at intermediate risk using current models, according to a study presented at the American Heart Association's scientific sessions, held in Chicago Nov. 13-17.

Researchers reported that incorporating genetic information into current models led to the reclassification of almost a third of the individuals evaluated.

The Mayo Clinic researchers, part of the Electronic Medical Records and Genomics (eMERGE) trial, looked at medical records of 1,262 people with no history of heart disease. Using medical records data they estimated the patient's Framingham Risk Score (FRS), or 10-year probability of a heart attack based on conventional risk factors

including age, sex, blood pressure, cholesterol levels, and smoking status. Then, they tested for the presence of 11 gene variants, including the 9p21, a locus on chromosome 9. The selected single-nucleotide polymorphisms (SNPs) have been validated as potential risk factors for heart attacks in genomewide association studies.

Comparing the predictive value of genetic data alone with FRS predictions and models that included both data sets, the researchers revised the classifications of heart attack risk in 386 patients across the risk spectrum.

While the findings need to be validated in prospective studies before they are used in patient care, the researchers are optimistic genetic information can provide cardiologists with better risk estimates and can better target therapy accordingly.

Using Electronic Medical Record Alerts Improves Adherence to Testing Guidelines

Targeted "pop-up" alerts in electronic medical records improve clinician adherence to testing guidelines, according to a study published in the November issue of the *American Journal of Managed Care.* Researchers at Kaiser Permanente report that the messages significantly decreased physician orders for the D-dimer blood test, a test that is notoriously ineffective in elderly populations.

The risk of developing blood clots increases exponentially with age; however, the accuracy of the quantitative D-dimer test worsens as patients get older. The test's accuracy is only 35 percent for patients older than 65.

Despite national clinical testing guidelines, Kaiser Permanente researchers report that more than one-third of D-dimer tests ordered in their system are for patients 65 and older.

The researchers conducted a randomized trial involving eight ambulatory care clinics within the Kaiser Permanente health care system in Colorado. During the study an electronic alert appeared in the electronic medical record order module the moment a physician ordered a blood test for an elderly patient, reminding the physician of the inaccuracy of the D-dimer test in older populations and suggesting alternate diagnostic imaging.

As a result, the rate of D-dimer tests for patients over 65 decreased significantly, from 5.02 to 1.52 per 1,000 patient visits, a relative reduction of nearly 70 percent. When the alert was finally activated in the control clinics after 20 months, they saw a similar drop in test orders from 2.11 to 0.81 per 1,000 patient visits. The researchers were encouraged that the rate remained persistent throughout the intervention.

"To avoid alert fatigue, a very targeted alert to a specific condition and specific age group is more heeded and followed," says the study's lead author, Ted Palen, M.D., Ph.D., a clinician researcher at Kaiser Permanente's Institute for Health Research. "In other alert systems clinicians click-out and ignore them. It is like pop-ups when surfing the Internet; how many do we really look at? Our hope is that these studies help inform the design and use of decision support systems."

Researchers credit the alert's success because it provided an alternative diagnostic suggestion, rather than just discouraging the use of the D-dimer test.

Diagnostic-Pharmaceutical Partnerships Increasing

Companies Working Together to Develop Companion Products

Diagnostics and pharmaceutical companies increasingly are forming partnerships with an eye toward developing companion products, ultimately benefitting not only patients but also the companies involved.

Scientific advances in understanding the human genome have created the ability to tailor drug therapy to an individual's unique genetic makeup. Pressure to increase drug effectiveness has changed how pharmaceutical companies bring products to market. The industry has done away with the blockbuster drug model and increasingly relies upon stratifying patient populations to identify ideal candidates for targeted therapeutics. With this shift comes a newfound recognition by pharmaceutical companies of the importance of diagnostic products and the companies that develop them.

"If we take a historical perspective, there was not a lot of interest in diagnostics in the past," says Peter Tolias, Ph.D., professor and executive director of the Institute of Genomic Medicine at the UMDNJ-New Jersey Medical School. "There was still the mind-frame of going after blockbuster drugs. The low-hanging fruit is picked and then it became more and more difficult [to develop new drugs] and we became more interested in segmenting the market until, now, it is absolutely required."

Technological advances in biomarkers, cost-containment efforts by health care payers, and changes in the regulatory landscape are driving an increased interdependence between therapeutics and diagnostics, necessitating that pharmaceutical companies work with diagnostics companies.

"Partnerships will become a must-have, not a nice-to-have."
—Harry Glorikian, Scientia Advisors

Of the roughly 40 commercially available companion products, most were developed separately. But, increasingly, there is a trend for pharmaceutical and diagnostics companies to develop companion products in tandem, ideally using the same Phase III trial to demonstrate both the efficacy of the drug and the clinical utility of the diagnostic.

"Partnerships will become a must-have, not a nice-to-have," predicts Harry Glorikian, managing partner of Scientia Advisors, a life-science consulting firm based in Cambridge, Mass. "Companion products will be part of the development lifecycle. Competing just on drug merits is too difficult and companies don't have a whole lot of choice with regulation changes and comparative effectiveness."

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) are encouraging the use of companion diagnostics both in the drug approval process and for actual clinical use of prescription drugs as dictated by drug labels. Companion diagnostic tests help to identify patients most likely to benefit from the therapy and assist in appropriate dosing. While impending regulatory directives might incent pharmaceutical companies to submit a companion diagnostic if it will increase chances of a therapeutic's approval, aligning incentives for pharmaceutical and diagnostics companies to work well together may prove to be an additional hurdle.

A Sampling of 2010 Pharmaceutical-Diagnostics Partnerships

Cancer drugs remain the primary target for companion diagnostics with tests intended to target therapeutics and predict toxicity, efficacy, and drug dosage. Some estimate up to 1,000 oncology products in pharmaceutical company pipelines, most of which have associated biomarkers that could lead to companion tests. In 2010 new partnerships focused on oncological diagnostic tests continued to form.

- In November **Roche** (**Basel, Switzerland**) and **OSI Pharmaceuticals Inc.** (**Melville, N.Y.**) agreed to collaborate on the development of a PCR-based companion diagnostic test to identify people with non-small cell lung cancer (NSCLC) that harbors Epidermal Growth-Factor Receptor (EGFR) activating mutations.
- In the spring **Prometheus Laboratories Inc.** (**San Diego**) announced a research collaboration and license agreement with **Bayer Schering Pharma AG** (**Germany**) that pairs Prometheus's proprietary oncology diagnostic platform with Bayer's broad oncology pipeline in an effort to stratify patients to appropriate drug candidates.
- Earlier in the year **Pfizer Inc.** (**New York**) and **DxS** (a wholly owned subsidiary of QIAGEN (**Venlo, the Netherlands**) announced an agreement to develop a companion diagnostic test kit for PF-04948568 (CDX-110), an immunotherapy vaccine in development for the treatment of glioblastoma multiforme (GBM). The QIAGEN assay is designed to identify patients whose tumors express the EGFRvIII mutation, allowing for the possibility of more targeted and personalized treatment. Financial terms of the diagnostic agreement were not disclosed.
- **AstraZeneca and Dako Denmark A/S** announced a collaboration agreement to develop companion diagnostic tests for multiple AstraZeneca oncology projects, including biologics and small molecules, in various stages of discovery and development.

While the field of oncology continues to dominate in the development of companion products, collaborations in other medical specialties emerged in 2010.

- In December the biopharma company **Sirnaomics Partners** (**Gaithersburg, Md.**) announced a partnership with an unnamed Chinese pharmaceutical company for development of its small interfering RNA (siRNA) therapeutic (STP705) for scarless wound healing.
- **Prometheus Laboratories Inc.**, and **Tarrot Laboratories**, a business unit of **Cedars-Sinai Medical Center** (**Calif.**), executed an exclusive research collaboration and license agreement. The collaboration will focus on identifying genetic or serologic markers associated with clinical responses to anti-TNF (tumor necrosis factor) therapies such as Cimzia, Humira, and Remicade utilized in the treatment of Crohn's Disease and the subsequent development of diagnostic tests.
- In the summer **Merck** announced a nonexclusive license agreement with **Laboratory Corporation of America Holdings** (LabCorp) for the commercialization of a genetic test that may help predict the response of patients with Hepatitis C virus (HCV) infection to peginterferon alpha-based therapy.

"The development risk and time to market associated with drug candidates make the development of a companion diagnostic significantly less attractive to major diagnostics manufacturers than the revenues currently available from its more traditional target market of clinical laboratories," says Tolias. "The diagnostic company is not going to make the commitment until there is certainty of viable products. It is different if they devise a test for a drug out there. It is less risky. If a drug fails, the diagnostic product fails too."

This ingrained risk differential, says Tolias, puts the onus on pharmaceutical companies to pay the bills. Increasingly, he predicts, diagnostics companies will start to get royalties on drugs with the profit potential making the risk more bearable.

Pharmaceutical companies feel the need to partner as diagnostic tests are now influencing market approval of drugs and the pricing of drugs.

"Diagnostics information can increase the value of the therapeutic," explains

Keith F. Batchelder, M.D., chief executive officer, Genomic Healthcare Strategies, speaking of Prometheus's experience of increasing drug sales fivefold by stratifying patient selection for the inflammatory bowel disease (IBD) drug Entecort licensed from AstraZeneca. "A company says if you use our diagnostic, there is talk about willingness to pay a higher cost because there is some level of efficacy that they were not sure of before. It is the tail wagging the dog, with diagnostics becoming more important."

While a power shift is occurring, diagnostics companies benefit from the partnerships too, particularly by gaining expertise in branding and marketing from pharmaceutical companies.

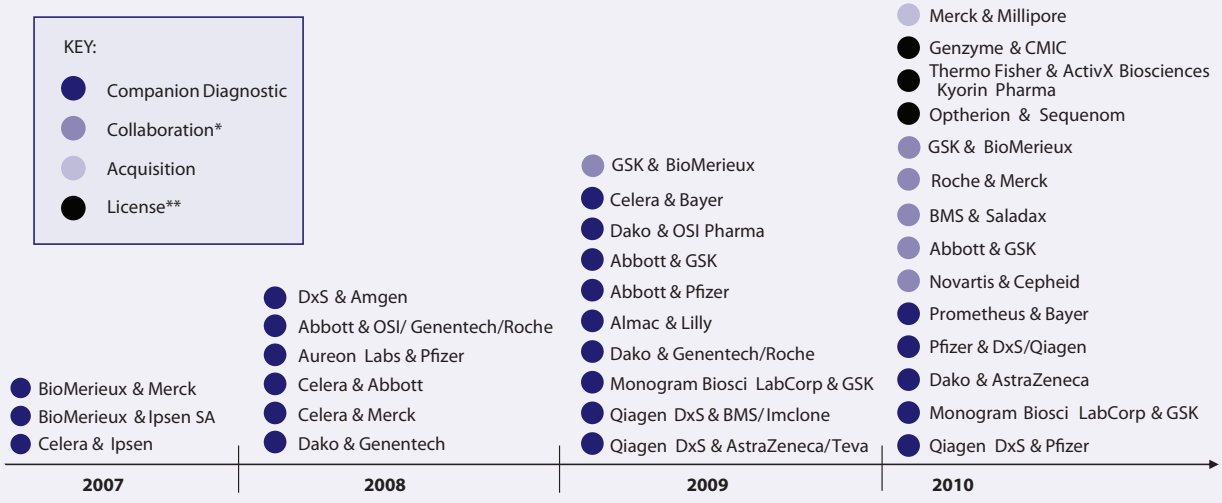
"Patients can tell you the brand name of a drug, but most have no clue of the brand name of a diagnostic test," says Batchelder. Branding and marketing decisions are even influencing diagnostics products prior to commercialization.

"Before, biomarker set points were set by [research and development], but it is now becoming a brand management issue," says Glorikian. "If you set the biomarker low most people get through the system, but if you set it high is the trial big enough? It is not a science decision; it's a marketing decision. It affects market size and penetration."

As the business models behind partnerships evolve and personalized medicine matures, the interdependence of pharmaceutical and diagnostic companies will continue to grow.

"We will see certain advances in oncology and pop-ups in chronic disease management," said Batchelder of future companion diagnostics. "It will be a logarithmic expansion, episodic, but rapidly accelerating. Those who think [expansion of companion diagnostics] is five years from now will miss the bandwagon."

Pharmaceutical-Diagnostics Partnerships



^- List is Not Exhaustive

* Collaboration refers to partnerships biomarker discovery and assay development
**License refers to biomarker or assay licensing deals

Source: *Scientia Analysis*

Genzyme Genetics Acquisition Allows LabCorp to Expand Esoteric Testing

The December completion of Laboratory Corporation of America's (Burlington, N.C.) $925 million acquisition of Genzyme Genetics strengthens LabCorp's position as a provider of personalized medicine products for the oncology field and allows Genzyme Corp. (Cambridge, Mass.) to focus on its therapeutics business.

The Genzyme assets, when combined with Monogram Biosciences assets that LabCorp previously acquired in 2009, will further advance the company's desired expansion of its esoteric testing business and will enhance the company's oncology testing capabilities. The acquisition is expected to bring LabCorp's esoteric testing percentage to about 40 percent of total testing.

"Closing the acquisition of Genzyme Genetics firmly establishes LabCorp as the premier genetics and oncology laboratory in the United States and further strengthens LabCorp's leadership position in personalized medicine," David King, chairman and CEO of LabCorp, told investors in a conference call.

The acquisition also furthers Genzyme's strategic plan to divest its three, noncore business units, Genzyme Genetics, Diagnostic Products, and Pharmaceutical Intermediates, to focus on its therapeutic business, possibly to become an attractive acquisition candidate by another pharmaceutical company. In November the company announced that it has entered into an agreement under which Sekisui Chemical Co. Ltd., part of Sekisui Medical Co. Ltd. (Tokyo), will acquire Genzyme's Diagnostic Products business for $265 million in cash. The proceeds from these divestitures may be used to finance the remaining half of the company's planned $2 billion stock repurchase plan.

CRP Levels Do Not Improve Risk Assessment, Say Researchers

Presentations at the American Heart Association's scientific sessions, held in Chicago Nov. 13-17, demonstrated how diagnostics testing could alter clinical practice assessments of a patient's risk for having an adverse cardiovascular event.

Screening for high-sensitivity C-reactive protein (CRP), an inflammatory marker, does not improve conventional heart disease risk assessment in patients with traditional risk factors, researchers found. The results question the clinical utility of CRP levels in risk evaluation.

Researchers analyzed 4,853 patients in the United Kingdom and Ireland in the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), which compared the cholesterol-lowering effects of atorvastatin (Lipitor) to a placebo. Pfizer, which manufactures the drug, funded the study. CRP was measured at baseline and at six months.

Over five years 485 participants had a cardiovascular event. Those cases were matched with 1,367 controls who hadn't had a cardiovascular event. Statistical models tested the association between cardiovascular events and patients' cholesterol and CRP levels.

The researchers found that participants' baseline levels of low-density lipoprotein (LDL) cholesterol and levels of CRP were both predictive of cardiovascular events. However, after the researchers considered other risk factors, neither baseline nor on-treatment CRP provided useful information about the efficacy of statin treatment to reduce cardiovascular events beyond LDL reduction.

While the merits of CRP testing continue to be debated at professional cardiology meetings, the researchers concluded that the results do not support current proposals to measure CRP in the clinical setting either to assign statins to patients on the basis of an elevated CRP alone or to monitor CRP levels as an indicator of the efficacy of statin treatment.

Study Validates First Test for Common Orthopedic Condition

Kenneth Ward, M.D.

Researchers have validated the first DNA test panel with prognostic capability for a common orthopedic condition. The study, in the December online edition of *SPINE*, shows that the Scolioscore AIS Test is 99 percent accurate in predicting which children with mild adolescent idiopathic scoliosis (AIS) are least likely to progress to a severe curve that could require a surgical intervention. The test could substantially change the protocol of prescribed monitoring of AIS patients.

Only 10 percent to 15 percent of the estimated 7 million scoliosis sufferers have progressive disease and only 2 percent to 4 percent of patients diagnosed with AIS develop curves severe enough (more than 45 degrees) to warrant surgery. Until now, there has been no clinical means of predicting which children presenting with mild AIS (less than 25 degrees of curvature) are most likely to have the progressive form of the disease.

"There were mild curves that at the initial consultation were told because of family history the physician was very worried and the patient may have been put into a brace at an earlier stage and 40 to 60 X-rays later, at 18 years of age, the curve was the same as it was when they were 10 years old," explained Kenneth Ward, M.D., the study's lead author and chief scientific officer of Axial Biotech Inc., the developer of the test and the laboratory that conducts the DNA analysis. "With this test we can get rid of all that unnecessary stuff. We want children to receive care, but if they have a normal variant that they will outgrow, why would they want to sign up for all of this."

The laboratory-developed CLIA test lists for $2,950 and is reimbursable using standard CPT codes.

Logistic regression was used to develop an algorithm to predict spinal curve progression incorporating genotypes for 53 single nucleotide polymorphisms, selected from previous genomewide association study, and the patient's presenting spinal curve or Cobb angle.

The Scolioscore prognostic test produces a score of 1 to 200 indicating a patient's risk for developing a spinal curve of more than 40 degrees. A score of 50 or less is low-risk, 51 to 180 is intermediate-risk, and 181 to 200 is high-risk. The study found the test was 99 percent accurate in identifying low-risk patients. Risk of progression increases exponentially with an increasing score.

The laboratory-developed CLIA test lists for $2,950 and is reimbursable using standard CPT codes. In the past year nearly 2,500 patients have been tested. Version 2.0, due out late in 2011, will likely incorporate algorithms for minority populations. The developers are also optimistic it will include a positive predictive value. Preliminary data show that 97 percent of patients with scores greater than 190 have progressed to severe curve with 98 percent of these patients having undergone fusion surgery.

HIV Testing Increases, but Effort Needed to Boost Earlier Diagnosis

The number of people in the United States who report ever being tested for HIV is increasing according to a new study released by the Centers for Disease Control and Prevention (CDC). However, nearly one-third of diagnoses still occur too late to prevent further transmission of the disease and to take advantage of the life-enhancing benefits of anti-retroviral therapy. The CDC is working to increase testing efforts nationally, particularly among high-risk populations.

The number of adults aged 18-64 years ever tested for HIV increased by 11 million people to 45 percent in 2009 after remaining stable at 40 percent from 2001 to 2006. The percentage of people with late diagnoses of HIV infection (defined as an AIDS diagnosis made less than 12 months from an initial HIV diagnosis) decreased from 37 percent from 2001 to 2004 to 32 percent in 2007, the most recent data available.

The CDC estimates that one in five of the 1.1 million HIV-positive people in the United States are unaware of their infection and that 56,000 Americans are newly infected each year. In 2010 the National HIV/AIDS Strategy announced new goals to increase the proportion of HIV-infected individuals who know their status to 90 percent and reduce HIV incidence by 25 percent by the year 2015.

Current recommendations encourage health care providers to expand routine HIV screening so that all adults are tested. The CDC recommends routine HIV screening for all patients aged 13-64 in health care settings. High-risk individuals should be tested at least annually.

Transgenomic to Acquire Diagnostic Assets From Clinical Data

Transgenomic (Omaha, Neb.) has agreed to purchase the diagnostics business of Clinical Data Inc. (Newton, Mass.) for $15.4 million in a mix of cash and notes. Clinical Data's genetic and pharmacogenomic testing and biomarker development business and its CLIA-certified laboratory are included in the sale. The transaction is expected to close in late December, pending regulatory approval.

Transgenomic will receive Clinical Data's genetic testing assets including 11 commercialized tests for inherited heart diseases under the Familion brand, PGxPredict tests gauging drug response, and a pipeline that includes tests targeting Fc gamma receptor biomarkers for oncology and a Plavix response test.

"This is a significant transaction for our company. It brings a well-established and growing molecular diagnostic business addition, a substantial and established revenue base, and validated new biomarker assays along with a talented diagnostic team," Craig Tuttle, CEO of Transgenomic. For Clinical Data the transaction will provide the company with funds to support ongoing development and potential sales and marketing efforts for its two late-stage drugs, the anti-depressant vilazodone that is awaiting a January Food and Drug Administration decision and coronary vasodilator Stedivaze that is in Phase III studies.

"Once closed, this sale will complete Clinical Data's strategic transition to a pharmaceutical company and the monetization of our noncore assets, thereby permitting us to fully focus our resources on advancing our late-stage therapeutic programs," Drew Fromkin, president and CEO, said in a statement.

IVD Stocks Climb 10%; Beckman Coulter Jumps 30% on Buyout Buzz

The G-2 Diagnostic Stock Index gained 10 percent in the four weeks that ended Dec. 17, with 15 stocks up in price, two down, and one unchanged. The G-2 index is up by 13 percent since January, while the Nasdaq is up 14 percent and the S&P 500 is up 9 percent over the same period.

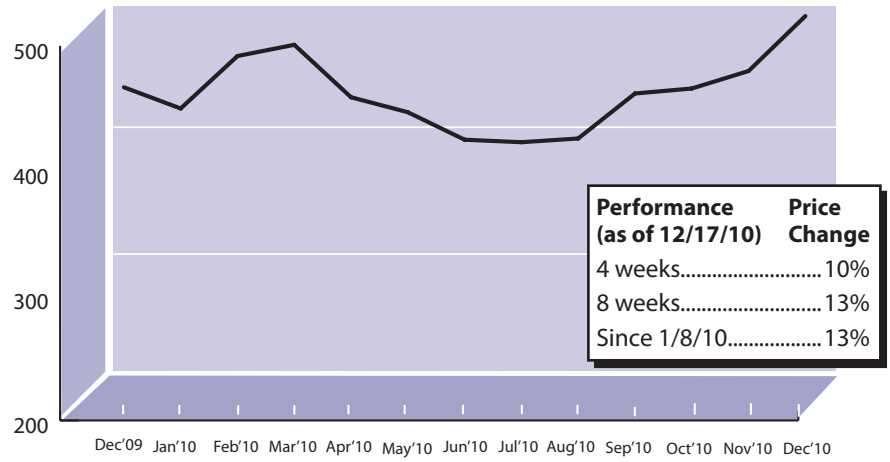
Gaining the most ground in recent weeks was **Beckman Coulter** (Brea, Calif.), which soared 30 percent to close at $72.07 per share with a market capitalization of $5.2 billion. In early December, news broke that the maker of laboratory equipment and diagnostic tests was exploring a sale and has enlisted Goldman Sachs to manage the process. Among the companies expected to bid for Beckman are Danaher, Thermo Fisher, and private-equity firms such as the Blackstone Group.

Another big winner for the period was **OraSure Technologies** (Bethlehem, Pa.). Shares in the oral fluid diagnostics company gained 25 percent to close at $5.61 per share with a market capitalization of $257 million. OraSure recently announced that it has enrolled the first subject in its final phase of clinical studies for U.S. Food and Drug Administration approval of its OraQuick Rapid HIV-1/2 test for sale in the U.S. over-the-counter market. In November, the FDA granted an Investigational Device Exemption that allowed OraSure to begin the final phase of clinical testing for the at-home HIV test kit.

Correction—In the November-December issue the Gen-Probe pie chart reversed the clinical diagnostics and the research products and services titles. Gen-Probe's clinical diagnostics revenue was $74.9 million and its research products and services revenue was $3.1 million for 2009.

Meanwhile, molecular diagnostics leader **Gen-Probe** (San Diego) shares got a 16 percent boost to close at $58.22 following the company's announcement that it has acquired GTI Diagnostics for $53 million in cash. Privately held GTI has focused on the transplantation, blood bank, and specialty coagulation markets. Its portfolio of specialty diagnostics includes histocompatibility testing products and immunoassay products that measure a patient's immune response to Heparin and Factor VIII therapies.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 18 IVD companies.

Up	Price	% Chg
Abaxis	$27.81	6%
Abbott Labs	48.40	2
Affymetrix	5.08	18
Alere	35.17	15
Beckman Coulter	72.07	30
Becton Dickinson	85.21	9
Bio-Rad	103.61	9
Cepheid	22.79	12
Gen-Probe	58.22	16
Immucor	20.28	9
Luminex	19.05	11
Meridian	24.20	9
Nanosphere	5.29	2
OraSure	5.61	25
Quidel	14.09	10
Unchanged		
Sequenom	7.19	0
Down		
Clinical Data	16.75	-7
Johnson & Johnson	62.54	-2

G-2 Insider

EEOC issues final rules on genetic discrimination . . . The Equal Employment Opportunity Commission (EEOC) has issued its final rule for employers to prevent the misuse of genetic information in the workplace. The rule will go into effect Jan. 10, 2011.

In implementing Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA), the EEOC warns that employers are prohibited from requesting genetic information and from using genetic information in a discriminatory way in making employment decisions, including determining health benefits, and that any disclosed genetic information must be kept confidential. The final rule restricts employers from intentionally seeking genetic information through requests, requirements, or purchases of the data.

The rules explicitly prohibit employers from listening to third-party conversations or conducting Internet searches on an individual including reading social networking sites where genetic disclosures are likely. But the guidelines do provide lawful allowances in cases where genetic information is accidentally revealed to the employer, such as in compliance with certification requirement of the Family Medical Leave Act, voluntary employee wellness programs, or through voluntary employee disclosure.

Congress enacted GINA to address public fear that results from genetic testing could jeopardize an individual's health insurance or employment status. GINA's employment provisions caused concern over employer liability upon inadvertently learning an employee's genetic status. Title II of GINA is applicable to private employers with 15 or more employees.

Company References

Axial Biotech 801-984-9100
Beckman Coulter 714-993-5321
BG Medicine 781-890-1199
Clinical Data 617-527-9933
Complete Genomics 650-943-2800
Fluidigm 650-266-6081
Genomic Healthcare Strategies 617-715-3508
Gen-Probe 858-410-8000
Genzyme Genetics 800-357-5744
Institute for Genomic Medicine 216-445-7862
Kaiser Permanente 503-335-2400
LabCorp 336-229-1127
Mayo Clinic 507-284-2511
Orasure Technologies 800-869-3538
Pacific Biosciences 650-521-8000
Pfizer Pharma GmbH 212-573-1226
Rules-Based Medicine 866-726-6277
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