Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Management Shakeup At Abbott Diagnostics As Consent Decree Costs Head Toward $1B

In a series of management changes, Abbott Laboratories (Abbott Park, IL) has announced that Thomas Brown, 54, senior vice president/diagnostics operations, will retire after 28 years with the company. His departure follows recent news that Abbott's immunoassay diagnostics operations in Lake County, IL, still fail to comply with quality system regulations of the U.S. Food & Drug Administration (*DTTR, June '02, p. 1*). Under a consent decree finalized with FDA in November 1999, Abbott agreed to a partial product shutdown and a penalty until manufacturing problems have been corrected.

"It's difficult to predict when we'll have conformity with our Lake County diagnostics operations. We're not going to try to provide a deadline or range that we cannot meet," said Miles White, Abbott chairman and CEO, during a June 11 conference call.

Abbott says it will take a "one-time" charge of approximately $140 million for payments to the U.S. government related to the consent decree, inventory write-offs and other restructuring charges. This comes on top of the initial $168 million write-off Abbott took in 1999 for costs associated with the consent decree, including a $100 million payment to the U.S. government. After taking into account the depressed operating earnings at Abbott Diagnostics (well in excess of $200 million per year of reduced profits for 2000, 2001 and 2002), the company's costs related to the consent decree total close to $1 billion, *Diagnostic Testing & Technology Report (DTTR)* estimates. *Continued on p. 2*

Dade Behring Nears Debt Restructuring Accord

DTTR has learned that Dade Behring (Deerfield, IL) has reached an initial verbal agreement with its creditors to swap approximately $700 million of its total $1.5 billion in outstanding debt for a majority stake in the company. It is anticipated that a final resolution will be completed within the next two to three months. Sources tell *DTTR* that one of the primary implementation options could be a "pre-packaged" Chapter 11 bankruptcy filing with creditors. This would involve zero disruption to customers, suppliers and employees, sources say. For more on Dade Behring, see *Inside The Diagnostics Industry, pp. 5-7.*

In the four weeks ended June 14, shares of Abbott dropped 28% to $36.75, shedding $23 billion in market value

▲ Management Shakeup At Abbott Diagnostics, *from page 1*

During the recent conference call, White appeared to express some frustration over Abbott's inability (after nearly two and a half years of trying) to understand what exactly FDA wants the company to do. "Since November of 1999 [when the consent decree was signed], I can assure you that the senior management team of Abbott, including Rick Gonzalez, Tom Brown and many others as well as literally thousands of Abbott employees at all levels of this company, have worked tirelessly to meet the expectations of FDA. In addition, professionally certified quality experts have assisted us in this effort, and we have hired as full-time employees a number of people who have previous experience working in FDA and in other companies.

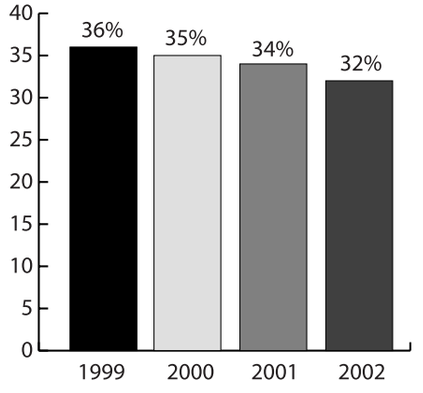
"The bottom line is that we have spared no expense or manpower upgrading quality systems in both our Lake County diagnostics operations as well as our global manufacturing facilities company-wide in every one of our major operating divisions.

"And, most important, we have made a comprehensive, deliberate and sincere effort. But FDA has concluded that we need to do more work to enhance our quality systems in our Lake County diagnostics operations. Therefore, we will move forward with a commitment to fully understand and meet the agency's expectations and requirements for success."

White sought to quell rumors that a poor relationship between Abbott executives and FDA regulators might have influenced FDA's decision with respect to the consent decree. White said that while Abbott has "had a fair amount of debate" with FDA regarding interpretation of the agency's quality system regulations, all contact has been "professional and very respectful."

Nonetheless, Abbott has made a host of management changes at its diagnostics division. In addition to Brown's departure, Abbott says Marcia Thomas, 54, vice president for diagnostics quality assurance, regulatory affairs and compliance, is retiring after 33 years with the company.

Abbott's Shrinking Share Of $4.5B*Global Immunoassay Market



*Excluding blood banking
Source: Abbott and *DTTR* estimates

No successor to Brown has yet been announced; however, John Landgraf, 50, has been named vice president for operations/diagnostics. Landgraf has been with Abbott for more than 24 years and most recently was vice president of corporate engineering. In his new position, he is expected to be Abbott's primary communicator with FDA in achieving compliance with the consent decree. In addition, Edward Michael, 45, has become vice president for diagnostics commercial operations. He previously was vice president for diagnostic assays and systems. According to Abbott, Landgraf and Michael will report on an interim basis to Richard Gonzalez, president and chief operating officer of the medical products group.

White said Abbott will hire a new consulting firm to help it interpret and implement FDA quality system regulations.

Abbott had previously used Quintiles Consulting (Durham, NC), which had validated Abbott's Corrective and Preventative Action Plan and had certified that the company was in compliance. White said he would like to see a lot more communication between the company's new consulting firm and the FDA.

During the conference call, Gonzalez said the tone of FDA's nearly 200-page report of its recent inspections of the Lake County facilities was "stern and direct." He noted that "the report suggests that ADD [Abbott Diagnostics Division] still has fundamental systemic issues with its quality systems." Gonzalez anticipates that FDA will require another on-site inspection of the Lake County operations.

Since signing the consent decree with FDA in November 1999, Abbott has been forced to suspend U.S. sales of some 60-70 immunoassays that had generated roughly $250 million in annual revenue. The decree allows Abbott to continue to sell approximately 150 tests deemed medically necessary, including certain assays for hepatitis, retrovirus, cardiovascular disease, cancer and thyroid disorders. However, the company must pay the U.S. government a 16% fee on all U.S. sales of these medically necessary tests.

The consent decree prohibits Abbott from launching new immunoassay products (such as its PRISM system) until compliance is achieved. Abbott had anticipated getting a green light from FDA and launching several new assays for PRISM this summer. But the failed inspection has now caused the company to write-off millions of dollars of inventory it had built up for the launch.

Gonzalez said Abbott expects its worldwide diagnostics division to report flat sales growth for both this year and 2003 (including the impact of currency changes). Abbott had previously voiced hope of growing its diagnostics business by 10% next year. Further, Abbott's share of worldwide immunoassay sales (a total market estimated at $4.5 billion) has declined from 36% in 1999 to 32% this year, Gonzalez noted, adding that despite the erosion, Abbott remains the worldwide market share leader in immunoassays.

Diagnostic Products Corp. To Launch Immulite 1000 Automated System

Diagnostic Products Corp. (DPC-Los Angeles, CA) says its Immulite 1000 automated immunoassay system is scheduled for availability worldwide in the second half of 2002, pending regulatory approvals. The system will be previewed at various upcoming professional meetings this year. According to DPC, the Immulite 1000 will launch with the same menu and reagents as those on its Immulite platform, which includes a menu of almost 100 assays.

Separately, *DTTR* notes that the absence of Abbott from the U.S. immunoassay market has helped propel DPC to a stronger position in this arena. In 2000 and 2001, sales at DPC increased at an average annual rate of 15%. In the three months ended March 31, 2002, shipments of Immulite products grew 16% over the same period in 2001. Immulite product line sales grew 14% to $62.4 million, or 83% of total first-quarter 2002 sales of $74.7 million.

Medicare Sets Pay Rates For At-Home Prothrombin Time Test

The Centers for Medicare & Medicaid Services has established reimbursement rates for at-home testing of prothrombin time (PT) for patients who have mechanical heart valves and are on warfarin, a blood-thinning drug better known by the brand name Coumadin (made by DuPont Pharma). The agency announced national coverage of the at-home testing late last year (*DTTR, Nov. '01, pp. 1, 5-7*).

Reimbursement for the testing will be paid under the Medicare physician fee schedule, effective July 1, 2002. The national payment rate (unadjusted for geographical practice cost differences) works out to be $20.54 per test. This is significantly higher than the maximum $5.43 Medicare pays for traditional PT testing under the lab fee schedule. CMS says the monitor and home testing must be prescribed by a physician. Reimbursement is limited to once per week, and Medicare will not cover self-testing for patients with porcine valves.

Physicians will be able to bill $102.08 for demonstration and instruction to patients starting their at-home PT testing. Reimbursement for monitors and test strips will be covered under a single code (HCPCS G0249) at $72.40 per four tests—equivalent to $18.10 per test. Physician review of test results will not require a face-to-face consultation and will be billed using G0250 at $9.77 per four tests—equivalent to $2.44 per test.

Medicare Payment For At-Home PT Testing

G0248	Demonstration at initial use. RVUs=2.82 ($102.08)
G0249	Test equipment and supplies; per 4 tests. RVUs=2.00 ($72.40)
G0250	Physician review of test results; per 4 tests. RVUs=0.27 ($9.77)

Source: CMS. Note: above rates not adjusted for geography

Larry Cohen, president of International Technidyne Corp. (ITC-Edison, NJ), says some 225,000 heart valve patients are now eligible for Medicare coverage, and about half are physically able to handle home coagulation monitoring. He estimates that the annual market for testing mechanical heart valve patients in the home is greater than $100 million. ITC makes the ProTime Microcoagulation System for PT testing at home and in physician offices. Other manufacturers with PT testing systems cleared for home use include Roche Diagnostics/CoaguChek and Lifescan/Harmony. In addition, Beckman Coulter recently entered the market by acquiring Avocet Medical's AvoSure PT System.

i-Stat Gets FDA Clearance For Prothrombin Time Test

i-Stat Corp. (East Windsor, NJ) has received clearance from the U.S. Food & Drug Administration to market its prothrombin time test, which will run on the hand-held i-Stat analyzer. The test is used to monitor patients on anti-coagulant therapy, such as Coumadin, to prevent blood clot formation. Company chairman William Moffitt expects the PT test cartridge to be priced to end-users at an average $5-$6 each. Separately, i-Stat has hired Jeff Randall as senior vice president of finance, chief financial officer and treasurer, replacing Roger Mason. Most recently, Randall served as vice president and chief financial officer for CFM Technologies Inc. (Exton, PA), a semiconductor equipment manufacturer that was recently acquired by Mattson Technology Inc. (Fremont, CA).

Dade Behring Seeks To Regain Financial Footing

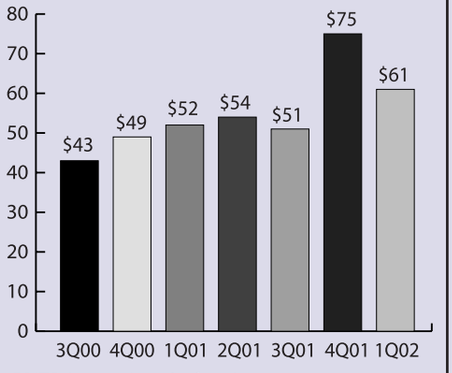
Dade Behring's $700 million debt-to-equity swap agreement will, assuming its completion, save the company approximately $50-$60 million in annual interest expenses. This will cut the Deerfield, IL-based company's current overall interest expense by nearly 50% and allow it to make increased investment in research & development and marketing. It also will allow Dade to begin paying down the principal on the remaining $800 million in debt it will still have following the transaction.

Final details of the transaction are still be fleshed out. But sources tell *DTTR* that initial terms call for Dade's creditors, including 60-70 banks and 50-60 bondholders, to gain a majority stake in the company. Current Dade shareholders—which include Bain Capital (Boston, MA), Goldman Sachs (New York City), Aventis (Frankfurt, Germany) and company management—will have their ownership stakes reduced. Following the transaction's final resolution, the management team at Dade is expected to remain intact, and Jim Reid-Anderson will continue as chief executive.

News of Dade's imminent financial restructuring has helped push the price of both the company's bank debt and bonds to above par value. In the darkest days in early 2001, the company defaulted on an interest payment to its bondholders. At that time, its bank debt had traded as low as 50 cents on the dollar and its bonds got below 10 cents on the dollar.

In recent years, Dade has struggled to keep up with $100+ million per year of interest payments associated with its $1.5 billion of outstanding debt. In late 2000, the company replaced its then-CEO Steven Barnes with Reid-Anderson, who initially joined Dade in 1996 as chief financial officer. Reid-Anderson was given the task of cutting costs to increase cash flow. In the six quarters through Sept. 30, 2000 (just prior to Reid-Anderson's promotion), Dade had recorded pretax losses totaling $143.2 million.

Dade Behring's EBITDA* *($MM)*



*EBITDA=earnings before interest, taxes, depreciation and amortization

Source: Dade Behring

Cost-cutting measures implemented under Reid-Anderson have included a reduction in the employee headcount to 6,500 currently from 7,500 in September 2000. In addition, the company sold two non-core products. Its IVD pump service business was sold to Baxter International (Deerfield, IL) in June 2001. This unit had employed about 250 people and generated annual revenue of approximately $56 million with low profit margins. In 2001, Dade sold its Switzerland-based immunohematology business (approximately $4 million per year of revenue). No further divestitures are anticipated.

Effective July 1, 2001, Dade completed its transition to direct distribution of its coagulation and MicroScan products. This move generated some $10 million in added prof-

its per year with the elimination of the distributor margin. Since the transition, Dade says it has booked substantial sales growth in both these product lines.

In total, Dade's cost-cutting measures, employee headcount reduction and divestitures have reduced expenses by more than $50 million per year, with operating expense dropping from 43% of sales in 1999 to around 33% currently.

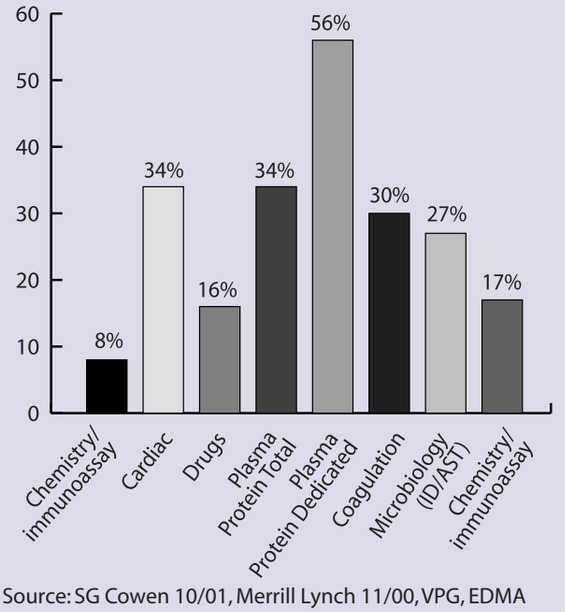
The combination of cost-cutting measures plus interest expense savings from the pending financial restructuring will add up to more than $100 million per year in savings, *DTTR* estimates.

Most recently, Dade reported that revenue for first-quarter 2002 was $306 million, up 3.5% from the same period a year earlier after adjustments for foreign exchange, sold businesses and the adoption of SAB101 (a new accounting standard). EBITDA on an adjusted basis was $61 million, an 11% increase over the same period in 2001, and 20% of sales. Note: On a reported basis (without adjustments), Dade's first-quarter 2002 revenue of $306 million was down 8% from $334 million in first-quarter 2001.

Dade Behring's Market Share Positions

Dade Behring is the worldwide market leader in cardiac, plasma proteins and coagulation markets, but the cornerstone of its product line is the Dimension line of routine chemistry/immunoassay analyzers. Sales of Dade's chemistry products will total an estimated $472 million in 2002, or about 36% of its overall revenue of $1.3 billion, according to *DTTR* estimates based on data from SG Cowen Securities (New York City). Dade currently has a total of 6,700 of its Dimension clinical chemistry instruments installed at roughly 4,500 laboratories worldwide.

Dade's Market Share Positions By Revenue



Source: SG Cowen 10/01, Merrill Lynch 11/00, VPG, EDMA

Although the company now holds only an estimated 8% share of the worldwide routine chemistry/immunoassay market (behind Abbott, Roche and Beckman Coulter), it appears to be gaining share. SG Cowen estimates that this business line is growing by 8% annually.

Dade says sales of its Dimension RxL platforms and related reagents have grown by some 20% per year. The company now has 3,435 installed RxL instruments throughout the world. The Dimension RxL integrates clinical chemistry and heterogeneous immunoassay testing on one workstation that can perform more than 95% of the most requested tests. The system is targeted at small and medium-sized hospitals with throughput of 788 tests per hour.

In mid-2001, Dade launched the Dimension Xpand, a low-volume version of the RxL. The instrument can perform 340-475 tests per hour and is targeted for use in small hospital labs or as a back-up system in medium-sized labs. Xpand's initial menu includes nine heterogeneous immunoassays, plasma proteins and drugs-of-abuse assays. Dade has more than 300 Xpand instruments installed worldwide. More than 40% of recently sold Xpand units are conversions from competitive chemistry systems such as the Ortho Vitros 250 system and ECI system, Abbott Spectrum system, Beckman Coulter CX7 and Access systems and Roche Hitachi 911 system.

For higher-volume customers, Dade introduced its StreamLab modular automation system earlier this year. It can integrate up to four Dimension RxLs and will eventually accommodate other instruments as well.

Finally, Dade is developing a next-generation chemistry platform named Epsilon, which will target all levels of customers in one box.

Dade's second-largest product segment is in coagulation, where the company generated an estimated $165 million of revenue in 2001, according to SG Cowen estimates, for a worldwide market share of 30%. Future growth should come from the recent introduction of the company's CA 1500 instrument (for mid-volume testing) and a new test for D-dimer. The CA 1500 is manufactured by Sysmex Corp. (Kobe, Japan) and distributed by Dade. Later this year, the company will introduce Sysmex's CA-7000, a product aimed at the highest-volume laboratories.

Other coagulation products include the BCS for mid- and high-volume labs that perform broad menu (routine and specialty) testing. This instrument recently achieved its 1,000th placement. Dade says it plans to broaden its specialty coagulation testing business through utilization of Third Wave Technology's format for tests such as Factor V Leiden.

Dade Behring's Estimated Revenue Breakdown *($MM)*

	2000	2001	2002	2005	% Chg 2000-05
Clinical Chemistry	400	432	472	588	8.0%
—Dimension	390	423	464	583	8.4%
—Other	10	9	8	5	-12.9%
Immunoassay	256	245	242	220	-2.9%
—Stratus/Stratus CS	53	56	58	61	3.2%
—Syva	123	117	116	109	-2.4%
—Other IA	80	72	68	50	-9.0%
MicroScan	128	130	133	141	2.0%
Infectious Disease	92	93	96	101	1.9%
Coagulation	139	165	176	210	8.7%
Plasma Proteins	155	155	163	178	2.8%
Other	14	15	15	17	4.0%
Worldwide Total	1,184	1,235	1,297	1,455	4.2%

Source: *DTTR* based on data from SG Cowen

Roche To Compete With Digene In HPV Testing Market

Roche Diagnostics (Basel, Switzerland) has acquired a broad portfolio of patents pertaining to the human papillomavirus (HPV) from the Institut Pasteur (Paris, France) for an undisclosed sum. Roche's entrance into HPV molecular testing would put it in direct competition with Digene Corp. (Gaithersburg, MD), which has the only HPV test approved by the U.S. Food & Drug Administration.

In a press release, Roche notes the potential for HPV molecular tests to be used as the primary screen for cervical cancer detection, replacing traditional Pap smear testing. In 2001, Roche estimates, worldwide HPV molecular diagnostic sales were approximately $21 million. The total market potential, if HPV molecular tests are adopted as a primary screening test, could exceed $600 million annually by the year 2010, the company forecasts. "HPV represents the next significant molecular target for us after our involvement in the blood screening market," says Heino von Prondzynski, head of the Roche Diagnostics Division. "The unique association of HPV with cervical cancer, combined with the benefits of screening, early intervention and available treatments, make this an ideal product for the diagnostics market." Roche says it potentially could develop an HPV product in two years or less.

Meanwhile, Digene has issued a press release noting that the Roche acquisition does not include the rights to Digene technology related to three HPV subtypes. Roche says it may want to gain access to these three subtypes or it may seek other paths with smaller companies that provide alternatives to Digene.

Abbott, OraSure Sign Distribution Deal For Rapid HIV-1 Test

Abbott Laboratories (Abbott Park, IL) and OraSure Technologies (Bethlehem, PA) have agreed to jointly distribute OraSure's rapid test for detection of antibodies to the human immunodeficiency virus type 1 (HIV-1). The test, named OraQuick, provides results within 20 minutes from oral fluid and whole blood samples. OraSure has submitted an application to the U.S. Food & Drug Administration for the whole blood method for use at labs certified to perform CLIA moderately complex testing. OraSure plans to file another application for oral fluid specimens by year's end.

Under terms of the deal, which is restricted to the U.S., Abbott will market OraQuick primarily to hospitals and physician office labs. OraSure will market the test to the public health and criminal justice markets. Abbott also has agreed to license to OraSure certain lateral-flow patents related to the test design. OraSure will pay Abbott up-front fees and ongoing royalties.

Garrett To Head Beckman's Clinical Diagnostics Division

Beckman Coulter (Fullerton, CA) has named Scott Garrett as president of its clinical diagnostics division, effective June 17. Garrett replaces Albert Ziegler who retired from the company last April. Garrett previously served as chief executive of Garrett Capital Advisors and as chief executive for Kendro Laboratory Products, LP, which was acquired last year by SPX Corp. (Muskegon, MI).

Visible Genetics Up For Sale

Visible Genetics Inc. (VGI-Toronto, Canada) is in discussions with third parties regarding various strategic alternatives, including a potential sale of the company, and has hired Bear Stearns (New York City) as an advisor. VGI says any potential sale transaction being discussed would likely include a modest premium to its current share price. Shares of VGI closed at $2.83 on June 12 for a market capitalization of $54 million. The stock had been as high as $119 in March 2000.

VGI is suffering from unmet expectations for sales of its new Trugene HIV-1 Genotyping test kit and system, which became the first DNA sequencing technology cleared by the U.S. Food & Drug Administration for routine clinical use in September 2001. The company recently lowered its estimated revenue range for 2002 from $32-$37 million to $20-$25 million.

In first-quarter 2002, VGI reported a net loss of $10.8 million vs. a net loss of $9.4 million in the same period last year; revenue was up 21% to $4.3 million. Since beginning operations in 1993, VGI has accumulated losses totaling $147.5 million.

Ventana Develops Test For Novartis Drug, Gleevec

Ventana Medical Systems (Tucson, AZ) has developed a diagnostic test for use with the drug Gleevec, made by Novartis AG (Basel, Switzerland). Ventana has just begun offering the test in home-brew form and plans to file a premarketing approval application with FDA for the test kit by year's end, according to Christopher Gleeson, chief executive of Ventana. He says Ventana charges $40 per test; reimbursement is paid via the Medicare physician fee schedule under CPT code 88342 at $84.34 ("pure" fee, unadjusted for geographic practice costs).

Gleevec was first approved in 2001 by FDA for use with chronic myeloid leukemia patients. The drug's labeling was extended in February 2002 for treatment of patients with c-kit positive inoperable and/or metastatic malignant gastrointestinal stromal tumors (GISTs). An estimated 5,000 Americans a year develop GISTs, usually in the stomach or small intestine. This form of cancer can spread within the abdomen or the pelvis and usually kills if not caught early.

Gleevec works by blocking enzymes essential for cancer growth. As these abnormal enzymes are largely confined to tumors, the pill does relatively little damage to healthy cells. However, the drug is extremely expensive, and patients need to take the pill every day for the rest of their lives. A one-year supply of 100 mg capsules costs $6,752 per year, according to the online pharmacy service, Rx USA Inc. (Long Island City, NY). Gleevec had sales of 183 million Swiss francs (US $117 million) in the first quarter of 2002, Novartis reports.

The Gleevec test will be the second targeted diagnostic kit developed by Ventana. It already markets the Pathway Her-2/neu diagnostic kit for guiding breast cancer treatment. Ventana says its pharmacogenomics efforts have been propelled by its acquisition in March 2000 of Quantitative Diagnostic Laboratories (QDL-Elmhurst, IL) for $2.5 million. QDL is a specialty reference laboratory that provides tissue staining services to pharmaceutical companies during clinical trials.

Meridian To Acquire Biotrin Holdings

Meridian Bioscience (Miami, FL) has agreed to acquire Biotrin Holdings PLC (Dublin, Ireland) for an undisclosed sum. Biotrin currently generates revenue of about $7 million annually. Key products include a test for parvovirus, a viral pathogen that is often associated with serious complications in pregnancy and can also be a factor in transplant recipients. Biotrin is also active in the field of predictive toxicology, the science of using specific cells from key organs to predict the potential toxic effects of new drug compounds as they are being evaluated for safety and efficacy. Meridian says the acquisition will further its efforts to expand into the life sciences market. In the three months ended March 31, 2002, Meridian reported net income of $1.425 million vs. a net loss of $1.616 million in the same period a year earlier; revenue grew 9% to $15.092 million.

IVAX Completes Purchase Of Sigma Diagnostics' EIA Product Line

IVAX Diagnostics (Miami, FL) has completed its purchase of the enzyme immunoassay (EIA) product line of Sigma Diagnostics, a subsidiary of Sigma-Aldrich Corp. based in St. Louis, MO (*DTTR, June '02, p. 1*). The purchase price was $2.25 million. IVAX will add approximately $7 million per year in revenue from the acquisition.

Duane Steele, vice president of business development at IVAX, says that as a result of the deal, IVAX's base of installed automated EIA instruments in the U.S. will more than double. Before the acquisition, Sigma Diagnostics marketed EIA instruments and reagents throughout the world, including products purchased from IVAX. Now, IVAX will no longer sell instruments or reagents to Sigma Diagnostics (its largest customer for the past three years), but will market and sell them directly.

IVAX Diagnostics In Brief

	For three months ended ($000)	
	3/31/02	***3/31/01***
Revenue	$2,506	$3,288
Operating loss	-833	-1,079
Net loss	-714	-1,320
Current assets	30,068	31,481
Current liabilities	2,852	2,871

Source: IVAX

Separately, IVAX reported a net loss of $714,000 in the three months ended March 31, 2002 vs. a net loss of $1.32 million in the same period last year; revenue declined 24% to $2.506 million. IVAX attributed the revenue fall-off to declining sales to Sigma Diagnostics.

Calypte Appoints Actor Martin Landau To Its Board

Calypte Biomedical Corp. (Alameda, CA), which is struggling to maintain ongoing operations, has named actor Martin Landau to its board of directors. Among Landau's acting honors is an Academy Award (Best Actor in a Supporting Role) for his 1994 portrayal of Bela Lugosi in *Ed Wood*. "His willingness to accept the invitation to join our board adds tremendous credibility and stature to our organization," stated Calypte CEO Anthony Cataldo in a press release. The company makes the only two FDA-approved HIV-1 antibody tests that can be used on urine samples. It recently got a cash infusion commitment from a group of private investors and reversed a previous announcement that it was winding its business down (*DTTR, June '02, p. 9*).

IVD Stocks Tumble 12% In Latest Four Weeks

Roche non-voting equity shares, which trade on the Zurich stock exchange, are down 3% to 114.75 Swiss francs year-to-date. Shares of Bayer, which trade on the German stock exchanges, are down 10% at 32.05 euros per share

The 21 stocks in the G-2 Diagnostic Stock Index tumbled an unweighted average of 12% in the four weeks ended June 14, 2002, with 15 stocks declining in price and six rising. Year-to-date, the G-2 Index has fallen 16%, compared with a 12% drop for the S&P 500 and a 23% drop for the Nasdaq.

Shares of **Abbott Laboratories** (Abbott Park, IL) declined 28% to $36.75 per share, lowering the company's market capitalization to $58 billion (*for more on Abbott, see p. 1*).

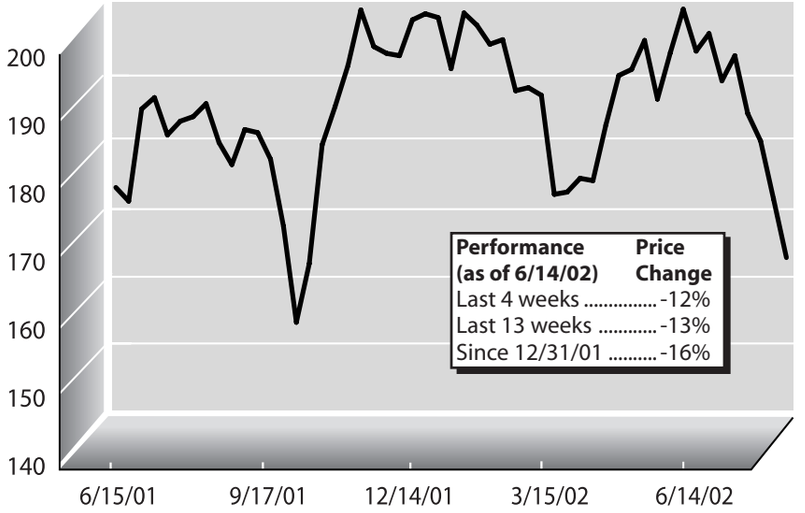
Cygnus (Redwood City, CA) fell 50% to $2.08 per share, giving the company a market capitalization of $73 million. **Careside** (Culver City, CA) was off 47% to $0.08 per share for a market cap of $2 million.

Inverness (Waltham, MA) was down 36% to $17.50 for a market cap of $188 million. The company recently raised gross proceeds of $36.8 million from a secondary offering of 1.6 million shares priced at $23 per share.

Cytyc (Boxborough, MA) was down 32% to $11.12 per share for a market cap of $1.4 billion. **Digene** (Gaithersburg, MD) fell 33% to $15.64 per share for a market cap of $282 million. Cytyc and Digene declined on news that Roche Diagnostics has acquired a broad human papillomavirus (HPV) patent portfolio from the Institut Pasteur. Digene, which is being acquired by Cytyc, currently has the only FDA-approved test for HPV (*details on p. 8*).

Immucor (Norcross, GA) was the leading gainer in the four-week period, rising 24% to $18.30 per share for a market cap of $143 million. Other gainers include **Beckman Coulter** (Fullerton, CA) and **TheraSense** (Alameda, CA) both up 9%.

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 6/14/02

UP	Price ($)	% Chg
Beckman Coulter	49.02	+9
Bio-Rad	48.60	+6
Cholestech	17.30	+8
Immucor	18.30	+24
Quidel	6.17	+6
TheraSense	20.70	+9
DOWN		
Abbott Labs	36.75	-28
Becton Dickinson	34.99	-4
Biosite	25.20	-13
Careside	0.08	-47
Cygnus	2.08	-50
Cytyc	11.12	-32
Diagnostic Products	44.85	-3
Diametrics	4.04	-8
Digene	15.64	-33
Igen	35.50	-10
Inverness Medical	17.50	-36
i-Stat	4.64	-15
Johnson & Johnson	56.82	-8
Meridian	6.40	-13
Ventana	20.63	-12

G-2 Insider

Are Miles White's days numbered at Abbott? Continuing quality system problems at Abbott Laboratories' Lake County diagnostics facility have led to the retirement of Thomas Brown and other diagnostics executives (*see p. 1*). But Miles White has managed to hold onto his job as Abbott's CEO, even though he headed the diagnostics unit when the problems with FDA first surfaced. Yet, with Abbott's stock price now down 25% since White became CEO in January 1999, one would suspect that the company's board of directors may start looking at the top for answers.

Aetna CEO backs uniform laws for genetic testing. "I believe there is a pressing need for the health insurance industry to establish guidelines for covering genetic testing in a way that promotes disease prevention and disease management, while at the same time respecting members' privacy," said John Rowe, MD, chairman and CEO of Aetna (Hartford, CT), in a speech at The Inaugural Symposium on Genetic Privacy & Discrimination, held at the University of Rochester (NY) on June 15. Rowe said Aetna believes that a small investment in testing today can prevent or mitigate human suffering, while saving on future healthcare costs.

"Mad cow" disease continues to spread. A 10-year old cow in Israel has been identified as infected with bovine spongiform encephalopathy (aka "mad cow" disease), the first such case reported in that country. The Israeli Agriculture Ministry says the brains of all cows aged more than 30 months will be tested prior to releasing their meat to the market.

Correction: In our June issue (*p. 4*), we incorrectly identified the developer and distributor of Fujirebio Diagnostics' new test for monitoring treatment of pancreatic cancer (CA 19-9 Radioimmunoassay). Fujirebio Diagnostics alone developed the test; Polymedco Inc. (Cortlandt Manor, NY) is the U.S. distributor.

Company References

Abbott Labs 847-937-6100

Beckman Coulter 714-871-4848

Calypte 510-749-5100

Cytyc Corp. 978-263-8000

Dade Behring 847-267-5300

Diagnostic Products 310-645-8200

Digene 301-944-7000

i-Stat 609-443-9300

IVAX Diagnostics 305-324-2338

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Ventana 520-887-2155

Visible Genetics 416-813-3240

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