Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

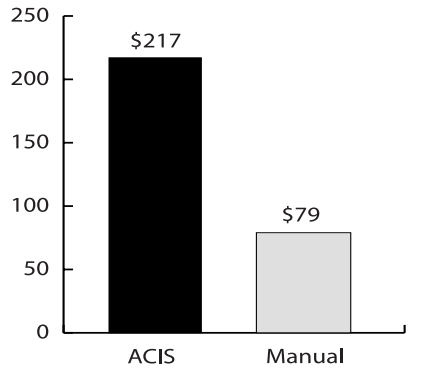
Established 1979

High Reimbursement May Drive Growth Of Automated Microscopy Systems

Automated microscopy systems hold the promise of enhancing the acumen of even an inexperienced pathologist to a level above that of an expert pathologist using manual microscopy to quantitate immunohistochemistry-stained tissue specimens. Clinical studies suggest that the uniformity of testing results from automated systems made by companies like ChromaVision (San Juan Capistrano, CA) can also reduce misdiagnoses, thereby cutting overall healthcare costs.

But a more potent factor may be driving demand for automated equipment: current Medicare reimbursement for automated microscopy is extremely favorable vs. manual microscopy exams. For example, the national Medicare allowable for HER-2/neu analysis using ChromaVision's Automated Cellular Imaging System (ACIS) is set at approximately $217 per test vs. $79 for manual microscopy. For more on the trend toward automated microscopy, see *Inside The Diagnostics Industry*, pp. 5-7.

ACIS vs. Manual Microscopy Payment For HER-2/neu Analysis



Source: *DTTR (see p. 6 for details)*

"Mad-Cow" Fear Creates $100+ MM European Market

The threat of "mad-cow disease" is only beginning to grab the attention of consumers, cattle ranchers, and government officials in the U.S., but in the European Community (EC) hardly a day passes without newspaper editorials criticizing EC governments for not taking greater preventive action against this public health danger.

Some 91 Europeans are known to have been infected and to have died or to be dying. The upshot is that demand for mad-cow testing has exploded in Europe, creating a $100+ million market almost overnight for test kits.

Continued on p. 2

▲ **"Mad-Cow" Fear,** *from page 1*

This new market has not escaped the attention of Roche Diagnostics (Basel, Switzerland). It has announced an agreement with Prionics Inc. (Zurich) to take over worldwide distribution of Prionics-Check, a test for detecting Bovine Spongiform Encephalopathy (BSE), more commonly known as mad-cow disease. The agreement also calls for Roche to contribute its expertise in test automation to further develop Prionics-Check into a more user-friendly test.

At present, only dead animals can be tested for BSE. Heino von Prondzyski, head of Roche's Diagnostics Division, says Roche will work with Prionics to develop a blood-based test for BSE that can be used with live animals.

Manfred Baier, head of Roche Molecular Biochemicals, notes that the spread of BSE is also having an impact on blood banks. As a result, Baier says the development of a blood test for detecting new-variant Creutzfeldt-Jacob Disease (vCJD) is a high priority at Roche as well. The human version of BSE is know as vCJD to distinguish it from a form of CJD that occurs naturally in about one in a million people.

BSE, vCJD, and related diseases such as scrapie are caused by prions—nerve system proteins that are normally benign but which can take on a misshapen form that can cause holes to form in the brain. The first official diagnosis of BSE was made in Britain in 1986. The disease spread throughout Europe after cattle were fed the ground-up remains of their own species.

vCJD is caused by eating infected beef and is fatal. More than 80 people have died of vCJD in Britain and three in France. Experts still do not know how extensively the disease will spread. It can take 5-10 years for humans to show symptoms, which include insomnia, memory loss, anxiety, and eventually loss of coordination, incontinence, and blindness. Symptoms of cattle stricken with BSE include loss of coordination, aggressive behavior, and nervousness, hence the moniker "Mad Cow."

Prionics-Check is one of only three tests approved by the European Commission to screen for BSE. Testing involves submerging a three-inch sample of brain tissue in liquid with proteinase, a powerful enzyme that can identify the misshaped prion proteins that cause the disease.

Mad-Cow Disease: *A Brief History*

1986	First official diagnosis of Bovine Spongiform Encephalopathy (BSE or mad-cow disease) is made in Britain
1988	Britain prohibits feeding cattle with meal containing cattle meat and bones
1994	European Union prohibits use of cattle feed containing cattle meat and bones
1995	First human death from new-variant Creutzfeldt-Jacob disease, the human version of BSE
1997	Prionics develops first efficient test for BSE
1997	U.S. Food & Drug Administration bans feeding cattle with meal containing cattle meat and bones
1999	In March, European Commission issues draft report warnings that BSE has likely spread from Britain to cows elsewhere
2000	Denmark discovers its first mad-cow case in February; Germany and Spain find their first case in November
01/01	European Union commences mandatory testing of all beef livestock over the age of 30 months; Italy finds first case of mad-cow disease, in McDonald's supplier
02/01	United Nations Food & Agriculture Organization announces that at least 100 countries are at risk for mad-cow disease
02/01	Lithuania's state food and veterinary service announces that mad-cow disease might be present in the country's cattle herds
02/01	U.S. Dept. of Agriculture orders destruction of 350 Vermont sheep suspected of having scrapie

Source: *DTTR* compilation from *The Wall Street Journal*, *Financial Times*, and other newspapers

Each year in the U.S., specimens from about 3,000 high-risk dead cattle are tested for BSE at the National Animal Disease Center in Ames, IA

On Jan. 1, 2001, all countries in the European Union (EU) commenced mandatory testing of all beef livestock over the age of 30 months, indicating the need to test seven million cattle this year. The EU pays 15 euros each (US $14) for BSE testing kits, indicating a market of 105 million euros (US $98 million). The market could grow to 30 million tests if all cattle in Europe were to be screened. Although no formal BSE screening requirements have been announced in the U.S., the potential is enormous. There are approximately 100 million cattle in the U.S., according to the National Cattlemen's Beef Association. It should be noted that no cases of BSE have been reported in the U.S.

In addition to Prionics-Check, BSE tests approved by the EU include Platelia-BSE, made by Bio-Rad Laboratories (Hercules, CA). Bio-Rad says it delivered approximately 100,000 BSE tests in the fourth quarter of 2000 and has been increasing production capacity dramatically. In addition, the company says it has received orders for another 1+ million BSE tests from European customers.

Enfer Technology Ltd. (Dublin, Ireland), an animal diagnostics company, is the third company with a test approved by the EU. In addition, privately owned German pharmaceuticals firm Boehringer Ingelheim announced in December that it had applied for a global patent for a blood test to detect BSE in living cattle. The company says its animal health subsidiary, Vetmedica GmbH, developed the test, which it hopes will be available later this year in Europe.

Decode, Roche Move Closer To Genetic Test For Schizophrenia

Decode Genetics (Reykjavik, Iceland) and Roche say they have made progress in turning two gene discoveries into diagnostic tests and drug treatments for schizophrenia and peripheral arterial occlusive disease (PAOD). The advance marks the first time that drug targets have emerged from the alliance between the two firms and is worth up to $200 million to Decode in royalty and milestone payments from Roche.

Both disease genes were identified by Decode through genome-wide scans revealing strong population-wide linkages. Decode has bought exclusive access to Iceland's health records and is analyzing the population's unique genetic composition—stable since the Vikings arrived in the 9th and 10th centuries—to uncover the genetic basis of disease.

Approximately 0.5-1% of people worldwide will develop schizophrenia during their lifetime. The onset usually occurs in early adulthood and affects its victims lifelong. Current therapies have limited effectiveness because of insufficient understanding of the disease's biology and molecular pathology. Finding specific disease-linked gene variants may produce better targets for better medicines. It also may allow prevention through predisposition diagnostics.

PAOD is a narrowing of the arteries of the arms and legs that strikes between 2-5% of people worldwide over age 65. It results in pain, diminished mobility, the need for invasive surgery and, in extreme cases, loss of the affected limbs.

Luminex 100 System Reaches 389 Placements

Luminex Corp. (Austin, TX) reports that it sold 120 of its Luminex 100 systems in the fourth quarter of 2000, giving it a total placement of 389 since sales were initiated in 1999. The Luminex 100 is a benchtop analyzer that performs up to 100 biological tests simultaneously on one drop of fluid.

The system utilizes Luminex's LabMap (laboratory multi-analyte profile) technology, which detects the presence and measures the strength of specific molecular interactions such as those involving DNA or proteins. It uses lasers to distinguish the color intensities of fluorescently dyed microspheres that carry the bioassays on their surface, allowing the system to identify the test being performed.

To date, the Luminex 100 has been used primarily by pharmaceutical firms and biomedical research organizations like Eli Lilly and Novartis. Last November, however, Luminex submitted to the U.S. Food & Drug Administration its device master file (DMF) for the *in vitro* diagnostic version of the Luminex 100. This will allow the company's strategic partners to refer to the DMF in their individual 510(k) submissions. Luminex management has projected that the first LapMap-based IVD kit will likely be commercialized by a strategic partner by March 31, with more to follow in the second quarter.

Luminex raised gross proceeds of $83 million from a March 2000 initial public offering at $17 per share. Co-founders and brothers Mark Chandler (chairman) and Van Chandler (vice president of instruments) own nearly 25% of the company. In full-year 2000, the firm posted a net loss of $12.474 million vs. a net loss of $12.608 million in 1999; revenue rose 175% to $8.57 million.

CytoLogix Raises $26 Million From Venture Investors

CytoLogix Corp. (Cambridge, MA) has secured $26 million in financing from a group of venture capital firms led by EGS Healthcare Capital Partners, LLC. CytoLogix, a privately held company, manufactures the Artisan system for automating both special stains and immunohistochemistry on one platform. H.C. Wainwright & Co. Inc. managed the placement. This financing brings total venture investment to date in CytoLogix to more than $40 million.

Separately, CytoLogix recently announced it had filed a lawsuit in U.S. District Court for the District of Massachusetts against Ventana Medical Systems (Tucson, AZ), alleging that Ventana's Benchmark and Discovery instruments infringe on CytoLogix's patented slide heating technology. In a previous filing, CytoLogix alleged that Ventana misappropriated CytoLogix's technology from a confidential business plan and incorporated it into its Benchmark and Discovery instruments. CytoLogix seeks a permanent injunction against Ventana's infringing devices as well as damages.

Christopher Gleeson, president of Ventana, tells *DTTR*, "Ventana's products do not infringe on CytoLogix's patents, and the lawsuits have not affected our freedom to do business."

After Slow Start, ChromaVision's ACIS Is Catching On

The initial microscopic analysis of pathology slides, still performed manually, may represent the largest non-automated sector of all clinical laboratory testing

In an effort to improve on traditional cancer cell counting techniques, ChromaVision (San Juan Capistrano, CA) has developed an automated microscopy system for the evaluation of tissue specimens with immunohistochemistry (IHC) stains. The company's Automated Cellular Imaging System (ACIS) was cleared by the U.S. Food & Drug Administration in July 1999 "to detect, count, and characterize cells of interest that are stained with IHC."

ACIS has a current menu of 10 tests, including micrometastases, estrogen and progesterone receptors, as well as quantification of HER-2/neu, protein expression (P53), and cell-proliferation (Ki-67). Although studies indicate that ACIS is more sensitive than manual microscopy testing methods, adoption of the new technology has been slower than expected. In full-year 2000, for example, ChromaVision reported a net loss of $14.752 million on revenue of only $1.196 million.

But attitudes in the market appear to be changing. "Many pathologists have taken a defensive or skeptical attitude toward ACIS, but they are beginning to see it more as a useful tool, rather than something that will put them out of business," notes Ron Opel, an analyst at H.C. Wainwright & Co, a Boston-based brokerage and investment banking firm.

For years, manual microscopy of IHC-stained slides has been the principal diagnostic test method used to detect cancers, infectious diseases, and genetic disorders. In a series of labor-intensive steps, patient tissue samples are washed and stained. Pathologists then view these specimens under a microscope, looking for abnormal cells based on color, size, and shape. Manual microscopy is used to determine the type of cancer, the site of the primary tumor, the degree of malignancy, and whether the cancer has metastasized.

Manual microscopy works well for simple diagnoses and for cases where disease is obvious. But it is laborious and subjective, particularly when identifying "rare cellular events" such as finding a few cancer cells in a patient sample containing millions of cells. Among the factors contributing to this subjectivity is the lack of a standardized methodology for both the handling and the staining of the specimen.

In addition, the human eye, even with the aid of a microscope, has limited ability to discriminate between slight color variations associated with the staining process or to detect differences in the form and structure of cells. Examining cells under this method can result in variations in reportable results, ranging from modest and probably insignificant differences to cases of incorrect diagnoses.

ChromaVision's ACIS is a cell-locating device that combines a proprietary color-based imaging technology with a fully automated, computer-controlled micro-

ChromaVision says its ACIS system is capable of detecting one cancer cell among 100 million normal cells. Existing manual microscopy methods can detect one cancer cell among 10,000 normal cells

scope system. The system uses color as the primary means of detecting disease and achieves greater sensitivity than existing methods through its ability to discriminate among up to 256 levels of intensity of any chosen color, the company says. ACIS hardware includes a computer with a modem and a monitor, a digital camera, an Olympus microscope, and a color printer.

ACIS automatically scans the slides, initially at low magnification to identify abnormal cells by measuring their color intensity. It then re-images the abnormal cells at a higher power and, using additional color criteria and pattern recognition software, confirms the significance of the targeted cell. An image of the abnormal cells is displayed on the computer monitor, then stored for scoring and review by a pathologist.

David Weisenthal, ChromaVision's vice president of marketing, says the company asked the American Medical Association's CPT Advisory Committee how laboratories that use ACIS should bill. AMA responded with a letter of opinion suggesting use of CPT code 88358 (both professional and technical components) and CPT 88342-TC. Medicare reimbursement for 88358 billed globally is $185.93 (unadjusted for geographic cost differences); for 88342-TC, $30.99 (unadjusted). The total reimbursement is $216.92 vs. the global rate of $78.81 for traditional manual microscopy tests billed under CPT 88342.

Joe Plandowski, president of Lakewood Consulting Group (Lake Forest, IL), points out that the ChromaVision system may not make economic sense for hospital laboratories, which typically receive payment of less than $60 for the technical component of the test, but have to pay ChromaVision $75 per test. "Hospital-based pathologists are clamoring for the [ACIS] system because they keep the professional component of $158.77, but the hospital facility incurs a loss on every ACIS test." Plandowski adds that the technical/professional split is not an issue for independent labs.

Per Test Medicare Payment: ACIS vs. Manual Microscopy

	Tests Using ChromaVision's ACIS	*Tests Using Manual Microscopy*
Prof. Component, CPT 88358	$158.77	--
Tech. Component, CPT 88358	$27.16	--
Prof. Component, CPT 88342	--	$47.82
Tech. Component, CPT 88342	$30.99	$30.99
Total reimbursement per test	$216.92	$78.81
ChromaVision fee per test	$75.00	--
Gross profit per test	$141.92	$78.81

Source: *DTTR* from ChromaVision and the Health Care Financing Administration

Weisenthal says Medicare contractors and managed care companies have been willing to reimburse ACIS because its sensitivity cuts down on unnecessary treatment arising from false positive results. Take, for example, metastatic breast cancer. In the U.S. last year, 165,000 women were diag-

nosed with it; of this number, about 25-30% who overexpress HER-2/neu are candidates for Herceptin, Genentech's FDA-approved drug against the disease. According to analyst Ricky Goldwasser at Warburg Dillon Read, it costs the healthcare system about $17,256 to treat a patient with Herceptin (24 infusions at $719 per infusion). Clinical studies have reported false positives of at least 10% among women tested as candidates for the drug using manual microscopy. Eliminating these false positives with a more sensitive test like ACIS can potentially save more than $4,000 per patient tested, according to one ChromaVision-sponsored clinical study of 129 breast cancer patients.

ChromaVision offers ACIS to customers for a minimum monthly fee of $4,000 or $75 per test (the customer pays whichever is greater). ChromaVision does not charge for the instrument itself. As of mid-February this year, the company had placed approximately 40 ACIS units in the U.S. and 25 in Europe, according to Weisenthal. Customers include Cytometry Associates (Brentwood, TN), Mayo Clinic (Rochester, MN), Specialty Laboratories (Santa Monica, CA), and the University of Texas MD Anderson Cancer Center (Houston).

In December 2000, ChromaVision signed as a client Dianon Systems (Stratford, CT), one of the largest pathology companies in the Nation with $100 million in annual revenue. And earlier this year, Pathology Service Associates (PSA—Florence, SC) agreed to jointly market ChromaVision's ACIS product to PSA members. PSA provides billing and management services to some 80 pathology groups.

However, ChromaVision is not expected to keep the automated microscopy market for cancer tissue analysis all to itself. In March 2000, Ventana Medical Systems (Tucson, AZ) announced a multi-year agreement to provide development funds to AccuMed International Inc. (Chicago, IL) to build a customized automated cellular image analysis system for quantitating IHC-stained samples prepared by Ventana's instrument-reagent systems. AccuMed says FDA clinical trials for the new product will begin shortly.

Ventana plans to have an automated cellular imaging product on the market by early 2002, according to president Christopher Gleeson

Ventana is the market leader in automated equipment for tissue preparation and slide staining at histology labs with 2,000+ IHC systems placed worldwide. This past November, FDA approved Ventana's CB11 monoclonal antibody for breast cancer screening. Previously, Dako's Herceptest was the only approved test. In full-year 2000, Ventana posted a net loss of $27.295 million vs. a profit of $12.811 million for the prior year; revenue increased 3% to $71.149 million.

Applied Imaging Corp. (Santa Clara, CA) received FDA clearance in the third quarter of 2000 to market its MDS automated imaging system for detecting micrometastic cells associated with the spread of cancer. The company also makes the CytoVision, an automated system used in such chromosomal analysis as prenatal testing for Down's syndrome, and has installed it at over 800 sites. In full-year 2000, Applied Imaging posted a net loss of $4.193 million vs. a net loss of $6.009 million in 1999; revenue increased 18% to $16.689 million.

BioMerieux-Pierre Fabre Bids For Akzo's Diagnostics Unit

As speculated in our February issue (*p. 12*), Akzo Nobel NV (Arnhem, The Netherlands) has announced that it has received an offer from BioMerieux-Pierre Fabre (Marcy l'Etoile and Castres, France) for the diagnostics business of Organon Teknika (Boxtel, The Netherlands).

"The board of management will review the offer, which appears to be attractive and in line with the strategy of our pharma group," said an Akzo Nobel spokesman. The value of the bid was not disclosed; however, analysts have estimated a price of between 300-500 million euros. Organon Teknika, which had sales of 530 million euros in 1999, makes diagnostics and muscle relaxants such as Esmeron. Akzo says it will retain Organon's pharmaceutical business.

If completed, the deal would add about 275 million euros (US $252 million) in annual revenue to BioMerieux-Pierre Fabre's diagnostics products unit, bringing it to an annual run rate of roughly 850 million euros (US $780 million), according to *DTTR* estimates. BioMerieux-Pierre Fabre was created by the merger of Pierre Fabre and BioMerieux in December.

Exact Raises A Disappointing $56 MM From IPO

Wall Street's appetite for new genetic testing companies appears to have been sated following the red-hot market for initial public offerings in 1999-2000. On Jan. 31, Exact Sciences Corp. (Maynard, MA) raised gross proceeds of $56 million from an initial public offering of four million shares priced at $14 per share. The company initially had hoped to raise as much as $69 million at a share price of between $14 and $16. As of the close of trading on Feb. 12, Exact shares had fallen 17% to $11.63 per share. Merrill Lynch, CIBC World Markets Corp., and Thomas Weisel Partners LLC managed the IPO, reaping underwriting commissions of $0.98 per share or a total of $3.92 million.

Medicare's maximum payment per fecal occult blood testing, the most common screening test for colon cancer, is $3.50

Exact says net proceeds of approximately $51 million from the IPO will be used, in part, to fund clinical studies and trials for genetic tests that it is developing to screen patients for cancer. The company recently announced it has developed a novel colon cancer test in collaboration with the Mayo Clinic (Rochester, MN). Clinical studies at the Mayo Clinic indicate that Exact's colorectal cancer screening tests may be superior to current early detection screening methods. In a press release issued last Oct. 26, Mayo said the test is "about two years away from becoming widely available for public use."

Stanley Lapidus, founder and chairman of Exact, has stated that he expects the per test cost to be "a few hundred dollars." The company's prospectus warns, "If we fail to sufficiently reduce costs, tests using our technologies may not be commercially viable." The filing also notes that competitors such as Bayer, diaDexus Inc., Matritech, and Millennium Predictive Medicine Inc. are developing serum-based tests for colon cancer. At its present price of $11.63 per share, with about 18.8 million shares outstanding, Exact has a market capitalization of $218.6 million. The

company, which currently generates no revenue, recorded a loss of $6.784 million in the nine months ended Sept. 30, 2000 vs. a loss of $3.629 million in the same period a year ago.

Profits And Revenue Slip At Becton Dickinson

Becton Dickinson (Franklin Lakes, NJ) posted a net profit of $60.622 million for its fiscal first quarter ended Dec. 31, 2000, down 20% from $75.294 million in the same period a year ago; revenue dipped 2% to $843.257 million. Despite the sales decline, company president Edward Ludwig said he still expects to achieve 5% sales growth in fiscal 2001 (ending Sept. 30).

Becton Dickinson At A Glance
Three months ended Dec. 31, 2000 ($MM)

	2000	1999	% Chg
Medical systems	$438	$463	-5.2%
Clinical lab	277	271	+2.2%
Biosciences	128	125	+1.9%
Total revenue	843	859	-1.9%
Net income	61	75	-19.5%
Earnings per share	$0.24	$0.30	-20.0%

Source: Becton Dickinson

Fiscal first-quarter revenue at Becton Dickinson's clinical laboratory division increased 2% to $276.953 million. Within the clinical lab division, sales of preanalytical supplies (mostly evacuated blood collection) were up 1% to $133.624 million; sales of diagnostic systems (microbiology products) were up 3% to $143.329 million.

The biosciences unit (immunocytometry and Discovery Labware) reported a 2% gain in revenue to $127.87 million. Medical systems sales (mostly needles, syringes, and IV catheters) were down 5% to $438.434 million.

Fourth-Quarter Income Up 11% At Beckman Coulter

Beckman Coulter (Fullerton, CA) posted a net profit of $43 million for its fourth quarter ended Dec. 31, 2000, up 11% from $38.6 million in the same period a year ago; revenue increased 2% to $525.3 million. Company chairman John Wareham says he expects revenue growth in the range of 5-7% for full-year 2001.

Revenue at Beckman Coulter's clinical diagnostics unit was up 0.6% to $393.3 million. The strongest segment in clinical diagnostics was flow cytometry, up 7.5% to $46 million; the weakest was hematology, down 2% to $105.9 million.

Beckman Coulter At A Glance
Three months ended Dec. 31, 2000 ($MM)

	2000	1999	% Chg
Clinical diagnostics	$393	$391	+0.6%
Life science	132	126	+4.5%
Total revenue	525	517	+1.5%
Net income	43	39	+11.4%
Earnings per share	$0.69	$0.65	+6.2%

Source: Beckman Coulter

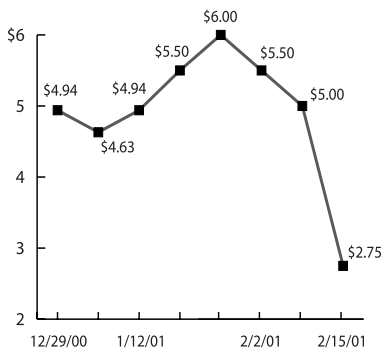
Beckman's life science research unit recorded a 4.5% revenue gain to $132 million. Robotic automation/genetic analysis led growth with revenue of $44.6 million, up 36%. Centrifuge sales were down 7% to $87.4 million.

For full-year 2000, Beckman Coulter reported a net profit of $125.5 million vs. $106 million for 1999; revenue was up 4% to $1.887 billion. Revenue from clinical diagnostics was up 4% to $1.472 billion; life science research revenue was up 6% to $414.7 million.

Meridian Suspends 30 Products; Shares Plummet 45%

In response to an FDA inspection of its manufacturing and quality procedures, Meridian Bioscience (Cincinnati, OH) has announced that it has suspended the manufacturing and distribution of approximately 30 products at its Cincinnati plant. Meridian says it is in the process of determining which of these products to revalidate for future sale. Meridian Bioscience (formerly Meridian Diagnostics) manufactures test kits for the rapid diagnosis of infectious diseases, including parasitic, gastrointestinal, respiratory, urogenital, and viral diseases.

Meridian's Stock Price



Source: *DTTR*

Meridian recorded a total of $9.271 million in charges in its fiscal first quarter ended Dec. 31, 2000 for inventory write-offs, reserves for potential product recalls, and other costs associated with the FDA inspection and its aftermath. As a result, the company reported a net loss of $8.192 million for fiscal first-quarter 2001 vs. net income of $1.47 million for the same quarter a year earlier; revenue was up 6% to $15.254 million. However, the company estimates that on an annual basis, the lost revenue and operating income impact from the pulled products will be $9 million and $2.5 million, respectively.

News of the 30-product suspension was released after trading on Friday, Feb. 9. Since then, shares of Meridian have plunged 45% to $2.75 per share as of Feb. 15.

Abbott Wins 5-Year Deal With AmeriNet For Safe Needles

Abbott Laboratories (Abbott Park, IL) has won a five-year agreement to supply AmeriNet member hospitals and healthcare facilities with VanishPoint single-use automated retraction blood collection tube holders and single-use retractable syringes. The contract began Jan. 1, 2001. AmeriNet (St. Louis, MO) represents approximately 14,885 member facilities in all 50 states, including hospitals, medical group practices, nursing homes, and surgery centers.

VanishPoint products utilize patented automated retraction technology, which reduces exposure to contaminated needles. Retractable Technologies Inc. (RTI—Little Elm, TX) manufactures VanishPoint syringes and blood collection devices. Abbott distributes RTI's VanishPoint products as part of its Needlestick Prevention Systems (NPS) product line.

Abbott says its NPS products satisfy new Occupational Safety & Health Administration needlestick prevention directives, implementing the Needlestick Safety and Prevention Act which became law last November. The Act requires hospitals and other healthcare facilities to take steps to protect workers from on-the-job sharps injuries and adopt safer needle technology that is commercially available. They also must keep a log of all needlestick injuries (not just those that result in injury or illness) and protect the privacy of individuals who suffer sharps injuries. According to the federal Centers for Disease Control & Prevention, 600,000-800,000 injuries from needlesticks and other hospital sharps occur every year.

IVD Stocks Flat In Latest 6 Weeks; Digene Falls 41%

The G-2 Diagnostic Stock Index was unchanged in the six weeks ended Feb. 9. Eleven stocks in the index fell in price, eight rose. Since the start of the year, the index is also flat, as are both the S&P 500 and the Nasdaq.

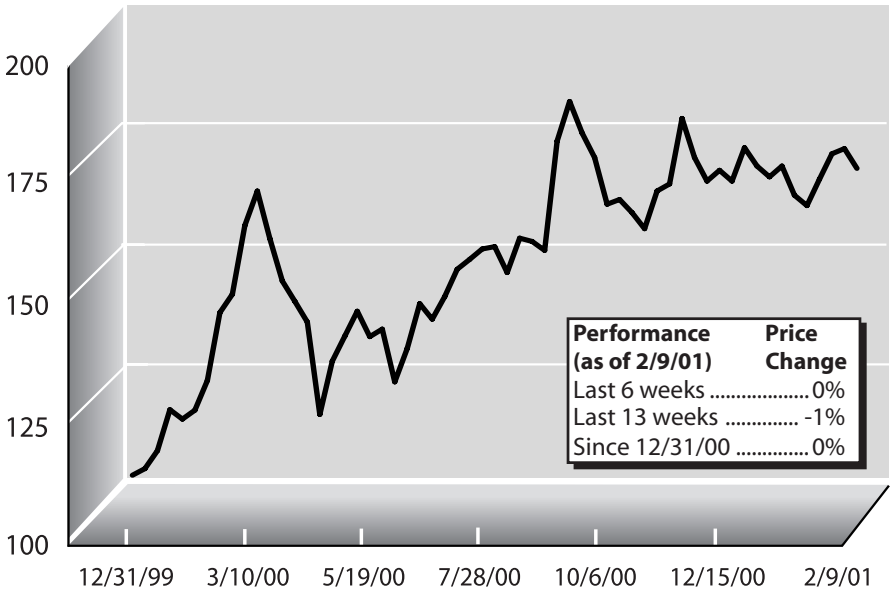
Digene Corp. (Gaithersburg, MD), which makes the Hybrid Capture2 HPV Test for detecting human papillomavirus, saw its stock drop 41% to $26.50 per share, giving it a market capitalization of $439 million. The company reported a higher-than-expected net loss of $1.578 million in the three months ended Dec. 31, 2000 vs. a net loss of $1.577 million in the same period a year earlier; revenue increased 48% to $7.755 million.

Shares of **Inverness Medical Technology** (Waltham, MA) declined 29% to $28.50 per share, giving it a market cap of about $928 million. In fourth-quarter 2000, Inverness posted net income of $3.906 million, up from $92,000 in fourth-quarter 1999; revenue was up 35% to $49.026 million.

Shares of **i-Stat** (East Windsor, NJ) declined 24% to $20.06 per share for a market cap of $387 million. In fourth-quarter 2000, i-Stat posted net income of $779,000 vs. a loss of $2.341 million in fourth-quarter 1999; revenue was up 29% to $15.621 million.

Careside (Culver City, CA) saw its stock jump 76% to $3.19 per share for a market cap of $29 million. In January, the company raised a much-needed $937,062 in gross proceeds from a private placement of 416,472 shares of common stock at $2.25 per share.

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, 6 weeks ended 2/9/01

UP

Becton Dickinson	+7.0%
Bio Rad Laboratories	+21.0%
Calypte	+24.0%
Careside	+76.0%
Cygnus	+12.0%
Diametrics	+1.0%
Meridian	+1.0%
Quidel	+7.0%

DOWN

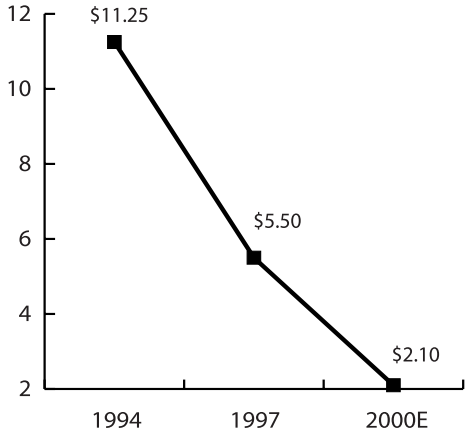
Abbott Labs	-1.0%
Affymetrix	-16.0%
Beckman Coulter	-7.0%
Biosite	-11.0%
Cholestech	-1.0%
Cytyc	-9.0%
Diagnostic Products	-9.0%
Digene	-41.0%
Inverness Medical	-29.0%
i-STAT	-24.0%
Johnson & Johnson	-10.0%

G-2 Insider

One of the biggest criticisms of point-of-care testing has been its cost. Today, centralized commercial and hospital labs are the low-cost providers of laboratory testing services due primarily to the economies of scale gained by testing batches of samples in large analyzers. But the cost advantage that large traditional labs have may not last.

POCT's Declining Cost

i-Stat's Avg Cartridge Cost



E=estimate. Source: Lab Industry Strategic Outlook 2000—Market Trends & Analysis

The majority of the testing expenditures at a centralized lab relate to labor-intensive functions such as sample collection and preparation, customer service, and general administration. With medical technologists and other lab staff in short supply, the cost of labor can be expected to increase in the 3-5% range per year.

In contrast, the majority of costs associated with point-of-care testing relate to the embedded technology in the testing analyzers and cartridges and the fixed manufacturing costs to assemble these devices. Witness i-Stat Corp., which makes blood analyzers for use at the patient's bedside. The declining cost of computer chips and the economies of scale associated with greater product shipments have led to a decline in the company's average cost to manufacture its cartridges from $11.25 per cartridge in 1994 to an estimated $2.10 per cartridge in 2000. And in fourth-quarter 2000, for the first time in its 17-year history, i-Stat reported a profit.

Company References

Abbott Labs 847-937-6100
Applied Imaging 408-562-0250
Beckman Coulter 714-871-4848
Becton Dickinson 201-847-6800
BioMerieux (St. Louis, MO) 314-731-8500
Bio-Rad Labs 510-724-7000
ChromaVision 888-443-3310
CytoLogix 617-576-0900
Decode Genetics 354-570-1900
Digene 301-944-7000
Exact Sciences 978-897-2800
Luminex 512-219-8020
Meridian Bioscience 513-271-3700
Roche Diagnostics 317-849-9350
Ventana 520-887-2155

Bayer Manufactures The Glucometer: A table in our February issue (*p. 7*) incorrectly identified Johnson & Johnson as the maker of the Glucometer Dex system for blood glucose monitoring. Glucometer Dex is made by Bayer Diagnostics (Tarrytown, NY).

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