Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

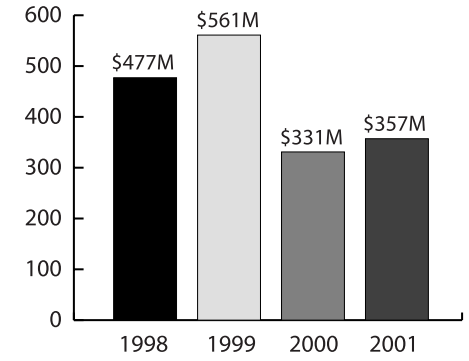
Abbott Diagnostics Facility Fails FDA Inspection

Abbott Laboratories (Abbott Park, IL has been informed by the U.S. Food & Drug Administration that its diagnostics manufacturing operations in Lake County, IL, still fail to comply with FDA's quality system regulations. This follows the facility's inspection, which concluded in January 2002. Abbott has not yet received a formal report from FDA and only after getting it will the company have a clear understanding of FDA's decision and the next steps.

Since signing a consent decree with FDA in November 1999, Abbott has been forced to suspend sales of some 60 immunoassay tests in the U.S. that had generated $250 million annually. As a result, the company took a charge of $168 million in 1999 and says there may be additional costs related to FDA's most recent decision. Operating earnings at Abbott Diagnostics have plunged since the consent decree, while revenue has stagnated.

"We are obviously deeply disappointed," stated Richard Gonzalez, president and chief operating officer of Abbott Medical Products Group, in a press release. Abbott executives had previously expressed hope of getting some of the suspended immunoassay products back on the market by May and growing the diagnostics business by 10% in 2003.

Abbott Diagnostics' Operating Earnings



Source: Abbott

Sigma-Aldrich Puts Diagnostics Business Up For Sale

Sigma-Aldrich Corp. (St. Louis, MO) has announced plans to sell substantially all of its diagnostics business and has hired Goldman Sachs to help find a buyer. Sigma-Aldrich says it will record a one-time charge of as much as $63 million for the discontinuation of this business, including write-offs of $21 million associated with its acquisitions of First Medical Inc. (Mountain View, CA) and Amelung GmbH (Lemgo, Germany). Sigma-Aldrich acquired First Medical, which makes the Alpha DX system for rapid cardiac testing, in July 2000 for $15 million. Amelung GmbH, which makes the AMAX systems for coagulation testing, was purchased in August 2000 for $28 million.

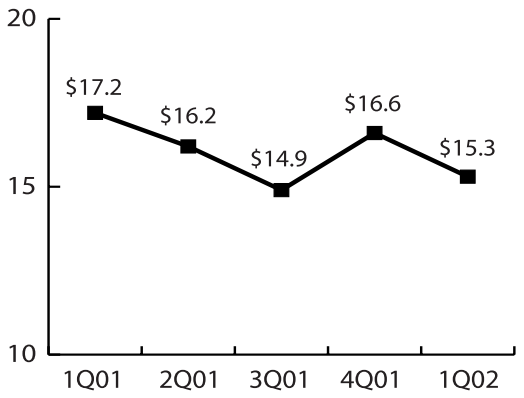
Continued on p. 2

▲ **Sigma-Aldrich,** *from page 1*

Bob Monaghan, who had orchestrated these acquisitions with the aim of achieving 10% annual revenue and profit growth for the diagnostics unit, has resigned as president of Sigma Diagnostics.

Sigma-Aldrich says certain catalog-based products marketed by its diagnostics unit, including its hematology and histology products as well as certain research and specialty chemistry products, have been merged into the company's scientific research unit. These products generate about $11 million in annual sales. In addition, the company has signed a non-binding letter of intent to sell its enzyme immunoassay product line to IVAX Diagnostics in Miami, FL (*DTTR, May '02, p. 9*).

Sigma Diagnostics' Revenue Trend *($MM)**



*Excludes diagnostic products being shifted to Sigma-Aldrich's scientific research unit. Source: Sigma-Aldrich

All remaining assets of Sigma-Aldrich's diagnostics business are up for sale, including routine chemistry reagents, coagulation analyzers and rapid immunoassay system. Excluding those products being shifted to the scientific research unit, Sigma Diagnostics generated a net loss of $2.92 million in the three months ended March 31, 2002 vs. a net loss of $2.74 million in the same period a year earlier; revenue was down 12% to $15.288 million. The diagnostics unit currently has 512 employees worldwide, including 180 on staff at company headquarters in St. Louis, MO.

Sigma-Aldrich says it will now focus on its core business of selling biochemical and organic chemical products and kits for use in the scientific and genomic research, biotechnology and pharmaceutical development markets.

Roche, Qiagen To Make Integrated PCR Test System

Roche Molecular Systems (Pleasanton, CA), a business segment of Roche Diagnostics (Basel, Switzerland), and Qiagen (Venlo, The Netherlands) have announced a partnership to develop an integrated diagnostic system for high-volume hepatitis and HIV-1 polymerase chain reaction (PCR) testing.

The customized system will combine automated sample preparation technology from Qiagen with a modified version of Roche's Cobas TaqMan Analyzer for real-time PCR analysis. Roche says it will distribute these integrated systems in the U.S. to large reference laboratories that process more than 200 PCR hepatitis B and C and HIV-1 tests per day. Financial details of the agreement were not released.

Separately, Qiagen reported net income of $9.506 million for the three months ended March 31, 2002, up from $5.957 million in the same period a year earlier; revenue was up 12% to $70.53 million. Qiagen makes nucleic acid separation and purification systems and consumables. To date, the majority of the company's revenue has come from sales to the academic research market and to pharmaceutical and biotechnology companies; however, Qiagen is positioning its products for greater sales to the clinical diagnostics market.

First-Quarter Revenue Up 5% At 10 Leading IVD Companies

Ten of the largest IVD manufacturers posted combined revenue of $4.322 billion in the three months ended March 31, 2002, up 5% from a year earlier (excluding adjustments for currency changes).

Roche Diagnostics (Basel, Switzerland) generated first-quarter sales of 1.79 billion Swiss francs (US $1.115 billion), up 9% from 1.644 billion Swiss francs (US $1.024 billion) in the same period a year earlier. Its fastest-growing segment was molecular diagnostics, where revenue grew 24% to 244 million Swiss francs (US $152 million). Roche's fastest-growing region is Japan, China and the Far East, representing about 10% of its overall diagnostics revenue and growing at better than 20% annually.

Revenue at the diagnostics division of **Abbott Laboratories** (Abbott Park, IL) fell 4% to $679 million; operating earnings fell to $62 million from $85 million (*for more on Abbott, see DTTR, May '02, p. 4*).

Johnson & Johnson's (New Brunswick, NJ) combined diagnostics operations, including **Ortho-Clinical Diagnostics** (OCD) and **Lifescan**, increased revenue by 13% to $587 million. Revenue at OCD was up 3% to $269 million, while Lifescan posted 23% growth to reach sales of $318 million.

Bayer Diagnostics (Tarrytown, NY) reported revenue growth of 8% to 500 million euros (US $454 million). **Beckman Coulter** (Fullerton, CA) grew revenue by 3% to $447 million; net income was $28 million vs. $23.4 million in the comparable period a year earlier.

Dade Behring (Deerfield, IL) reported first-quarter 2002 revenue of $306 million, down 8% from the $331 million reported for the same period a year earlier. Dade, which has more than $1 billion of debt outstanding, says it continues to work with its banks and bondholders to modify its capital structure through a debt-to-equity swap.

The fastest growing IVD company was **Cytyc Corp.** (Boxborough, MA), which reported revenue growth of 43% to $68 million; net income climbed to $17.6 million from $15.6 million. **Diagnostic Products** (Los Angeles, CA) reported sales of $74.7 million, up 10%; net income increased to $10.8 million from $8.6 million.

First-Quarter 2002 Revenue Growth At 10 Leading IVD Manufacturers *($MM)*

Company	*1Q02*	*1Q01*	*% Chg*
Roche Diagnostics[1]	$1,115	$1,024	+9
Abbott Diagnostics	679	704	-4
Ortho-Clinical/Lifescan	587	521	+13
Becton Dickinson[2]	483	451	+7
Bayer Diagnostics[3]	454	420	+8
Beckman Coulter	447	433	+3
Dade Behring	306	331	-8
Bio-Rad Clinical Diagnostics	108	103	+5
Diagnostic Products	75	68	+10
Cytyc	68	47	+43
Total, 10 companies	4,322	4,102	+5

[1]Data for Roche are based on an exchange rate of 1 Swiss franc = 0.623 US dollar.
[2]Becton Dickinson data include revenue from the company's clinical lab solutions and biosciences divisions.
[3]Data for Bayer are based on an exchange rate of 1 euro = 0.908 US dollar.
Source: *DTTR* from company reports

Fujirebio Test For Pancreatic Cancer Clears FDA

Fujirebio Diagnostics Inc. (FDI-Malvern, PA) has received approval from the U.S. Food & Drug Administration to market the first blood test for monitoring the effectiveness of treatment for pancreatic cancer. The test, called CA 19-9 Radioimmunoassay, was co-developed with Trinity Biotech (Dublin, Ireland) and will be marketed by Fujirebio Diagnostics under the FDI label. Pancreatic cancer is the fourth leading cause of cancer deaths in the U.S., killing some 29,000 Americans each year, according to the American Cancer Society. FDI, formerly known as Centocor Diagnostics, was acquired by Fujirebio Inc. in November 1998.

DiaSys Wins Premier GPO Contract

DiaSys Corp. (Waterbury, CT) has won a two-year contract to sell its R/S Series Laboratory Workstations to the group purchasing organization Premier (Oakbrook, IL) and its 1,600 hospital members. The contract represents a new product class for Premier.

DiaSys' R/S Series Laboratory Workstations are used for microscopic analysis of urine sediment to detect and monitor a broad range of abnormalities for patients with cancer and kidney disease and for expectant mothers. Microscopic urine analysis is also routinely performed as part of standard physical exams.

Kopp Investment Advisors To Raise Stake In Quidel

Quidel Corp. (San Diego, CA) says that upon the request of its largest shareholder, Kopp Investment Advisors Inc. (KIA-Edina, MN), its shareholder rights agreement has been amended to permit Kopp to raise its stake in the company up to 20%. KIA, an independent money management firm, currently holds approximately 14.9% of Quidel's common stock and otherwise would have been limited to 15% under the rights agreement.

Kopp's IVD Investments

Company	*Kopp Stake*[1]	*Market Value*[2]
Biosite	16.9%	$71M
Cholestech	8.3%	17M
Quidel	14.9%	26M
Ventana	16.1%	61M

1) Ownership stake is as of the latest filing with the U.S. Securities & Exchange Commission.
2) Market value of ownership stake is based on closing share prices for May 10, 2002.
Source: *DTTR*

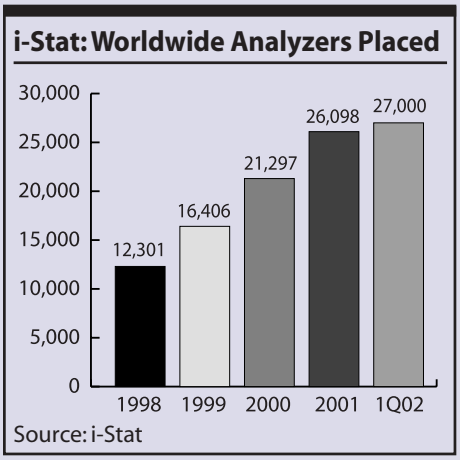
Quidel makes point-of-care tests for infectious diseases, including influenza A and B, strep, H. pylori, chlamydia, infectious mononucleosis and bacterial vaginosis. Quidel's OTC products include tests for pregnancy and ovulation prediction.

In the three months ended March 31, 2002, the company reported net income of $1.609 million vs. $417,000 in the same period a year earlier; revenue was up 6% to $21.212 million. Sales of pregnancy, strep A and influenza test kits accounted for approximately 77% of revenue in the first quarter.

Other IVD companies where KIA holds a significant ownership stake include Biosite (San Diego, CA), 16.9%; Cholestech (Hayward, CA), 8.3%; and Ventana Medical Systems (Tucson, AZ), 16%.

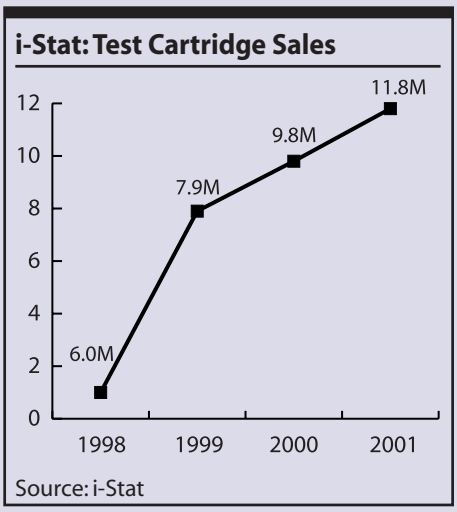
Will i-Stat Ever Earn A Profit On Its Huge Installed Base?

Since introducing its original point-of-care testing system in September 1992, i-Stat Corp. (East Windsor, NJ) has placed some 27,000 analyzers, making them the most ubiquitous hand-held IVD device in the world (excluding blood glucose testing devices). And the company continues to place 1,000+ more units in the field every quarter.

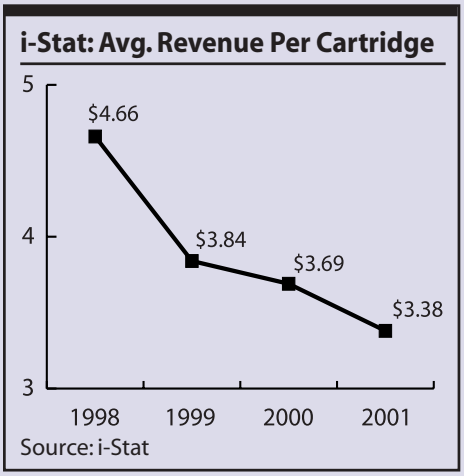


Test cartridge sales at i-Stat have grown rapidly also. In the three years ended Dec. 31, 2001, volume has grown by 25% per year to 11.835 million cartridges. Company chairman and CEO Bill Moffitt notes that an i-Stat cartridge is used somewhere in the world every 2.5 seconds. Going forward, Moffitt expects test cartridge volume to grow at an annual rate of roughly 20%.

Yet, despite the widespread presence of its products, profits have been elusive at i-Stat. In the latest quarter ended March 31, 2002, for example, the company reported a net loss of $4.4 million on revenue of $14.4 million. Since its inception in 1983, i-Stat has accumulated a staggering $223.9 million deficit.



A large portion of i-Stat's persistent losses can be attributed to a poorly constructed distribution contract with Abbott Laboratories (Abbott Park, IL), which has put downward pressure on the amount of money i-Stat collects per cartridge sale. In the three years ended Dec. 31, 2001, its average revenue collected per cartridge sold has declined by 10% per year to $3.38. Over the same time frame, the average selling price of cartridges to end-users has remained fairly stable at roughly $4.50. The spread, currently about $1 per cartridge, goes to Abbott.



Abbott also gets a percentage of all new i-Stat analyzers sold. The list price for the new i-Stat 1 analyzer, which runs both i-Stat cartridges and Abbott Medisense glucose strips, is $7,000; the average sales price to end-users (after discounts) is roughly $3,800-$4,400.

The Abbott contract became effective in November 1998 and runs through Dec. 31, 2003. In conjunction with the distribution agreement, Abbott purchased two million shares of i-Stat at $11.35 per share for a total investment of $20.6 million, or a 10% stake.

Under this agreement, the i-Stat system is sold exclusively worldwide by Abbott, except in Japan where it is marketed on a non-exclusive basis by both Fuso Pharmaceutical Industries and Dainabot Co. Ltd., Abbott's Japanese affiliate. Abbott gets a fixed percentage of all revenue derived from i-Stat analyzer and cartridge sales beyond i-Stat's existing base business of 4.5 million cartridge sales in the U.S. The contract also gives Abbott sole discretion to set prices.

Abbott sells the i-Stat system through its Medisense unit, which has 55 salespeople focused on marketing both Medisense and i-Stat products to the hospital market. A training and installation staff of 15 i-Stat employees is responsible for delivering the i-Stat analyzers. During 2001, approximately 84% of i-Stat's total revenue came from sales by Abbott.

Over the past three-and-one-half years, Abbott has helped expand the reach of the i-Stat system, particularly in international markets where i-Stat previously had minimal or no presence. For example, in the three months ended March 31, 2001, i-Stat sold 910,000 cartridges, or 34% of total volume of 2.69 million, outside the U.S. Of the 27,000 i-Stat analyzers placed worldwide, approximately 9,000-10,000 are in the U.S. and the remaining 17,000-18,000 are outside the U.S. The largest market outside the U.S. is Japan, with approximately 3,000 i-Stat analyzers placed and annualized sales of one million cartridges.

In exchange for its marketing services, Abbott is currently generating an estimated $4-$5 million in revenue from i-Stat each quarter. But it looks like i-Stat may be preparing to terminate or greatly restructure the Abbott contract and take the marketing responsibilities back in house. Both Abbott and i-Stat have until the end of this year to notify the other if they plan to cancel the current contract; termination would become effective Dec. 31, 2003. Otherwise, the deal is subject to automatic one-year extensions.

Moffitt says i-Stat will soon expand its own sales force from 4 people to 12. This team will focus on sales to high-volume accounts (defined as any customer who uses 15,000-18,000 cartridges per year). When asked directly about the status of the contract with Abbott, Moffitt would only say, "The companies are constantly talking about operating matters and strategic matters."

If i-Stat does choose to cancel, it will have to pay a $5 million termination fee to Abbott. In addition, it will have to make residual payments to Abbott for five years following the end of the contract. Moffitt says these residuals would be far less than what i-Stat currently pays Abbott.

Another scenario, *DTTR* speculates, could be that Abbott simply acquires i-Stat. Based on its stock price of $5.72 per share (as of May 17), i-Stat has a market capitalization of $114 million. This is equivalent to approximately two times i-Stat's annualized revenue of $58 million.

i-Stat In Brief

	For three months ended ($000)	
	3/31/02	3/31/01
Revenue	$14,400	$12,328
Operating loss	-3,941	-4,129
Net loss	-4,413	-3,826
Cash holdings	41,789	17,721

Source: i-Stat

After falling 70% in 2001, shares of i-Stat have dropped another 28% year-to-date

Looked at another way, i-Stat's current market cap values the company at only $4,222 for each of the 27,000 analyzers it has placed in the field ($4,222 X 27,000=$114 million).

Regardless of what happens with the Abbott contract, i-Stat is preparing to launch several new higher-priced test cartridges that should help boost its revenue. The i-Stat analyzer currently runs 13 tests: sodium, potassium, chloride, BUN, glucose, hematocrit, pH, PCO_2, PO_2, ionized calcium, creatinine, lactate and celite ACT. The analyzer also calculates the following six parameters: hemoglobin, anion gap, total CO_2, bicarbonate, base excess and oxygen saturation.

In February, i-Stat submitted its 510-K application to the U.S. Food & Drug Administration for its prothrombin time test for monitoring patients on anticoagulant therapy. Clearance and market launch are expected by the end of August. Moffitt says the PT test will be priced to end-users at an average of $5-$6 per cartridge.

Moffitt says i-Stat also plans to submit an application for a kaolin ACT test (for measurement of coagulation) within the next few months and another for troponin I (a cardiac marker) early next year.

Meanwhile, Moffitt says a recent manufacturing glitch that caused some cartridges to produce a higher than normal reject rate (aka "star out") has been repaired. However, the company did take a $1.6 million write-off in the first quarter to dispose of certain cartridges in inventory and replace certain cartridges in the field. i-Stat makes its cartridges at its manufacturing facilities in Kanata, Ontario, Canada. Moffitt says these facilities are currently producing about 12 million cartridges per year and have the capacity to make 40 million per year.

Diametrics CEO David Giddings To Step Down

Diametrics Medical Inc. (Roseville, MN) has announced that David Giddings has decided to step down as chief executive and president, effective June 1. Giddings had served as CEO since April 1996. Andre de Bruin, chairman, will assume the CEO role on an interim basis until a replacement is named.

Diametrics makes the IRMA system (immediate response mobile analysis) for hand-held analysis of blood gas/electrolytes and is a competitor of i-Stat. More than 6,000 IRMA analyzers are in place worldwide, and annual cartridge volume exceeds one million. The product is distributed by Philips Medical Systems, which is part of Royal Philips Electronics (Amsterdam, The Netherlands).

The departure of Giddings comes after Diametrics posted a $3.876 million net loss in 2001 vs. a net loss of $2.648 million in 2000; revenue slipped 3% to $24.489 million. Since its inception in 1990, Diametrics has accumulated losses totaling more than $136 million.

Fourth "Mad Cow" Case Found In Japan

The Japanese Health, Labor and Welfare Ministry has announced that a fourth Japanese cow has been found to have bovine spongiform encephalopathy (BSE), the brain wasting affliction better known as "mad cow" disease. All four cases have been found within the past six months, supporting theories that the disease may be prevalent in the country, according to ministry officials. Since last Oct. 18, Japan has BSE-screened all cows slaughtered for beef. About 650,000 have been tested so far.

Roche, ExonHit To Collaborate On Live BSE Test

Roche Holding (Basel, Switzerland) and ExonHit Therapeutics (Paris, France) have announced an agreement to develop a blood test to detect bovine spongiform encephalopathy (BSE, aka "mad cow" disease) in living animals. At present, there is no way to diagnose it or its human equivalent—new variant Creutzfeldt-Jakob disease (nvCJD)—without examining dead brain tissue or spinal cord matter. The two companies plan to combine Roche's polymerase chain reaction (PCR) technology with ExonHit's gene profiling technology and say they can have a test on the market for research and evaluation purposes within the next 12 months.

ExonHit, a privately held company with 64 employees, was founded in 1997 by three scientists from Rhone-Poulenc (Paris). The company is developing gene-based products and accompanying diagnostics for the treatment of cancer and neurological disorders. ExonHit's U.S. operations are based in Gaithersburg, MD.

Rapid "Mad Cow" Test Strip Under Review In Europe

Prion Development Laboratories Inc. (PDL-Buffalo Grove, IL) says preliminary tests at an independent European laboratory have demonstrated that its test strip for detecting "mad cow" disease has comparable sensitivity with the more time-consuming Bio-Rad BSE test, the current standard in Europe and Japan. The PDL test is designed to detect abnormal prion protein in cattle brain tissue at slaughterhouses to ensure that BSE-infected cattle do not enter the human food chain. The company says the test is similar to a home pregnancy test and can be completed in less than five minutes. It is anticipated that the test will be reviewed and evaluated in Europe within the next several months prior to being certified for commercial release for testing cattle.

Using its proprietary reagents, PDL says it also has recently validated the discovery of prions in urine, a finding previously thought to be improbable. The company says it is currently working to adapt its test for analysis of urine samples, which would provide the world's first pre-mortem test for BSE.

PDL is a privately held company formed in 1999. Members of its product development team include scientists at Case Western Reserve University (Cleveland, OH), a leading center for neurological research on human prion diseases, and The Institute for Basic Research and Developmental Disabilities (Staten Island, NY), a major research center for animal prion diseases. Genesis Bioventures Inc. (Surrey, British Columbia, Canada) has invested $2.4 million in PDL for a 33% stake.

Calypte Back In Business After Raising $1.5 Million

Calypte Biomedical Corp. (Alameda, CA), which makes the only two FDA-approved HIV-1 antibody tests that can be used on urine samples, has received from a group of private investors a commitment for a minimum investment of $1.5 million in new equity to be used to fund the company's operations. In light of this anticipated cash infusion, Calypte says it does not intend to wind down its business, as previously announced (*DTTR, May '02, p. 8*).

In conjunction with the new investment, Calypte has named Anthony Cataldo as executive chairman, with responsibility for directing overall operations of the company. Cataldo replaces David Collins who has resigned as chairman. "Going forward, we will have reduced our overhead and streamlined operations, which we expect to lower our breakeven point and allow us to begin to approach profitability. We look to leverage our patents through licensing rights into many markets, domestic and worldwide," Cataldo stated in a May 13 press release. Calypte reported a net loss of $9.2 million on revenue of $6.8 million in 2001.

The press release went on to say that while Cataldo "was with Senetek Plc (Napa, CA), its market capitalization increased by several hundred million." *DTTR's* check of filings with the U.S. Securities & Exchange Commission shows that Cataldo was chairman and CEO of Senetek, which is developing a treatment for erectile dysfunction, from 1996 to 1998. Senetek has a current market capitalization of about $50 million and last year reported net income of $385,000 on revenue of $8.9 million.

OraSure Receives FDA Approvable Letter For Rapid HIV-1 Test

OraSure Technologies (Bethlehem, PA) says it has been notified by the U.S. Food & Drug Administration that its OraQuick Rapid HIV-1 Antibody Test is approvable, subject to the company meeting certain conditions. The test is intended to detect HIV-1 antibodies in fingerstick whole blood within 20 minutes. Final approval is subject to OraSure submitting product labeling and resolving specific validation and design control issues identified during FDA's recent pre-approval inspection of the company's manufacturing facilities. Sam Niedbala, chief science officer at OraSure, says that subject to final approval, the company intends to begin selling the test in the second half of this year.

OraSure now gets most of its revenue from the sale of rapid tests for drugs-of-abuse to the life insurance risk assessment and workplace hiring markets. In the first quarter ended March 31, 2002, the company reported a net loss of $1.593 million vs. a net loss of $997,000 in the prior-year period; revenue was up 4% to $7.725 million.

First-Quarter Revenue Up 85% At ViroLogic

Though ViroLogic Inc. (South San Francisco, CA) reported a first-quarter 2002 loss of $9.206 million vs. a net loss of $7.017 million in the same period last year, its revenue was up 85% to $5.708 million. ViroLogic's lead product, PhenoSense HIV, tests the resistance of a patient's strain of HIV to existing antiviral treatments. The company is developing PhenoSense assays for hepatitis B and C as well.

Digene Reports Revenue Growth Of 58% In Latest Quarter

While Digene Corp. (Gaithersburg, MD) recorded a net loss of $3.319 million for the three months ended March 31, 2002 vs. a net loss of $1.646 million in the same period a year earlier, its revenue increased 58% to $14.213 million. Evan Jones, chairman of Digene, says revenue growth was led by sales of the company's Hybrid Capture 2 HPV Test kits, which grew 133% over last year's comparable quarter. (Note: Digene has agreed to be acquired by Cytyc in a transaction currently valued at $453 million. See p. 11 for update).

Jones notes that subsequent to the quarter, the American Society of Colposcopy and Cervical Pathology released consensus guidelines recommending testing for HPV (human papillomavirus) in managing women with borderline Pap test results known as ASCUS, and the U.S. Army announced its decision to adopt HPV testing of all ASCUS Pap test results.

Digene At A Glance *($MM)*

	For three months ended 3/31/02	3/31/01
Revenue	$14,213	$9,010
Operating loss	-3,550	-1,952
Net loss	-3,319	-1,646

Source: Digene

On March 8, the Microbiology Devices Panel at the U.S. Food & Drug Administration recommended that the agency approve, with conditions, Digene's premarket approval supplement (PMAS) for the DNA Pap. This approval would enable Digene to market its HPV test as a primary screening test, in conjunction with the Pap test, for women age 30 and older. FDA has informed Digene that additional information, an education program and a proposed post-market study plan must be submitted before the agency can complete its review of the PMAS application.

Anthem BCBS To Cover Cytyc's FirstCyte Ductal Lavage

The FDA-approved procedure is currently used to determine predisposition for developing breast cancer in high-risk women. There are approximately two million breast cancer patients in the U.S., and another three million at high risk for developing the disease, according to Cytyc

Cytyc Corp. (Boxborough, MA) says that Anthem Blue Cross Blue Shield (Indianapolis, IN) has approved coverage of its FirstCyte Ductal Lavage procedure to aid in breast cancer risk assessment. Anthem BCBS currently provides healthcare benefits to more than 7.9 million people and recently agreed to acquire Trigon Healthcare (Richmond, VA), which covers 2.2 million. Other insurers that have recently agreed to cover Cytyc's procedure include Empire Blue Cross and Blue Shield (New York City) and CareFirst BlueCross BlueShield (Owings Mills, MD).

Cytyc acquired the ductal lavage technology through its $161 million purchase of Pro-Duct Health Inc. (Menlo Park, CA) on Nov. 30, 2001. Ductal lavage examines cells from inside the milk ducts, where most breast cancers originate. The minimally invasive procedure takes about 30 minutes at a physician's office and makes use of a proprietary hair-thin catheter made by Cytyc to collect cells from the lining of the milk ducts. The cell specimen is sent to a laboratory for slide preparation using Cytyc's ThinPrep System and is then examined by a cytopathologist.

Physician reimbursement ranges from $400-$700 per patient. Cytyc receives approximately $300 per patient for supplies used in the procedure. Laboratories get $40-$100 for preparing and analyzing the slides, according to Cytyc.

IVD Stocks Falls 2% In Latest Four Weeks, Cytyc Drops 36%

Roche non-voting equity shares, which trade on the Zurich stock exchange, are up 3% to 121.75 Swiss francs year-to-date. Shares of Bayer, which trade on the German stock exchanges, are unchanged at 35.60 euros per share

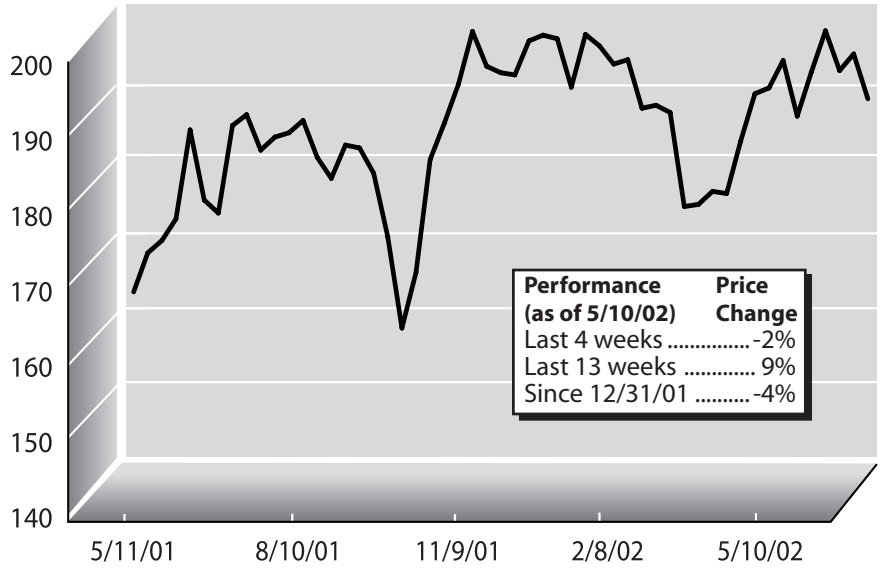
The 21 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 2% in the four weeks ended May 10, 2002, with 11 stocks declining in price and 10 rising. Year-to-date, the G-2 Index has fallen by 4%, compared with an 8% decline for the S&P 500 and an 18% drop for the Nasdaq.

Shares of **Cytyc** (Boxborough, MA) dropped 36% to $16.35 per share, giving the company a market capitalization of $2.1 billion. Cytyc recently lowered its revenue expectations for full-year 2002 to a range of $270-$285 million from previous expectations of $295-$305 million.

In addition, Cytyc says the close of its acquisition of **Digene** (Gaithersburg, MD) has been delayed by a request from the Federal Trade Commission for additional information regarding the transaction. On Feb. 18, Cytyc announced an agreement to purchase Digene for $76.9 million in cash, plus 23 million shares of Cytyc. At that time the transaction had been valued at $583 million; however, Cytyc's share price decline has lowered the transaction value to $453 million. Despite the drop, both companies say the transaction will move forward (pending FTC approval). Digene says that as of the close of business on May 8, approximately 58% of its total outstanding shares had been tendered and not withdrawn pursuant to Cytyc's offer.

Biosite Inc. (San Diego, CA) rose 26% to $28.80 per share for a market capitalization of $438 million. The company recently reported a first-quarter net profit of $1.634 million vs. $1.529 million in the prior-year period; revenue was up 23% to $18.648 million. Biosite says revenue growth was primarily driven by sales of its Triage BNP Test (designed to aid in the diagnosis of congestive heart failure), which grew to $4.1 million from $173,000 a year ago. Biosite says it now expects overall revenue growth of at least 35% in 2002 vs. previous expectations of 20%.

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 21 diagnostic test and equipment makers.

% price change, 4 weeks ended 5/10/02

UP	Price($)	% Chg
Bio-Rad	46.00	9
Biosite	28.80	26
Careside	0.15	7
Diagnostic Products	46.45	4
Diametrics	4.40	6
Igen	39.60	1
Immucor	14.75	13
Inverness Medical	27.41	10
Meridian	7.35	5
Ventana	23.37	19
DOWN		
Abbott Labs	51.25	-5
Beckman Coulter	44.77	-12
Becton Dickinson	36.27	-5
Cholestech	16.00	-7
Cygnus	4.20	-27
Cytyc	16.35	-36
Digene	23.20	-32
i-Stat	5.49	-23
Johnson & Johnson	61.85	-1
Quidel	5.80	-12
TheraSense	19.00	-3

G-2 Insider

Congress is urging the U.S. Department of Agriculture and other federal agencies to draft a plan to help states control the spread of chronic wasting disease (CWD) in deer and elk. CWD is closely related to "mad cow" disease and "mad cow's" human equivalent, Creutzfeldt-Jakob disease (CJD). These diseases eat away at the brain and nervous system and are always fatal. Sen. Wayne Allard (R-CO), who is a veterinarian, and other members of Congress have been pushing Agriculture Secretary Ann Veneman and Interior Secretary Gale Norton to come up with a coordinated, comprehensive strategy to combat CWD.

So far, deer and elk in eight Western and Midwestern states (Colorado, Wyoming, Nebraska, South Dakota, Montana, Kansas, Oklahoma and Wisconsin) have been found to be CWD-infected. And since 1997 at least five young men from Michigan, Maine, Oklahoma and Utah have died from CJD. The men, all under age 40, had all been hunters or had regularly eaten venison.

The annual incidence of CJD among people under age 30 is about five per billion, according to estimates from the Centers for Disease Control & Prevention. The spread of CWD in deer and elk, plus the recent deaths of hunters from CJD, suggest a link, though CDC researchers say they have found "no evidence of a causal link."

Meanwhile, there is growing reason to believe it won't be long before "mad cow" disease is found in cattle in the U.S. The first case was found in Britain in 1986, and the disease has since spread throughout Europe and most recently to Japan (*see p. 8*). The disease's human equivalent has killed more than 100 people in Europe.

Any detection of "mad cow" disease in the U.S. is sure to set off a rush for cattle testing. Of the 100 million cattle worldwide that are slaughtered for beef consumption each year, 37 million come from the U.S. The average selling price for "mad cow" tests is about $10, indicating a potential $370 million market for IVD test makers.

Company References

Abbott Labs 847-937-6100
Calypte 510-749-5100
Cytyc 978-263-8000
Diametrics 651-639-8035
Digene 301-944-7000
ExonHit 240-683-7070
Fujirebio Diagnostics 877-861-7246
i-Stat 609-443-9300
OraSure 503-641-6115
Quidel Corp. 858-552-1100
Roche Diagnostics 317-849-9350
Sigma Diagnostics 800-325-3424
ViroLogic 650-635-1100

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