Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

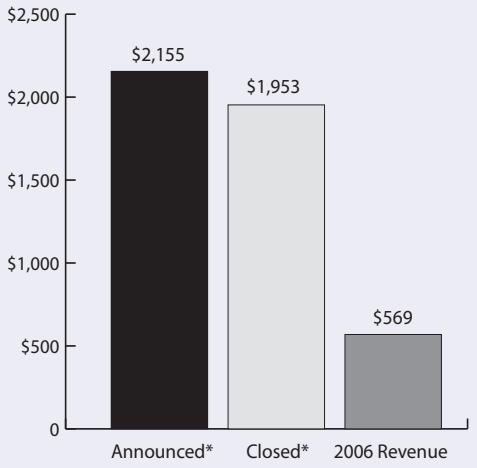
Established 1979

Buying Spree Continues at Inverness

After its May victory in the bidding war against Beckman Coulter for Biosite, Inverness Medical Innovations (Waltham, MA) still has an appetite for deals. A few weeks after closing on its $326 million purchase of cardiac testing maker Cholestech on September 13, the company announced two smaller international deals: the completed purchase of Bio-Stat Healthcare Group (Stockport, United Kingdom) for approximately $33.4 million and an agreement to acquire PanBio (Brisbane, Australia) for about $37 million.

These two deals are in line with Inverness's apparent strategy to buy its way into both growing market segments (with buys such as Matritech and Diamics, both specialists in cancer diagnostics) and international markets. This year, the company has announced $86.3 million in acquisitions for international diagnostics distributors, including those in Italy (Promesan), Canada (Med-Ox), and Benelux (Orange Medical).

Inverness's 2007 Acquisitions *(in millions)*



*As of October 9, 2007
Source: Inverness and *DTTR*

FDA Clears Nanosphere's Warfarin Sensitivity Test

The U.S. Food and Drug Administration has cleared the Verigene warfarin metabolism nucleic acid test, making it the first FDA-cleared genetic test for warfarin sensitivity. Manufactured and sold by Nanosphere (Northbrook, IL), the test detects variants of the CYP2C9 and VKORC1 genes that confer sensitivity to the blood-thinning drug warfarin (Coumadin) and therefore significantly alter a patient's required dose.

The Nanosphere test, which was cleared for use on the company's Verigene system, is for detection and genotyping of the *2 and *3 alleles of the CYP2C9 gene and a single point polymorphism (C to T at position 1173) of the VKORC1 gene, from whole blood samples. It is intended to be used along with clinical evaluation and other tools, including the internalized normalized ratio (INR), to determine optimal patient treatment.

Continued on p. 2

▲ **Nanosphere's Warfarin Sensitivity Test,** *from page 1*

The test is priced at approximately $60 per test, a company representative tells *DTTR*, and sells in packages of 12 test cartridges.

Nanosphere's Verigene system is a bench-top molecular diagnostics workstation that uses gold nanoparticle technology to detect nucleic acid and protein targets. Currently under FDA review are Verigene nucleic acid tests for the coagulation-related genes Factor 5 and Factor 2 (prothrombin), as well as for the MTHFR (5,10 methylenetetrahydrofolate reductase) gene. A test for the CFTR (cystic fibrosis transmembrane conductance regulator) gene is in development, as are tests in the areas of oncology and infectious diseases.

Warfarin sensitivity testing has been hailed as the first pharmacogenomic test to enter widespread clinical practice. The FDA's clearance of the Nanosphere test comes on the heels of the FDA's approval of updated labeling for Coumadin, manufactured by Bristol-Meyers Squibb (see *DTTR*, October 2007, p. 1).

The new labeling, which will also be added to warfarin (the generic version of Coumadin), explains how a person's genetic makeup may influence his or her response to the drug. The labeling change came nearly two years after an FDA subcommittee recommended testing for variations in the CYP2C9 and VKORCI genes.

Molecular tests can identify patients who require a higher or lower dose to achieve a target INR, may be at an increased risk for bleeding complications, and without the test, would require a longer period of time to achieve stable warfarin dosing. Labs that currently offer warfarin sensitivity testing include ARUP Laboratories, LabCorp, Mayo Medical Laboratories, Kimball Genetics, and PGXL Laboratories.

Study Finds New Breast Cancer Gene

The HMMR gene is mutated in approximately 10% of the population, while BRCA1 and BRCA2 gene mutations occur in less than 1% of the population.

Using a network modeling strategy, a consortium of researchers has identified HMMR as a gene associated with a higher risk of breast cancer, according to a study published October 7 in the advanced online edition of *Nature Genetics*. Mutations of the HMMR gene may increase a woman's risk of breast cancer by more than one-third.

HMMR, which is mutated in about 10% of the population, is a member of the transforming acidic coiled coil (TACC) gene family and encodes a hyaluronan-mediated motility receptor (HMMR). Previous studies have suggested that HMMR may have a role in centrosomal functions, which regulate such processes as cell division.

The new study demonstrates previously unknown functional associations of HMMR with the breast cancer-associated gene BRCA1, suggesting that HMMR plays a role in centrosome function in conjunction with BRCA1. Two case-control studies of incident breast cancer indicate that HMMR is associated with higher risk of breast cancer in humans. Additionally, the HMMR-associated risk of breast cancer was found to be independent of the presence of BRCA1 or BRCA2

mutations. Further analysis showed that higher HMMR expression is associated with early age at diagnosis.

The modeling strategy used in the study began with four known genes that encode tumor suppressors of breast cancer (BRCA1, BRCA2, ATM, and CHEK2). The researchers combined gene expression profiling with functional genomic and proteomic data from several species to generate a network of 118 genes that are linked by 866 potential functional associations. This integrated network created a ranking system that allowed them to classify potential network components from low to high likelihood.

The researchers note that their strategy should be useful for the discovery of additional cancer-associated genes. "Out network modeling strategy is applicable to other types of cancer," they conclude. "It will help to discover more cancer-associated genes and to generate a 'wiring diagram' of functional interactions between their products."

Emory Offers New Microarray-Based Tests for Muscular Dystrophy

Duchenne muscular dystrophy occurs in approximately 1 in 3,500 newborn males, and the incidence of Becker muscular dystrophy is approximately 1 in 18,000 newborn males. Two-thirds of these cases are inherited.

Researchers at Emory University (Atlanta, GA) have developed a new genetic test that targets the most common types of muscular dystrophy—those caused by mutations in the dystrophin gene. The microarray-based tests, known as EmArray Dystrophin, can be used to confirm clinical diagnoses, to test female family members who may be carriers, and to perform prenatal testing.

Muscular dystrophy includes more than 30 genetic diseases characterized by progressive weakness and degeneration of the skeletal muscles that control movement. Some forms are seen in infancy or childhood, while others may not appear until middle age or later. Duchenne muscular dystrophy (DMD) is the most common form of muscular dystrophy and primarily affects boys. It is caused by absence of dystrophin, a muscle protein that is involved in maintaining the strength of muscle fibers.

Developed by Emory's Michael Zwick, Ph.D., and Madhuri Hegde, Ph.D., EmArray Dystrophin testing detects 99% of mutations in the dystrophin gene including deletions, duplications, and point mutations. The test's microarray contains the entire sequence of the dystrophin gene, the largest known gene in humans. The test initially detects deletions and duplications, then microarray-based resequencing is used to rapidly identify subtle genetic variations that may cause muscular dystrophy.

The EmArray Dystrophin tests confirm clinical diagnosis of Duchenne and Becker muscular dystrophy in a male and characterizes the type and size of the mutation. Women with a family history of Duchenne or Becker who are at risk to be carriers can be tested, then, if found to be carriers, can have prenatal testing.

Now available through Emory Genetics Laboratory, the EmArray Dystrophin CGH array is priced at $1,580, and results are available in one week. The EmArray Dystrophin Resequencing Array is priced at $2,313, and results can take up to two weeks.

Plans for expanding the availability and reimbursability of the tests are in the works. "We will be partnering with another lab to develop the technology elsewhere," says Vanessa Rangel Miller, a genetic counselor at Emory Genetics Laboratory. "We are seeing reimbursement from insurance companies though we are limited to accepting only Medicaid from Georgia, not other states."

EmArray testing offers several advantages over currently used methodologies for dystrophin testing, namely multiplex PCR, southern blotting, sequencing, and multiplex ligation-dependent probe amplification. Not only are these methods time-consuming and labor-intensive, but they also do not accurately detect all types of mutations in the dystrophin gene. And while suitable for testing in males for deletions and point mutations, these approaches limit the ability to test females and to detect duplications.

FDA Licenses New Blood Typing Tests

The U.S. Food and Drug Administration (FDA) has licensed 15 new blood typing tests that were previously unavailable in the United States. The tests are the ALBAclone blood grouping reagents distributed by Alba Bioscience (Durham, NC), and they will be used to type blood donors.

The ALBAclone reagents include the common ABO and Rh tests, as well as tests for rare blood types. The reagents are monoclonal antibodies, highly specific antibodies that ensure product uniformity and availability. Alba Bioscience will launch the tests at the annual meeting of the American Association of Blood Banks, which will be held October 20-23 in Anaheim, California.

According to Jesse L. Goodman, M.D., director of FDA's Center for Biologics Evaluation and Research, the licensing will give blood establishments and transfusion services greater choice in testing and help to ensure a more stable supply of such tests.

Blood typing is a critical component of the transfusion process. If mismatched blood is administered to a patient, it may cause a serious and potentially fatal reaction. To prevent such problems, patients must receive compatible blood based on the results of blood typing tests.

The Durham-based company is the three-year-old North American distributor for Alba Bioscience (Edinburgh, Scotland), which was formerly known as Diagnostics Scotland and has approximately 60 employees. The company was formed in 1999, following the merger of two specialized National Health Service diagnostics manufacturing units in Scotland.

In August, Alba was acquired by Quotient BioResearch (Cambridgeshire, United Kingdom) for an undisclosed sum from the Scottish National Blood Transfusion Service. Established in early 2007, Quotient is focused on buying companies that provide analytical and safety evaluation services and products to the healthcare, pharmaceutical, and biotechnology sectors. Its first acquisition was HFL Limited, a U.K.-based provider of drug evaluation and drug testing services.

Partnering for Growth: Strategic Alliances in Molecular Diagnostics

The burgeoning field of molecular diagnostics has many stakeholders, including researchers, clinical laboratories, physicians, hospitals, biotech firms, pharmaceutical companies, venture capitalists, private equity firms, and, of course, patients. What are the alliance opportunities for laboratories that perform molecular testing? Once labs identify these opportunities, how can they best evaluate and negotiate deals? What are the best ways to build, manage, and grow those alliances? How can labs equip themselves to address the complex issues of license compliance and intellectual property? *DTTR* looked to industry experts to answer these questions and provide insight into how to initiate and maintain successful partnerships in a field that is constantly changing.

Understanding Alliances

What exactly is a strategic alliance? "In not so many words, it's a marriage, and it's a partnership—it's the molecular diagnostic dating game," says Colette F. Saccomanno, Ph.D., the former director of business development of Gene Express (Toledo, OH) who is now with DrugLogic (Reston, VA) as director of client research. "You're looking for people who can help advance your goals and objectives both on a business level and on a technical level. Our definition of a strategic alliance is a formal relationship between two or more parties to pursue a set of agreed-upon goals or meet a critical business need while remaining independent organizations."

In short, the reason that alliances exist is that no company today is an island. "We have two separate entities that want to combine their core strengths and create value. Is the alliance going to lead to a workable test that is going to make money?" says Saccomanno. "The bottom line is: Nothing happens unless a sale is made. Do you have something that is saleable?"

Alliances can originate from a number of sources, including customers, outsourcing vendors, or preferred providers. "We also hear about co-marketing partnerships all the time—also known as strategic partnerships or joint ventures," says Saccomanno. "Whatever you want to call them, they all involve the same philosophical approach, a group of people who have the skill set necessary to protect your interests as well as know when to downplay and woo a potential partner."

A New SWOT

When developing an alliance, you are really looking at a new type of SWOT—an analysis of your strengths, weaknesses, opportunities, and threats. "In an alliance, your strength is your product or technology. In other words, you need to identify your value proposition—that is, what do you have that is unique in this particular sphere? To identify your weakness, you need to perform a gap analysis. This means asking yourself what is keeping you from getting

your technology or idea out there. Where are the holes and how can they be filled? Your opportunity is really defined by that gap analysis because it identifies what you need to do to choose your partners. You can identify who has something that you need and, perhaps, find somebody that needs what you have. Finally, the threat in advancing the relationship, like any other relationship, is in being able to negotiate and maintain the alliance in a healthy and fair way," she explains.

Gene Express: SWOT in Action

About four years ago, Gene Express (which has been around since 1992 but was primarily involved in research and development for the first 10 years) began to commercialize its efforts in a particular way. "The core strength of Gene Express is its technology, StaRT-PCR," says Saccomanno. The end-point, quantitative polymerase chain reaction (PCR) method incorporates internal standards and normalizes data.

"That may not be very important on the drug development side when somebody is looking at 1,000 genes and trying to filter things down. However, in the clinic, when you need to know that you are not getting a false negative or positive, these kinds of things take on a life of their own," she adds. In clinical diagnostics, the internal standard or quality control is essential, something that everybody can agree on.

However, the weakness at Gene Express was that the technology was late to market versus the perceived competition. "I use 'perceived competition' respectfully because I think that the technology is complementary to many others," says Saccomanno. "That was something that I had to convince the company of, as well as develop a strategy in a more cooperative fashion with other companies that had some of these complementary technologies. The opportunity was for Gene Express to find the genomic players that would appreciate or could use the value that StaRT-PCR brought to the table."

A New Strategic Direction

"As an alliance strategy takes shape, it may require rethinking the way that your management has done things in the past," Saccomanno says. Initially, Gene Express commercialized itself as a boutique CRO. "In other words, here's StaRT-PCR, we're the only game in town, you need to come to us, and we'll run all your studies," she explains. "In short order, the company found out that was a hard to do—knocking on doors and trying to win business from some of the major players in the industry." In 2005, management reorganized, took on a more alliance-friendly approach, and decided to start licensing the technology.

"Initially, we went into the CRO marketplace looking for a company that already had a foothold. We established the first Standardized Expression Management (SEM) Center with proprietary high throughput methods and processes and, in October 2006, signed the first license with Gene Logic. Our

goal was to build on its reputation, and the benefit was that we didn't have to do all the marketing that goes into identifying the opportunity. Gene Logic already has a foothold in the genomic CRO marketplace and could help spread the word for us."

According to Saccomanno, another strategic direction the company is taking is adapting its technology as quality control reagents for other platforms. "Initially we were saying that we're end-point and that you don't need real-time any more. However, everyone now has a real-time platform in their lab, and they don't want it to become a dinosaur in the space of three or four years. So, as a company looking to fill a market need, we looked at our technology and how we could adapt it to a real-time platform. Thankfully, we could develop more validated assays. And, admittedly, each has other strengths and weaknesses that the other end-point assay can deliver. However, our thinking is that you need to have more than one tool in your toolbox—they all work to complement one another."

In addition, Saccomanno notes that the company is still working toward continuing with its contract services.

Alliance Management at Gene Express

Strength	Product/technology	StaRT-PCR uses internal standards and is normalized
Weakness	Perform gap analysis	Late to market versus perceived competition
Opportunity	Choose partner	Find genomics players that appreciate the value of StaRT-PCR
Threat (Challenge)	Negotiating and maintaining the relationship	Intellectual property issues and who owns what

Source: Colette F. Saccomanno, Ph.D.

A Growing Trend

"Alliance management is as simple as ABC—Amgen, BMS, and Celera are all doing it," she notes. Is it working? In June 2002, Celera formed a long-term strategic molecular diagnostics alliance with Abbott Laboratories to develop and commercialize products to detect and manage infectious diseases and chronic conditions such as cardiovascular disease and cancer. Celera focused on genetic marker discovery and validation and assay development. Abbott Laboratories focused on product development and worldwide sales and marketing.

"Alliance management is as simple as ABC—Amgen, BMS, and Celera are all doing it."

The key question is how well are the alliance efforts being organized. Saccomanno notes that BMS actually outlines its strategy on its Web site on how to approach it to form an alliance. "It's all about following a process, which begins as early as using its established point of contact."

The tricky part in a management situation is in how the alliance actually works. "It's getting both independent entities philosophically and strategically moving in the same direction in an atmosphere that is built around mutual respect," she says. "Everybody has value, and you need to bring players to your table who can represent your company, organization, and lab in a way that is full of integrity, openness, and fairness—and, of course, with an eye on protecting your interests."

A Perspective on an Alliance Model for Labs

Laboratories that want to get funded and build an alliance need to work within a business model in which they have mature tests that are going to be ready to market in one or two years," says Jorge Leon, Ph.D., president of Leomics Associates Consulting (Emerson, NJ). "To get to that point, labs need to spend three to five years developing the test, which can mean spending millions of dollars in the process. In most cases, investors will tell you that once you have a CLIA lab, develop the test, and it has been accepted, we will give you the money you need to market it. Although I don't believe in this model, it is the dominant model today."

While the model may work in the short term, according to Leon, the most significant problem is that it can take a substantial investment to market a test successfully—perhaps as much as $100 million. "This dilutes the expertise of the companies that have the know-how to develop new tests because they have to focus on just one thing—i.e., their major efforts are toward marketing and sales."

Within three years, the most powerful tests will be developed by approximately 30 CLIA labs, according to Leon. "They are taking away a lot of the innovation content from reference labs," he says.

Leon predicts that some of the large labs will buy the so-called "boutique" CLIA labs. The alternative? Get in earlier and with a greater investment. "You will need to invest earlier and be willing to share more of those benefits from studying a test," says Leon. "Instead of royalties of 5% to 10%, you might have to give royalties of 20% to 40% so that it's enticing for companies to have alliances where they can share with the big reference labs and develop a larger pipeline of five tests, instead of one."

"I think you'll see some of the big labs buying these boutique CLIA labs, or you will need to invest earlier and be willing to share more of those benefits from studying a test."

He also highlights a troubling potential consequence of this scenario: limited availability and distribution. "The dominant model is concerning because it really is clustering most of the content in a way that is not going to benefit society in the long term," he explains. "While they may be successful models, I think that in the long term these tests are not going to be available to society at the same level that they could be if they participated more actively in the distribution."

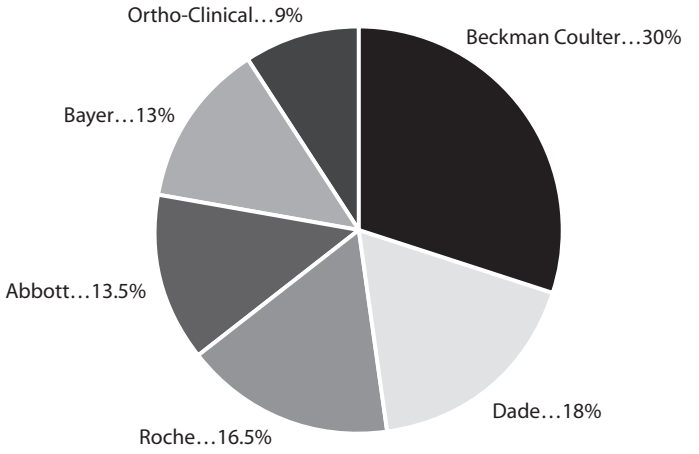
Labs Rank Beckman Coulter First in Reagent Vendor Survey

Clinical laboratories of all types and sizes view Beckman Coulter as the reagent vendor that offers the best value, a new survey by Washington G-2 Reports finds. The survey's 178 respondents from 41 states also gave Beckman top marks in price and customer service.

Of the 178 survey respondents, 76% were hospital and health-system laboratories, 13% were independent laboratories, and 6% were physician office laboratories. The remaining respondents were evenly split between pathology groups and "other." The average overall annual test volume of the labs surveyed was 1.7 million and the median was 1 million.

When asked which of the major reagent vendors offered the best value (i.e., service plus price), 30% of the 178 respondents pointed to Beckman Coulter. Dade Behring was second with 18%. Roche ranked third with 16.5% and Abbott fourth with 13.5%. Bayer was very close to Abbott, with 13%, and Ortho-Clinical Diagnostics ranked sixth, with 9%.

Which major reagent vendor offers the best value?



Source: Washington G-2 Reports' *Second National Reagent Vendor Survey* (2007), n=178

Beckman Coulter also emerged as the leader when it comes to price. The company was cited by 34% of survey respondents as offering the lowest prices. Roche came in second, with 18%, and Abbott was third, with 15%. Dade was close to Abbott, with 14%, followed by Bayer with 10%, and 9% of respondents indicated Ortho-Clinical Diagnostics offered the lowest prices.

Additionally, Beckman Coulter was chosen by 28% of respondents to be the most responsive to answering questions and fixing problems. From that position, response rates dropped off significantly, with Dade Behring cited 17% of the time, and both Roche and Ortho-Clinical Diagnostics cited 15% of the time. After that, Abbott was cited 13% of the time and Bayer Diagnostics 12%.

Roche Sees Stellar Response to Newly Approved HIV Test

According to Roche Diagnostics (Basel, Switzerland), the introduction of its newly approved HIV-1 test to the United States market is the most successful launch of a molecular test in the company's history. Within a few months of its May approval, approximately one-third of Roche Diagnostics's U.S. molecular customers had purchased or ordered the test.

The test, known as the Cobas AmpliPrep/Cobas TaqMan HIV-1 test, monitors HIV-1 viral replication and quantitates the virus present in patient samples over a

According to the Centers for Disease Control, each year in the United States approximately 40,000 people become infected with HIV.

dynamic range between 48 copies and 10,000,000 copies, a much wider spectrum than had been previously been available to physicians.

Approved by the FDA in May, the test is the first fully automated HIV-1 diagnostic tool using real-time PCR technology in the United States. The fully automated technology also delivers results relatively quickly—within approximately eight hours. A recent study conducted by Medical Laboratory Bremen (Bremen, Germany) concluded that the test can save laboratories 30 minutes of workflow time and can process up to 50% more samples in a single day's shift, compared with Abbott's RealTime HIV test.

The Roche test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy during the course of treatment. A primary goal of therapy is achieving and maintaining viral load that is below the limits of detection of approved molecular diagnostic tests. Analysis of 18 trials with over 5,000 participants with viral load monitoring had shown a significant association between a decrease in plasma viremia and improved clinical outcome.

The test is designed for use on an automated platform that combines the Cobas AmpliPrep instrument for automated sample preparation and the Cobas TaqMan analyzer or smaller Cobas TaqMan 48 analyzer for automated real-time PCR amplification and detection. Configuration options also include docked instruments for "sample in/results out" testing that eliminates manual intervention between steps.

The test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The test is not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection.

Over the summer, Oregon Medical Laboratories (OML; Springfield, OR) became the first regional reference laboratory on the West Coast to perform the test. According to OML, it will allow the lab to double its HIV testing capacity and reduce the time it takes to get results for a patient's HIV viral load.

As a Roche Molecular Center of Excellence, OML had access to the test as one of four participants in a nationwide study of its effectiveness. Currently, 21-year-old OML analyzes 5,500 HIV tests annually in Washington, Oregon, and Alaska. OML is Oregon's largest medical laboratory, performing approximately 7 million tests in 2006.

Meanwhile, on October 2, Roche announced its appointment of Jürgen Schwiezer as CEO of its Roche Diagnostics division. Schwiezer will assume the role on Jan. 1, 2008, succeeding Severin Schwan, who will replace Franz B. Humer as CEO of the Roche Group in March of 2008. Schwiezer is currently president of Roche Diagnostics for Europe, Middle East, Africa, and Latin America. In 2006, Roche's Diagnostics division posted sales of 8.7 billion Swiss francs (approximately $7.3 billion, at current exchange rates).

IVD Stocks Soar 44% Year to Date Led by Clinical Data and Ventana

Twenty IVD companies have risen an unweighted average of 44% through October 5, 2007, with 19 stocks up in price and only one down. This compares with the 15% rise in the Nasdaq and the S&P 500, which is up 10% for the year.

As in 2006, the best and worst performing stocks so far this year are those of molecular diagnostics companies. Biotechnology company **Clinical Data** (Newton, MA), a recent addition to the G-2 diagnostics index, has gained a whopping 143% to reach $26 per share for a market capitalization of $532 million. In early September, the company announced that its depression drug candidate, Vilazodone, showed positive results in a Phase III clinical trial.

Also performing very strongly is **Ventana Medical Systems** (Tucson, AZ), which is up 105% to $88.38 per share for a market cap of $3 billion. Since June, the tissue-based diagnostics specialist has been busy fending off buyout offers from Roche. Ventana management deemed the offers, which valued the company at $75 per share, "grossly inadequate."

The worst performing stock—and the only one to post a year-to-date loss in share price—was **Nanogen** (San Diego, CA), down 60% to 75 cents per share for a market cap of $59 million. The company recently announced that it is exploring options regarding its microarray business, including a possible sale or closure of the unit. In late September, it announced plans to lay off 13 employees in that business area, or about 4% of its total work force.

IVD Stock Performance, YTD Through October 5, 2007

Company (ticker)	12/29/06 Price	10/5/07 Price	YTD %Chg	P/E Ratio
Clinical Data (CLDA)	10.70	26.00	143%	N/A
Ventana (VMSI)	43.03	88.38	105	72
Meridian (VIRO)	16.10	31.79	97	53
Dade (DADE)	39.70	76.52	93	47
Third Wave (TWTI)	4.81	9.11	90	N/A
Cytyc (CYTC)	28.30	50.11	77	93
Quidel (QDEL)	13.62	19.72	45	28
Inverness Medical (IMA)	38.70	55.99	45	N/A
Luminex (LMNX)	12.70	16.96	34	N/A
Immucor (BLUD)	29.23	38.80	33	42
Abaxis (ABAX)	19.25	25.22	31	52
Gen-Probe (GPRO)	52.37	68.21	30	46
OraSure (OSUR)	8.26	10.47	27	87
Beckman Coulter (BEC)	59.37	75.09	26	22
Becton Dickinson (BDX)	69.47	83.31	20	26
Affymetrix (AFFX)	23.06	27.56	20	N/A
Bio-Rad (BIO)	82.52	95.34	16	29
Abbott Labs (ABT)	47.85	55.00	15	44
Johnson & Johnson (JNJ)	64.78	66.25	2	18
Nanogen (NGEN)	1.87	0.75	-60	N/A
Unweighted Avg.			44%	

G-2 Insider

A faster, cheaper, point-of-care test for bird flu . . . That's the promise of a team of researchers from Singapore who have developed a new chip-based method for detecting the virus. In a study published in the October issue of *Nature Medicine*, they describe an assay that can identify the highly pathogenic avian influenza virus H5N1 440% faster than commercially available tests—and at a cost savings of 2,000% to 5,000%!

The key to the test is its unique combination of droplet-based RNA sample preparation and real-time RT-PCR (RRT-PCR). A tiny droplet of liquid that contains supermagnetic particles (and can therefore be manipulated by magnets) functions as a pump, valve, mixer, solid-phase extractor, and real-time thermal cycler. It is able to retain or release RNA after solid phase extraction of a throat swab sample, passing the desired material on to the RT-PCR reaction.

Unlike conventional chip-based platforms, droplet-based architectures are flexible, easily scalable, and allow sample preparation to take place on the surface of the chip. The droplet-based test takes a total of 28 minutes, compared to the approximately four hours required to perform the RT-PCR-based bird flu tests offered by Roche, Veredus Laboratories, Qiagen, and Applied Biosystems. The test was found to be just as sensitive as currently available tests.

The researchers are currently developing a low-cost, easy-to-use, hand-held point-of-care instrument for the test. The prototype uses the power supply, motor, and optics of a CD-ROM drive. Experiments are also in progress to address transport- and storage-related issues.

Company References

Alba Bioscience
919-313-2888

Beckman Coulter
714-871-4848

Clinical Data 617-527-9933

Dade Behring 847-267-5300

DrugLogic 800-393-1313

Emory Genetics Lab
800-366-1502

Gene Express 419-380-9930

Inverness 781-647-3900

FDA OIVD 240-276-0450

Leomics Associates
201-248-8313

Nanogen 858-587-1121

Nanosphere 888-837-4436

Oregon Medical Labs
800-826-3616

Roche Molecular
925-730-8200

Ventana Medical Systems
520-887-2155

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