Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

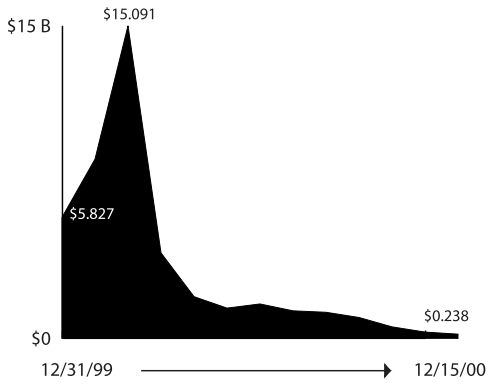
Shakeout In E-Health Supply Chain Management

Using the ubiquity of the Internet to unite buyers and sellers of medical equipment and supplies seemed like a great idea. Wall Street certainly had high hopes for the e-health supply chain management business as the combined market capitalization for three such vendors (Neoforma.com, SciQuest.com, and Ventro Corp.) reached a mind-boggling $15.1 billion late last February. At that price, the trio was valued at nearly 100 times the estimated $165 million in combined revenue they generated in 2000.

Enthusiasm for the e-health sector has since cooled. The combined market cap for these three e-health middlemen has shriveled to $238 million as of mid-December, down 98% from the peak reached in late February. Meanwhile, a planned initial public offering from another e-vendor, Medibuy. com, has been withdrawn.

What's changed over the past 10 months to cause such a reassessment for the prospects of the e-health supply chain management business? See *Inside The Diagnostics Industry*, pp. 5-7.

Market Cap Rise & Fall Of Three Big E-Health Middlemen*



*$ in millions; includes Neoforma.com, SciQuest.com, and Ventro Corp.

J&J's LifeScan To Pay $60M In Fines For Defective Blood Glucose Meter

On Dec. 15, LifeScan Inc. (Milpitas, CA), a subsidiary of Johnson & Johnson (New Brunswick, NJ), pled guilty to federal criminal charges and agreed to pay $60 million in fines for failing to report defects in its SureStep Blood Glucose Meter. The plea ends a three-year grand jury investigation, spearheaded by the U.S. Attorney's office in San Francisco, charging that LifeScan knew about defects in the product, but failed to alert customers or the government. Included in the $60 million in fines are a criminal fine of $29.4 million and civil penalties, damages, and restitution of $30.6 million.

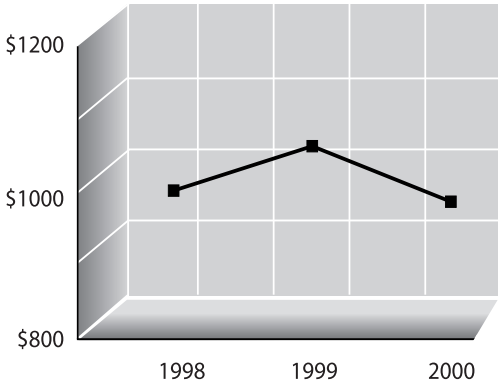
Continued on p. 2

▲ **J&J's LifeScan,** *from page 1*

Because of a software problem in SureStep meters manufactured before August 1997, individuals with very high blood sugar sometimes would receive an error message instead of a "HI" warning. A second problem related to test strips manufactured before March 1998, which could yield false low test results if the test strip containing the blood sample was not completely inserted into the meter. Johnson & Johnson says these problems were corrected by early 1998.

LifeScan admitted in the plea agreement that it failed to describe the defects to regulators at the Food & Drug Administration when it was seeking clearance to sell the new device. The company also admitted that it failed to notify customers of the defects and failed to notify FDA after patients who used the meter complained about the device and the injuries they suffered. The company received more than 2,000 complaints, and at least 61 users experienced illness or injury after using SureStep between the product's launch in May 1996 and July 1998, according to investigators from the Justice Department and FDA. LifeScan estimates that 290,000 defective units were sold.

LifeScan Sales Trends *(in millions)*



Source: *DTTR* based on data from J&J, Merrill Lynch, and SG Cowen

"Mistakes and misjudgments were made. We fully acknowledge those errors and sincerely apologize for them," said Ralph S. Larsen, chairman of Johnson & Johnson, in a written statement.

Although federal prosecutors said they were unable to find proof of intentional acts of wrongdoing on the part of LifeScan executives, a spokesman says that LifeScan's entire management team has been replaced in the wake of the episode. Specifically, in January 2000, Eric Milleage became group chairman of the unit and Robert Coradini was named president.

With the federal investigation behind it, LifeScan now faces a class-action lawsuit filed by the law firm of Milberg Weiss Bershad Hynes & Lerach (San Francisco, CA) and others seeking millions of dollars in damages for customers. "My suspicion is that Johnson & Johnson will move quickly to settle this suit," says Ira Loss, senior vice president at Washington Analysis, an investment research firm in Washington, DC. Loss believes the SureStep debacle is now largely behind the company and notes that the stock price of J&J barely budged on Dec. 15 when the settlement with the government was announced.

Regardless of how quickly and costly the resolution of the class-action lawsuit turns out to be, J&J's LifeScan business continues to lose share in the glucose monitoring market. In the three months ended Sept. 30, its sales declined by 3.3% worldwide, and sales for the full year are on track to decline by 4% to approximately $975 million.

The declines at LifeScan come as the overall glucose monitoring market is growing at 10-15% per year. Roche and Bayer in particular have been gaining share with new glucose monitoring products using electrochemical sensor technology that requires lower blood volume and provides faster result times.

Biosite Gets FDA Okay For Congestive Heart Failure Test

A prime market for the Biosite test kit—the first FDA-cleared blood test to help diagnose congestive heart failure—is the hospital emergency room where fast turnaround time is crucial

Biosite Diagnostics (San Diego, CA) received clearance on Nov. 22 from the Food & Drug Administration to market its Triage BNP Test for use with patients aged 55 and over. It's the first blood test cleared in the U.S. as an aid in the diagnosis of congestive heart failure (CHF). CHF occurs when the heart is unable to pump blood out of its left ventricle—symptoms include shortness of breath. The Triage BNP Test measures circulating levels of B-type natriuretic peptide (BNP), which is released by the left ventricle and is elevated during heart dysfunction in both symptomatic (late-stage) and asymptomatic (early-stage) CHF patients.

Currently, physicians rely on x-ray and physical evaluation in the initial assessment of potential CHF patients. However, it is often difficult to distinguish CHF from non-related respiratory problems. In clinical studies involving more than 1,200 patients, the Triage BNP Test had an overall sensitivity of 82% and a specificity of 96% for identifying patients with CHF.

Kim Blickenstaff, president of Biosite, says that 3-5 million patients are treated in hospital emergency rooms for possible CHF each year in the U.S., resulting in one million hospitalizations annually. Blickenstaff says the Triage BNP Test, which provides results in 15 minutes, will list for $27 per test and is aimed at use in emergency rooms. The test will be marketed by Biosite's 37-person direct salesforce.

ZstatFlu Test Receives CLIA Waived Status

Waiver status opens the way for the company to focus sales on the physician office market. ZymeTx expects a fourfold increase in sales, to one-half million kits, in the fiscal year ending next June 30

The Food & Drug Administration on Dec. 5 granted ZymeTx Inc. (Oklahoma City, OK) a CLIA waiver for the company's ZstatFlu 20-minute point-of-care flu test. The waived status makes the test available to some 100,000 physician office labs that are certified to conduct waived testing. In September 1997, the product had been cleared for professional use only. ZstatFlu detects influenza types A and B (average sales price, $13.70 per test) within 20 minutes using a simple throat swab and is the second CLIA-waived influenza test on the market. In October, Quidel Corp. (San Diego, CA) received a CLIA waiver for its QuickVue Influenza Test (*DTTR, Nov. '00, p. 12*).

The Medicare fee cap for influenza antibody testing (CPT code 86710) is $18.74 in 2001. However, ZymeTx says the more appropriate code for ZstatFlu is CPT 82657 (enzyme activity in blood cells, cultured cells, or tissue, not elsewhere specified; non-radioactive substrate, each specimen). CPT 82657 is capped at $24.96 in 2001.

ZymeTx recently signed a nationwide distribution agreement with Dade Behring (Deerfield, IL) to sell ZstatFlu. ZymeTx estimates it will sell approximately 500,000 kits in the fiscal year ending June 30, 2001, compared with 100,000 units sold in fiscal 2000. In the three months ended last Sept. 30, ZymeTx recorded a net loss of $1.422 million vs. a net loss of $1.736 million in the same period a year earlier; revenue increased to $64,780 from $9,773. Cash and securities totaled $2.186 million as of Sept. 30. In addition, the company raised net proceeds of $1.9 million from the sale of $2 million in convertible notes last Oct. 13.

Financing E-Health Procurement: *Losses Steep, But More Jump In*

Eight firms focused on developing Internet medical supply exchanges have raised more than $1 billion in gross proceeds from venture capital firms and initial public offerings over the past two years, according to data collected by *DTTR*.

Ventro Corp. (Mountain View, CA) has burned up cash the fastest. Over the past two years, the company has raised approximately $424 million, including $129.4 million from its IPO of 8.6 million shares priced at $15 per share in July 1999, plus another $250 million from a convertible subordinated notes sale in April 2000. Morgan Stanley Dean Witter was the lead investment bank for both offerings. As of Sept. 30, 2000, Ventro had accumulated net losses totaling $224 million on revenue of $108.1 million.

Meanwhile, Neoforma.com has accumulated net losses totaling $195.1 million and SciQuest.com has accumulated losses of $100.6 million. Finally, data filed with the Securities & Exchange Commission shows that Medibuy recorded a pro forma loss of $115.4 million in 1999 on revenue of $2.5 million.

Despite the outsized losses being recorded by e-health start-ups, two consortia containing some of the biggest medical equipment makers and supply and drug wholesaling firms have now jumped into the market, vowing to build their own Internet medical supply exchanges. One consortium brings together Abbott Labs, Baxter, GE Medical, Johnson & Johnson, and Medtronic who claim to generate 70% of medical supply sales. The other consortium unites McKessonHBOC, Cardinal Health, AmeriSource, and Fisher Scientific, four wholesalers with combined annual revenue of $65 billion. Fisher has also developed its own Website named Alchematrix.com.

Players In E-Health Supply Chain Management, December 2000

Company	*Founded*	*Alliances*	*Financial Transactions*
Alchematrix	2000	Owned by Fisher Scientific	Seeking investments from other instrument manufacturers
empactHealth	1999	HCA/HealthTrust Purchasing Group, 300 hospitals	Raised $40 million from HCA; has agreed to be acquired by Medibuy
GE and friends	3/00	Abbott Labs, Baxter, GE Medical, J&J, Medtronic	NA
Medibuy	1998	Premier, 1,850 hospitals	Raised $120 million in venture capital (VC); filed for IPO in 3/00; cancelled IPO plans 7/00
Neoforma.com	1996	Novation (VHA and UHC), 1,450 hospitals/550 medical groups	Raised $89 million in VC; completed IPO in 1/00, raising $104.7 million
NewHealthExchange	2000	McKessonHBOC, Cardinal Health, AmeriSource, Fisher Scientific	Four partners commit an estimated $50+ million
SciQuest.com	1995	850 supplier agreements	Raised $10 million from preferred stock in 11/98; raised $37.5 million from preferred stock in 6/99; completed IPO in 11/99, raising $138 million
Ventro Corp.	1999	Broadlane (joint venture with Tenet, 111 hospitals)	Raised $45 million in VC; completed IPO in 7/99, raising $129.4 million; raised $250 million from subordinated notes in 4/00

Source: *DTTR* and Corporate Research Group Inc.

It's "Do or Die" Time For Most E-Health Suppliers

"We expect high levels of customer service from our suppliers…We want trial tests of big systems…I don't think we'll ever do any buying over the internet," says Tom Mac Mahon, chairman of LabCorp

The management of the supply chain for hospitals, laboratories, and biotechnology companies remains a largely paper-based process with significant inefficiency. And the problems of supply chain management are exacerbated in healthcare because of the extreme fragmentation of both buyers and sellers of medical products. Online marketplaces aim to provide customers and suppliers with reduced order processing and tracking costs and with improved utilization of data relating to transactions and market trends.

However, despite its flaws, the current system of sales and distribution of medical supplies and instruments is likely to remain a relationship-driven business not easily replaced by faceless Internet connections (despite potential cost savings). Investors and e-health entrepreneurs have discovered that breaking up existing relationships between medical supply sales representatives and hospital administrators, physicians, and scientists is hard to do.

"Every day, thousands of on-the-ground salesmen [and women] from Abbott, Fisher, and Allegiance are having coffee and donuts with physicians and scientists. There's a lot of touching base and hand-holding," says Ken Peters, president of World Diagnostics (Miami Lakes, FL), a distributor of laboratory supplies and equipment. "It's not like buying a CD on Amazon.com."

Paul Landauer, director of external affairs at Abbott Laboratories (Abbott Park, IL), notes that Abbott sales reps "have invested years to develop their customer relationships … I can't imagine the Internet will change things much."

Gavin Mlinar, analyst at Sands Brothers (New York City), notes that unlike the rest of corporate America where purchasing managers can dictate how buying is done, buying decisions for scientific instruments in medical institutions and research organizations are controlled by physicians and scientists. "Unless the Internet is forced on these buyers, they're not ready to break-off existing relationships."

To be sure, Internet-based purchasing has gained little ground against the healthcare industry's entrenched door-to-door salespeople. In the nine months ended Sept. 30, 2000, three leading e-health middlemen—Neoforma.com, SciQuest.com, and Ventro Corp.—reported total revenue of $120.4 million, while net losses have totaled $364.5 million.

These skimpy sales figures come even as Internet-based distributors are practically giving away products to attract users to their Websites and meet Wall Street analysts' ex-

E-Health Supply Companies At A Glance

(Revenue and net income for 9 months ended Sept. 30, 2000, in thousands)

	Revenue	Net loss	Oper. CF*	Cash**
Neoforma.com	$8,172	-$139,059	-53,857	$50,478
SciQuest.com	37,618	-61,923	-43,700	68,230
Ventro	77,232	-166,520	-84,296	229,423

*Equal to net cash used in operating activities. **Includes cash and short-term investments as of Sept. 30, 2000

Source: *DTTR* from companies

pectations for revenue growth. For example, Mlinar says that of the total $19.691 million in revenue that SciQuest.com recorded in the third quarter, approximately 35-40% contributed zero dollars in gross profit. In order to entice key suppliers and buyers to use its Website, SciQuest has also issued approximately five million warrants allowing them to purchase common stock in SciQuest at an exercise price of $0.01 per share.

SciQuest.com (Research Triangle Park, NC), which operates an online marketplace of life sciences products for pharmaceutical, clinical, and biotechnology labs, recently announced a restructuring plan aimed at reducing operating costs. One of the first initiatives is to lay off 10% of its employee base—the company has more than 200 employees.

Peyton Anderson, vice president of business development at SciQuest, says, "The land grab in e-health commerce is over … It now comes down to execution." Anderson says SciQuest will no longer facilitate transactions between buyers and suppliers with zero markup. "We made it easy [for buyers and suppliers] to say 'Yes' to SciQuest … But we now expect to get paid up-front for value-added services."

For example, Anderson says SciQuest will now seek payment for system integration and employee training services it provides to purchasing clients. The company also will begin billing suppliers for converting and updating their catalogues to SciQuest's online marketplace.

SciQuest is not seeking to supplant existing relationships between salespeople and instrument buyers, Anderson says, but rather help them become more efficient. He estimates that 40% of the average saleperson's time is spent on non-selling activities such as tracking down invoices and shipments.

SciQuest offers online ordering of approximately 1.5 million analytical instruments and products from 850 suppliers, including Alltech, Ambion, Amersham Pharma Biotech, BioWhittaker, Endogen, PerkinElmer, Qiagen N.V., and Shimadzu Scientific Instruments.

Ventro Corp. (Mountain View, CA) says it will shut down its online marketplaces, Chemdex and Promedix, by March 31, 2001. The company had hired Broadview (Fort Lee, NJ), a high-tech mergers and acquisitions firm, to solicit buyers for these units, but was unable to obtain a suitable offer. Ventro expects to record approximately $380 million to $410 million in charges in the fourth quarter and to lay off 235 employees in connection with the restructuring.

Chemdex, Ventro's initial marketplace, had offered approximately 1.7 million life sciences products from more than 2,200 suppliers, including Becton Dickinson (Franklin Lakes, NJ). Promedix had distributed specialty medical products online.

Ventro says it will focus on providing technology services to online marketplaces in partnership with established vendors. For example, Ventro and Tenet

Healthcare Corp. (Santa Barbara, CA) recently formed an online medical supply joint venture named Broadlane Inc. (San Francisco, CA).

Over time, Broadlane is expected to assume the majority of contracts held by BuyPower, Tenet's group purchasing organization. BuyPower purchases nearly $3 billion worth of equipment and supplies annually for 1,500 member healthcare facilities, including Tenet's 111 hospitals.

Neoforma.com (Santa Clara, CA) has connected 65 hospitals to Marketplace@Novation, an online marketplace that the company is building for Novation (Irving, TX), a group purchasing organization representing 1,450 hospitals and 550 physician groups that are members of VHA Inc. (Irving, TX) and the University HealthSystem Consortium (Oak Brook, IL).

To land the contract with Novation, Neoforma issued 46.3 million common shares to VHA, representing approximately 36% of the company's outstanding shares. In addition, it issued warrants to VHA that will allow it to earn up to 30.8 million additional shares based on the purchasing volume driven through Marketplace@Novation over the next four years. UHC received 11.3 million common shares in Neoforma plus warrants for up to 7.5 million additional shares. The agreement also calls for Neoforma to share transaction fees from suppliers for products sold through the online marketplace.

Medibuy (San Diego, CA), a privately held company, has agreed to acquire Premier Health Exchange, the electronic commerce company of Premier Inc. (Westchester, IL). In connection with the deal, Medibuy has secured a 6-year contract as the exclusive provider of e-commerce to Premier's 1,850 member hospitals.

"We are handling a part of the world where the Abbott's and Bayer's do not have the same manpower they wield in Western Europe, the U.S., and Japan,"
says Ken Peters of World Diagnostics

In addition, Medibuy recently agreed to purchase empactHealth.com (Nashville, TN), the exclusive e-procurement provider to HCA (Nashville, TN), which operates 189 hospitals in the U.S. In connection with the deal, Medibuy will become the exclusive e-procurement provider to several members of HCA's group purchasing organization—The HealthTrust Purchasing Group—including HCA, LifePoint Hospitals, Triad Hospitals, and Health Management Associates.

Medibuy has secured supplier contracts with, among others, Dade Behring, Beckman Coulter, and Roche Diagnostics.

World Diagnostics Inc. (WDI) has launched Websites for selling diagnostic tests and laboratory equipment in 20 emerging markets, including The Netherlands, Austria, Vietnam, and South Korea. Ken Peters, president, says WDI-contracted distributors in each country manage the Websites and provide person-to-person customer service. Peters says WDI has focused on emerging markets because the large manufacturers (Roche, Abbott, Johnson & Johnson, Bayer, etc.) have locked up their market share in the U.S., Europe, and Japan.

Becton Dickinson To Buy Genetest Corp. For $29M

Becton Dickinson & Co. (BD—Franklin Lakes, NJ) has agreed to buy privately held Genetest Corp. (Woburn, MA) for $29 million in cash in a transaction expected to close by Jan. 31, 2001. Incorporated in 1982, Genetest is a leading developer of specialty reagents for P450 drug metabolism and toxicology. Genetest's products enable pharmaceutical and biotechnology companies to screen drug candidates, *in vitro*, for adverse drug-to-drug interactions and toxicity, including liver toxicity. The company generated approximately $8.6 million in revenue in 2000. The acquisition of Genetest is part of BD's strategy to expand its presence in the growing area of reagents and systems for pharmaceutical drug discovery research, says Deborah Neff, president of BD Biosciences.

HandyLab Gets $2.4M To Develop Hand-Held DNA Analyzer

Tom Dodson, director of operations at HandyLab, says each thumbnail-sized test chip will be priced at less than $100. The company is aiming to submit an application to FDA by year-end 2001

Privately held HandyLab Inc. (Ann Arbor, MI) has raised $2.4 million from four Michigan venture firms to complete development of a working prototype of its hand-held DNA analyzer.

Leading the investment round were three Ann Arbor-based investors—EDF Ventures, Avalon Investments, and Wolverine Fund—plus XR Ventures (Grand Rapids). EDF Ventures had previously provided approximately $75,000 in seed funding to HandyLab, which was launched about a year ago.

The HandyLab product could potentially drive tests like viral load testing for HIV and hepatitis C out of reference labs and hospitals and into physician offices. The device can analyze DNA from a nanoliter specimen in microchannels on a microchip using polymerase chain reaction (PCR). The company has exclusively licensed the technology that moves the specimen through the microchannels from the University of Michigan's College of Engineering microelectromechanical research program. Kalyan Handique, PhD, founder and president of HandyLab, was formerly a graduate student research assistant at the University's Department of Chemical Engineering.

Applied Imaging Raises $4M From Private Placement

Applied Imaging Corp. (Santa Clara, CA) raised $4 million in mid-December from the private placement of 1.3 million shares and warrants to purchase 422,700 shares of common stock. H.C. Wainwright (Boston, MA) managed the offering. Applied Imaging makes automated imaging systems used by genetics and pathology laboratories for the analysis of chromosomes in cancer and prenatal disorders. The company has an installed base of more than 2,000 systems in over 35 countries. In the three months ended Sept. 30, Applied Imaging recorded a net loss of $939,000 vs. a net loss of $1.979 million a year earlier; revenue increased to $3.982 million from $3.098 million. As of Sept. 30, the company had $4.785 million in cash and securities.

FDA Seeks More Data From Visible Genetics

With approval to sell in Europe and FDA approval expected soon, VGI is ramping up its manufacturing capabilities. Its Pittsburgh facility is now capable of producing 280,000 test kits per year, and production at a new manufacturing plant in Atlanta (capacity for 500,000 kits per year) is expected to begin by mid-2001

Visible Genetics Inc. (VGI—Toronto, Canada) says the U.S. Food & Drug Administration is demanding additional information on the company's 501(k) application for its Trugene HIV-1 Genotyping Kit and OpenGene DNA sequencing system. The application was filed with FDA last September. VGI says FDA has asked for documents cited, but not included, in the application. FDA is not seeking any new data analysis and has no fundamental concerns about the technology's usefulness, according to Richard Daly, VGI chief executive. He says the company will submit its response to FDA by the end of January 2001 and still hopes to launch the test in the first quarter of 2001.

Separately, VGI has announced that it has been granted French regulatory approval for its Trugene HIV-1 Genotyping Kit by the Agence Francaise De Securite Sanitaire Des Produits de Sante. Trugene is the first sequence-based DNA test to be approved in the French market. With French approval, the company is now able to market the Trugene test in the rest of the European Union member countries.

The Trugene HIV-1 Genotyping Kit helps physicians determine, based on the genetic sequence of the HIV virus, which drugs are likely to be ineffective against the virus. Currently, there are approximately 200,000 patients receiving HIV drug treatment in Europe and approximately 350,000 in the U.S. With HIV patients changing drugs every 4.5 months, that creates a potential market of roughly 1.5 million genotyping tests per year. Based on an estimated selling price of $150 per Trugene test, the dollar value of the U.S. and European market is estimated at roughly $225 million per year.

In the nine months ended Sept. 30, 2000, VGI recorded a net loss of $9.713 million vs. a net loss of $7.030 million a year earlier; revenue (primarily from sales to the clinical research market) fell to $3.008 million from $3.486 million. As of Sept. 30, the company had $88.7 million in cash and securities. As of Dec. 15, VGI had a market capitalization of $523.5 million.

Vysis Seeks Approval For Bladder Cancer DNA Test

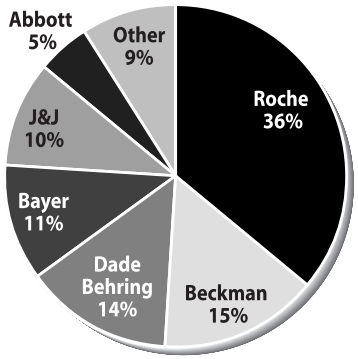
Vysis Inc. (Downers Grove, IL) has submitted its clinical trials data to the Food & Drug Administration for its UroVysion assay for monitoring recurrence of bladder cancer. The assay is based on the genetic changes in bladder cells utilizing Vysis' proprietary fluorescence DNA-probe technology. According to the American Cancer Society, there will be an estimated 53,000 new cases of bladder cancer diagnosed in 2001. Approximately 50% of bladder cancer patients experience a recurrence within two years after an initial diagnosis. This high rate requires that patients be monitored up to four times a year. The current monitoring is done by cytoscopy, an invasive procedure, and by urine cytology, which has been proven to be unreliable. Vysis collaborated with the Mayo Clinic on the development of the UroVysion assay. Oil giant BP Amoco (London, England) owns more than 65% of Vysis, which currently markets DNA-based tests for breast cancer and prenatal diagnosis of chromosome abnormalities.

Beckman Coulter To Launch Closed-Tube Chemistry System

Beckman Coulter (Fullerton, CA) says it will begin marketing in early 2001 the Synchron LX20 Pro, a new routine chemistry analyzer with closed-tube sampling and a highly sensitive detection system. The LX20 Pro eliminates the need for laboratory workers to remove the caps from Becton Dickinson's Hemogard blood tubes. In addition, the new analyzer features a highly sensitive, near-infrared particle immunoassay detection system, allowing a larger menu of tests.

The LX20 Pro is an upgrade (listed price= $75,000) to Beckman's LX20 chemistry analyzer, which was launched in the U.S. in 1997 and now has more than 570 placements worldwide. Overall, Beckman ranks second in worldwide chemistry sales, with an estimated $528 million of revenue in 2000. Roche Diagnostics (Indianapolis, IN) leads with an estimated $1.265 billion in chemistry sales.

$3.5B Chemistry Global Market, 2000



Source: Merrill Lynch estimates

TriPath Renews National Contract With Kaiser

TriPath Imaging (Burlington, NC) says it has renewed its national pricing contract for its thin-layer Pap smear preparation kits with Kaiser Permanente (Oakland, CA). Kaiser also has purchased four of TriPath's AutoPap Systems for its northern California clinical laboratory. AutoPap is a fully automated system that screens Pap smear slides using algorithms to identify patterns and to score slides.

In the three months ended Sept. 30, 2000, TriPath recorded a net loss of $2.866 million vs. a net loss of $12.388 million a year earlier; revenue nearly doubled to $8.093 million from $4.772 million. As of Sept. 30, cash and securities totaled $14.3 million.

Last September, Roche Holding AG (Basel, Switzerland) agreed to acquire five TriPath shares at $8 per share. After the $40 million investment, Roche will own 24% of shares outstanding and could buy an additional five million, boosting its stake to 34%. Closure of the deal is pending legal and antitrust approvals.

TheraSense, APBiotech Pull IPOs, Citing Market Conditions

TheraSense Inc. (Alameda, CA), which makes blood glucose meters, has delayed plans for an initial public offering "due to the volatility of the public capital markets," it says. Last October, the company had filed for an $86.25 million IPO (*DTTR, Nov. '00, p. 10*) and had planned to go public in late December. Separately, Nycomed Amersham (London, England) and Pharmacia Biotech (Peapack, NJ) say the IPO of their jointly owned life sciences business, APBiotech Inc. (Piscataway, NJ), is not now expected before the end of February 2001 (*DTTR, Nov. '00, p. 10*).

Diagnostic Stocks Rise 2% In Latest Four Weeks

The G-2 Diagnostic Stock Index rose 2% in the four weeks ended Dec. 15, with 10 stocks in the index rising and nine falling. Since the start of the year, the index has risen 44% vs. a loss of 11% for the S&P 500.

Stocks With Double-Digit Advances

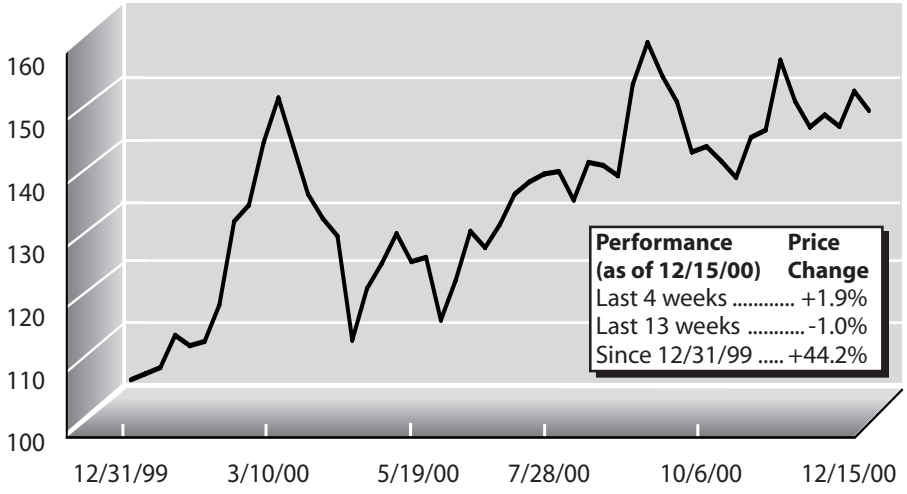
Inverness Medical Technology (Waltham, MA) was up 37% to $36 per share, giving the company a market capitalization of $1.16 billion. **Diagnostic Products** (Los Angeles, CA) rose 23% to $57.25 per share, giving it a market cap of $815.4 million. **Biosite Diagnostics** (San Diego, CA) rose 19% to $36.94 per share for a market cap of $577 million. Biosite recently received FDA clearance to sell its Triage BNP Test for diagnosing congestive heart failure (*see story, p. 3*). **Cytyc Corp.** (Boxborough, MA) was up 15% to $61.44 per share for a market cap of $2.27 billion. **i-Stat Corp.** (East Windsor, NJ) rose 13% to $24 per share for a market cap of $433.4 million.

Stocks With Double-Digit Declines

Calypte Biomedical Corp. (Alameda, CA) fell 30% to $1.31 per share, giving it a market cap of $33 million. **Careside** (Culver City, CA) slipped 24% to $2.38 per share for a market cap of $21.7 million. **Diametrics Medical** (St. Paul, MN) declined 22% to $6.13 per share for a market cap of $163.5 million.

Abbott Laboratories (Abbott Park, IL) declined 10% to $46.81 per share for a market cap of $72.5 billion. Abbott recently agreed to purchase the pharmaceutical business of BASF (Ludwigshafen, Germany) for $6.9 billion in cash. Top selling pharmaceuticals from BASF include Synthroid for the treatment of thyroid insufficiency, Rythol/Rytmonorm for arrhythmia, and Meridia/Reductil for the management of obesity.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change of 19 diagnostic test and equipment makers.

% Price Change, 4 weeks ended 12/15/00

UP

Beckman Coulter	+4.3%
Bio-Rad Laboratories	+7.5%
Biosite	+19.2%
Cytyc	+14.7%
Diagnostic Products	+22.8%
Digene	+11.4%
Inverness Medical	+37.1%
i-Stat	+12.6%
Johnson & Johnson	+3.6%
Meridian	+8.6%

DOWN

Abbott Labs	-10.2%
Affymetrix	-7.1%
Becton Dickinson	-2.0%
Calypte	-30.0%
Careside	-24.0%
Cholestech	-0.9%
Cygnus	-5.9%
Diametrics	-22.2%
Quidel	-6.4%

G-2 Insider

Medicare processes for determining payment levels for new technologies for outpatient clinical laboratory services should be revamped, says a congressionally mandated study released Dec. 7, 2000 at a briefing by the Institute of Medicine.

Though radical change is not needed now, the report asserts, Congress and the Health Care Financing Administration should fix the current system to avert a potential future crisis. The study found no evidence that beneficiaries have trouble obtaining lab services, but did conclude that payments for certain individual tests likely do not reflect the cost of providing the service and that future advances in lab technology will likely magnify flaws in the current payment system.

Specifically, the report said that HCFA should create a committee of laboratorians, pathologists, other physicians, scientific experts, health service policymakers, and economists to advise on the setting of interim relative values or national fees for new technologies.

"There should be an open process for determining which technologies are truly innovative and sufficiently different from existing ones to merit a detailed cost analysis and new fee, and which tests and methods are incremental improvements and could be paid at the same rate as an existing test. The manufacturer and others should be allowed to present data to the committee showing quantifiable improvements in treatment outcomes and other advantages of the new test that might justify a higher payment rate," concluded the 12-member IOM study committee.

The 241-page report has been sent to key congressional members and staff as well as regulators at HCFA. In turn, policymakers have the option of tapping the findings as the basis for overhauling Medicare's lab payment statutory authority and reimbursement scheme. To purchase a copy of the IOM report, call 1-800-624-6242 or 202-334-3313.

Company References

APBiotech 732-457-8000
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