



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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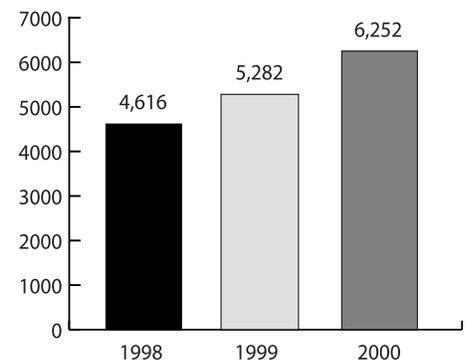


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Roche Diagnostics Revenue Up 18% In 2000

Roche Holding AG (Basel, Switzerland) reports that revenue at its diagnostics division increased by 18% last year to 6.252 billion Swiss francs (US \$3.8 billion) from 5.282 billion Swiss francs in 1999. The division's operating profit in 2000 was 822 million Swiss francs (US \$500 million) vs. 633 million Swiss francs in 1999. Diagnostics sales represented 22% of Roche Holding's overall revenue of 28.672 billion Swiss francs in 2000, compared with 19% of overall revenue of 27.567 billion Swiss francs in 1999. At Roche's annual media conference in Basel on Feb. 28, Franz Humer, chief executive, noted that the company's Accu-Chek blood glucose meter is now Roche Holding's top-selling brand, with sales of roughly 2 billion Swiss francs (US \$1.2 billion). For an in-depth look at Roche Diagnostics, which is expanding its lead as the world's largest IVD manufacturer, see pp. 5-7. 🏠

Roche Diagnostics: Total Sales
(Swiss francs in MM)



Source: Roche

Bayer Shareholders To Vote On Breakup

A proposal by the New York-based investment firm of Tweedy, Browne Co. to split Bayer AG (Leverkusen, Germany) into three separate companies will be put to a vote at the company's annual shareholders meeting in Leverkusen on April 27. Thomas Shrager, managing director of Tweedy, Browne, set the wheels in motion for a potential breakup of the company via his letter to Bayer chairman Manfred Schneider last December (*DTTR*, Feb. '01, p. 1). In the letter, Shrager proposed that Bayer divide its operations into three separate and distinct entities: 1) healthcare; 2) chemicals and polymers; and 3) agricultural chemicals. "We confirm that the request meets the requirements of German law. Consequently, the requested topic will be added to the agenda of our upcoming shareholders meeting," said Bayer's head of investor relations, Alexander Rosar, PhD, in a letter to Shrager. *Continued on p.2*

▲ **Bayer Shareholders**, from page 1

Bayer management has recommended that shareholders vote against the proposed breakup. "We are sure that we would not enhance Bayer's value over the long term by splitting the company into separate entities or by spinning off and then divesting parts of our current portfolio, as some people in the capital markets are demanding," Schneider said at the company's financial news conference on March 15 in Leverkusen.

For full-year 2000, Bayer reported net income of 1.816 billion euros, down from 2.002 billion euros in 1999; revenue was up 13% to 30.971 billion euros (US \$27.8 billion). Bayer has a current market capitalization of approximately 36.6 billion euros (US \$32.9 billion), based on 729.3 million shares outstanding and currently priced at 50.20 euros per share.

Shrager believes, however, that Bayer's healthcare unit, which includes pharmaceuticals, diagnostics, and over-the-counter (OTC) products, could easily be worth 30+ billion euros (US \$27+ billion) as a stand-alone company. In full-year 2000, the unit generated an operating profit of 1.337 billion euros vs. 848 million euros in 1999; revenue increased 20% to 10.028 billion euros (US \$9 billion). Pharmaceutical sales increased 23% to 6.14 billion euros, and revenue from OTC products (including Bayer Aspirin, Alka-Seltzer, One-A-Day brand vitamins, etc.) grew 14% to 1.923 billion euros. Revenue at Bayer Diagnostics rose by 17% to 1.965 billion euros in 2000. Rolf Classon is president of Bayer Diagnostics, which has worldwide headquarters in Tarrytown, NY, and employs a total of 7,300 workers.

In order for Shrager's breakup proposal to be implemented, it must get a majority of the total votes cast at the annual meeting and by proxy—a majority of the total shares outstanding is not needed. Tweedy, Browne owns 1.9 million shares for a 0.3% stake. Other U.S. investors with significant stakes include Capital Research and Management and Merrill Lynch. Bayer's single largest shareholder is the insurance giant, Allianz Group (Munich), which owns approximately 36 million shares for a 5% stake.

Shrager says he has been phoning Bayer's largest shareholders to ask for support of his proposal. "Generally, most shareholders I have talked to are in support of the breakup. It's not that I have anything against Bayer management. But the best solution [for increasing shareholder value] is to the break the company up."

Bayer At A Glance (in millions of euros)

	2000	1999	%Chg
Total revenue	30,971	27,320	13%
Revenue from cont. operations	29,986	24,738	21%
—Health Care	10,028	8,367	20%
—Agriculture	3,455	3,094	12%
—Polymers	11,398	8,922	28%
—Chemicals	4,275	3,630	18%
Operating income from cont. operations	3,183	2,202	45%
Net income	1,816	2,002	-9%

Source: Bayer

At Bayer's recent financial news conference, Schneider noted that Bayer stock increased 23% last year. In addition, he announced that the company planned to raise its dividend by 10 cents to 1.40 euros per share. Schneider also stressed that Bayer has implemented a restructuring program at its pharmaceutical business and cost-containment measures at its diagnostics and OTC products business groups. He said the goal is to raise the healthcare unit's operating margin to 20% by 2002, from 15% last year. ▲

Quest Diagnostics Buys Sequenom's MassArray System

Sequenom Inc. (San Diego, CA) has announced that Quest Diagnostics (Teterboro, NJ) has purchased its MassArray system for high-throughput single nucleotide polymorphism analysis (aka SNP genotyping). SNP genotyping is used to determine an individual's susceptibility to inherited diseases and responsiveness to various drug therapies. The MassArray system, which sells for \$400,000, has been installed at Quest's Nichols Institute in San Juan Capistrano, CA.

Since commercial launch early last year, Sequenom has placed 23 MassArray systems. Most customers are using the system for research, including the U.S. Department of Agriculture and the National Cancer Institute. Customers using it for clinical diagnostic purposes include Nichols Institute, Specialty Labs, and the Center for Human Genetics at Boston University School of Medicine.

Common genetic tests run by clinical labs on the MassArray system include tests for Factor V, Cystic Fibrosis, hemochromatosis, and HCV genotyping, according to Jim Leushner, PhD, director of business development at Sequenom. He says Sequenom supplies cartridges and reagents to customers at an average price of roughly \$1 per test kit. Leushner says the key benefit of MassArray is its high throughput (3,840 samples in under 45 minutes) combined with the accuracy of mass spectrometry.

	4Q00	4Q99
Revenue	\$3,738	\$98
Net income	-7,518	-6,384
Long-term debt	0	0
Cash holdings	138,424	21,616

Source: Sequenom

Sequenom recorded a net loss of \$7.518 million in fourth-quarter 2000 vs. a net loss of \$6.384 million in the same period a year earlier; revenue increased to \$3.738 million from \$98,000. Fourth-quarter 2000 revenue included \$2.4 million in MassArray sales, \$350,000 in sales of consumables, and \$950,000 from assay design and validation services.

During a Feb. 15 conference call, Sequenom president Toni Schuh, PhD, said he expects the company to generate revenue of approximately \$30 million this year, including \$12 million in MassArray sales (30 new placements). Sequenom expects to burn about \$60 million in cash this year. As of Dec. 31, 2000, it had \$138.424 million in cash and short-term investments. 🏠

Vysis Posts Fourth-Quarter Profit Of \$904,000

Vysis Inc. (Downers Grove, IL), which makes genetic tests for the breast cancer, leukemia, and prenatal markets, earned a profit of \$904,000 in fourth-quarter 2000 vs. a loss of \$1.557 million in fourth-quarter 1999; revenue was up 14% to \$6.549 million. The company's FDA-approved genetic testing products were its fastest-growing segment, with revenue up 55% to \$1.832 million. Products include PathVysion, used to detect amplification of the HER-2/neu gene in breast cancer tissue specimens, and AneuVysion, used to detect Trisomy 13, 18, 21 (Down syndrome) and chromosome X and Y aneusomies (such as Klinefelter and Turner syndromes). Vysis manages a direct sales force in the U.S. and Europe and has a marketing partnership in Japan with Fujisawa Pharmaceutical Co. (Osaka). 🏠

Visible Genetics' Sequencers Installed At 96 U.S. Labs

Visible Genetics Inc. (VGI—Toronto, Canada) has placed its OpenGene DNA sequencing system at 96 laboratories in the U.S., according to company president Richard Daly. In addition, Daly says, VGI has taught 215 laboratory technicians to use the OpenGene system at one-week training sessions held at its facility in Atlanta.

FDA approval would give VGI the first genotype test kit on the market for sale to clinical laboratories and could decentralize this testing away from the larger commercial labs

This preparation is geared toward immediate rollout of the OpenGene system and TruGene HIV-1 test kit following FDA approval. VGI submitted a 501(k) application to FDA for both last September. The company could gain approval as early as next month, now that it has responded to labeling and package insert questions posed by FDA in December.

Genotype tests such as VGI's TruGene HIV-1 sequences genes of the HIV virus. Physicians use this information to better understand a specific patient's resistance profile. Decisions can then be made as to which antiretroviral drug therapy is likely to work best against the patient's infection. Because HIV mutates so rapidly, it can develop resistance to a drug treatment in a matter of 3-6 months. Consequently, HIV patients often get genotype tests several times a year to determine if their drug therapy needs to be modified.

Today, most physician offices and labs refer their genotype testing needs to larger reference labs operated by the likes of Quest Diagnostics (Teterboro, NJ) or Laboratory Corp. of America (Burlington, NC). These mega-labs use proprietary "home brew" tests that do not require FDA approval.

Effective Jan. 1, 2001, the Health Care Financing Administration recognized CPT 87901 for genotype analysis of HIV-1 and set the Medicare maximum allowable under the lab fee schedule at \$355.78. In addition, VGI says Blue Cross/Blue Shield plans in Texas, California, and Illinois as well as Aetna and Cigna each reimburse genotyping for HIV-1 at roughly \$450 per test.

Daly says the company's current installed base of 96 labs could potentially provide genotype tests to about 200,000 of the 350,000 HIV patients now receiving treatment in the U.S. At a sales price of \$225 per test kit and assuming two genotype tests per patient per year, the immediate market potential for VGI is \$90 million per year. The company has a 40-person sales force in the U.S. and a 43-person staff in Europe. VGI received regulatory approval to market its OpenGene system in France late last year.

Visible Genetics At A Glance (\$MM)

	4Q00	4Q 99
Revenue	\$3.013	\$4.954
Net income	-10.415	-7.752
Long-term debt	0	0
Cash holdings	80.399	42.688

Source: Visible Genetics

In the fourth quarter of 2000, VGI recorded a net loss of \$10.415 million vs. a net loss of \$7.752 million in the same quarter a year earlier; revenue (primarily from sales to the clinical research market) fell to \$3.013 million from \$4.954 million. As of Dec. 31, 2000, the company had \$80.4 million in cash and short-term investments. Daly expects the company to reach profitability in four or five quarters after FDA approval. 🏠

inside the diagnostics industry

Diagnostics Take On Bigger Strategic Role At Roche Holding

“**W**ith annual sales of over 6 billion Swiss francs, double-digit growth, and margins approaching those in the pharmaceutical sector, Roche Diagnostics has become a mainstay business with an increasingly important strategic role for the entire Roche Group,” noted Franz Humer, chief executive of Roche Holding, at the company’s recent media conference in Basel, Switzerland. Last year, Roche Diagnostics recorded an EBITDA (earnings before interest, taxes, depreciation, and amortization) margin of 26%, compared with 28% for the company’s pharmaceuticals business and 20% for its vitamins and fine chemicals unit.

Roche Diagnostics is headed by Heino von Prondzynski and includes four divisional business units with a total of 15,631 employees worldwide. Prondzynski joined Roche in February 2000. From 1976 to 1996 he worked for Bayer, and from 1996 to 1999 he was with Chiron, most recently as president of its vaccines business.

The fastest-growing unit at Roche Diagnostics is Roche Molecular Systems (Pleasanton, CA), which includes the company’s Cobas HIV and HCV Monitor products for viral load testing. Revenue from the unit increased by 26% in 2000 to 750 million Swiss francs. New products expected to be launched this year include the Cobas AmpliPrep, an automated PCR sample preparation machine.

The largest divisional business unit at Roche Diagnostics is Patient Care, which includes the company’s Accu-Chek products. The unit’s revenue increased by 25% in 2000 to 2.554 billion Swiss francs. Roche bolstered its Patient Care business through the acquisition last year of AVL Medical Instruments (Schaffhausen, Switzerland). AVL sells the OPTI and OMNI blood gas systems for hospital point-of-care testing and has placed more than 15,000 analyzers worldwide. New products include the Roche OPTI R Analyzer, a portable blood gas analyzer that can perform 25 tests with a single cartridge.

Financials For Roche Diagnostics

(in millions of Swiss francs)

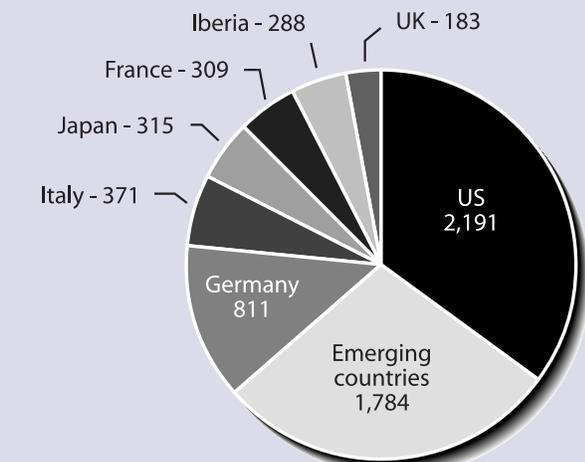
	2000	1999	% Chg
Total revenue	6,252	5,282	18%
—Laboratory Systems	2,437	2,212	10%
—Patient Care	2,554	2,042	25%
—Molecular Systems	750	596	26%
—Molecular Biochemicals	511	432	18%
EBITDA	1,639	1,380	19%
Depreciation and amortization	816	746	9%
Operating profit	822	633	30%

Source: Roche

Roche Diagnostics’ Laboratory Systems unit generated 2.437 billion Swiss francs in 2000, up 10% from 2.212 billion in 1999. The unit includes the company’s clinical chemistry, immunoassay, coagulation, and hematology instruments and reagents. Among the new products is the E-170 Modular immunoassay analyzer, which can be integrated into Roche’s clinical chemistry system.

The fourth divisional business unit is Molecular Biochemicals, which manufactures instruments and reagents for

Roche Diagnostics: Sales By Major Market
(Total sales: 6,252 million Swiss francs)



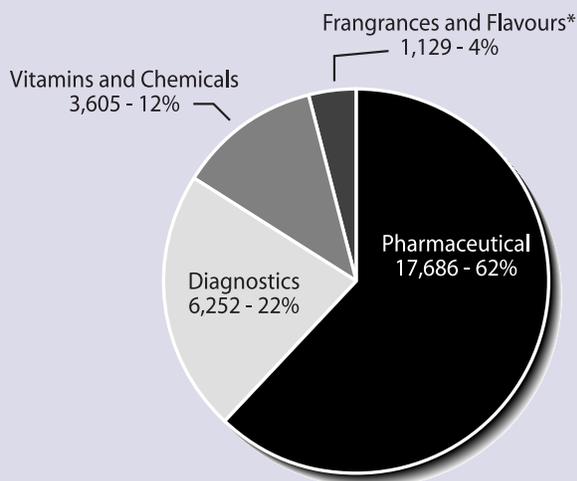
Source: Roche

The largest geographic market for Roche Diagnostics is the United States, with sales last year of 2.191 billion Swiss francs (US \$1.3 billion), up about 10% from the prior year (in local currency terms). In January 2000, Martin Madaus became head of Roche's U.S. diagnostics operations, headquartered in Indianapolis, IN, and employing 3,000 workers. Madaus succeeded Dennart Ware, who retired after 28 years with Boehringer Mannheim and Roche. In its biggest acquisition ever, Roche bought Corange Ltd. in 1998 for US \$10.2 billion; its subsidiary, Boehringer Mannheim, was merged into Roche Diagnostics. Madaus formerly was head of Roche Molecular Systems as well as Boehringer's Canadian diagnostics unit.

gene analysis, used in biomedical research to investigate the causes of or predisposition to disease. The unit generated 511 million Swiss francs in 2000, up 18% from 432 million in 1999. Key products include the LifeCycler system, which allows scientists to complete a typical PCR experiment in less than 30 minutes.

As of Feb. 1, Molecular Biochemicals also distributes Prionics-Check, a test for detecting Bovine Spongiform Encephalopathy (BSE, aka "mad-cow" disease) that is manufactured by Prionics Inc. (Zurich, Switzerland). The agreement also calls for collaboration on developing a blood test to detect BSE in living animals and a test for the early diagnosis of Creutzfeldt-Jakob disease in humans.

Roche Holding's Revenue By Division
(Total sales: 28,672 million Swiss francs)



*Roche spun off this unit (Givaudan) in June 2000 Source: Roche

Last year's sales gain has made Roche Diagnostics the largest IVD manufacturer in the U.S. Johnson & Johnson has slipped to second place after combined U.S. revenue from its Ortho-Clinical Diagnostics and Lifescan units slipped 2% to \$1.159 billion in 2000 (see p. 9 for details).

The emerging and less-developed countries in Asia, Africa, and South America represent Roche Diagnostics' fastest-growing markets, with combined sales increasing 20+% last year to 1.784 billion Swiss francs. Japan was the weakest market, with sales declining by roughly 5% to 315 million Swiss francs.

Roche's top-selling drugs are Rocephin (an injectable antibiotic) and Roaccutan for acne treatment. Other products include obesity

treatment Xenical; AIDs drug Invirase; Herceptin for breast cancer treatment; and Tamiflu for prevention and treatment of influenza. Over-the-counter products include analgesic Aleve and antacid Rennie.

Sales at the company's Vitamins and Fine Chemicals Division, which has 7,257 employees worldwide, declined by 3% in 2000 to 3.605 billion Swiss francs. The drop was caused by declining vitamin prices and the sale of a medicinal feed additives business in early May 2000.

Overall, Roche Holding reported net income of 8.647 billion Swiss francs in 2000 vs. 5.764 billion in 1999; revenue increased 4% to 28.672 billion Swiss francs. Excluding special gains and costs (such as gains on the sale of Genentech and LabCorp shares), Roche had net income of 5.014 billion Swiss francs in 2000 vs. 4.401 billion in 1999.

Net income in 2000 was bolstered by a pretax gain of 660 million Swiss francs from the sale of four million common shares of Laboratory Corp. of America (Burlington, NC) last Oct. 18. The sale reduced Roche's stake in LabCorp to 11.353 million shares, or 32.7%, from 15.353 million shares, or 44.5%. After commissions, Roche received \$115.10 per share from the sale. Also, in June 2000, LabCorp called for redemption of its convertible preferred stock held by Roche, resulting in a pretax gain to Roche of 296 million Swiss francs. LabCorp was formed in 1995 from the merger of Roche Biochemical Laboratories and National Health Laboratories.

In addition, Roche earned a pretax gain of 3.949 billion Swiss francs from the sale of 34.6 million common shares (split-adjusted) of Genentech (South San Francisco, CA) on March 29, 2000. After commissions, Roche received \$80.12 per share (split-adjusted) from the sale. Roche currently owns 306.6 million shares in Genentech for a 58.4% stake, worth US \$15.56 billion.

Roche spent 3.95 billion Swiss francs on research and development in 2000, with the Pharmaceuticals Division accounting for 81% of this total. R&D expenditures for Roche Diagnostics last year were 558 million Swiss francs, up from 516 million in 1999.

Roche Holding At A Glance

(in millions of Swiss francs)

	2000	1999	% Chg
Revenue	28,672	27,567	4%
EBITDA	11,126	8,874	25%
Net income	8,647	5,764	50%
Cash and securities	20,648	18,866	9%
Long-term debt	16,167	15,962	1%
Market capitalization	148,153	174,384	-15%

Source: Roche

Roche plans to raise its dividend to 115 Swiss francs per share from 100, subject to shareholder approval. As of Dec. 31, 2000, Roche's balance sheet showed current assets of 34.7 billion, including 20.6 billion Swiss francs in cash and securities vs. current liabilities of 13.9 billion Swiss francs. Long-term debt totaled 16.2 billion Swiss francs at year-end 2000. Roche's stock market capitalization fell by 15% last year to 148.2 billion Swiss francs as of Dec. 31. 🏠

Abbott's Miles White Earns Total Of \$28M In 2000

Abbott Laboratories (Abbott Park, IL) awarded its chairman and chief executive, Miles White, total compensation of \$28.21 million last year, according to the company's latest shareholder proxy statement. White's compensation included 10-year options to purchase 450,000 shares of Abbott stock at a base price of \$34.70 per share. These options could be worth \$24.886 million if Abbott's stock price were to appreciate 10% annually until their expiration date in February 2010. White also received a salary of \$1.391 million last year, plus a bonus of \$1.8 million and other compensation totaling \$132,827.

For full-year 2000, Abbott reported net income of \$2.786 billion, up 14% from \$2.446 billion in 1999; revenue rose 4% to \$13.746 billion. Abbott's stock price rose 33% last year to \$48.44 per share. From the time White became chief executive in January 1999 through February 2001, Abbott's stock price has declined by 1%.

Robert Parkinson Jr., who stepped down as president and chief operating officer in September 2000, received total compensation of \$24.458 million from Abbott last year. Parkinson's compensation included 10-year options to purchase 325,000 shares of Abbott stock potentially worth \$17.973 million (assuming 10% annual stock appreciation). Abbott also paid Parkinson \$4.263 million in exchange for his agreement not to compete with Abbott until July 31, 2002. In addition, Parkinson got a salary of \$982,769 last year, plus a bonus of \$1.089 million and other compensation totaling \$149,515.

Richard Gonzalez, executive vice president of medical products (including diagnostics), received total compensation in 2000 of \$8.795 million, including options to purchase 120,000 shares of Abbott stock potentially worth \$6.987 million. Gonzalez also got a salary of \$469,673, a bonus of \$517,000, restricted stock worth \$767,188, and other compensation totaling \$54,368. 🏠

Abbott To Market Enfer's Tests For "Mad-Cow" Disease

Earlier this year, Roche Holding announced a similar marketing agreement with Prionics Inc. (Zurich, Switzerland), which makes the Prionics-Check test for mad-cow disease (DTR, March '01, p. 2)

Abbott Laboratories has signed an agreement to distribute two tests made by Enfer Scientific Ltd. (Tipperary, Ireland) that are used to detect Bovine Spongiform Encephalopathy (more commonly known as mad-cow disease) in dead cattle.

Abbott will market the two tests under the Enfer name in all countries, except Ireland and Germany where Enfer will continue its own marketing, says Abbott spokesman Don Braakmann.

The first test is a four-hour ELISA (enzyme-linked immunosorbent assay), approved by the European Commission. Features of the test include its rapid turnaround time and high-throughput capabilities, according to Abbott. The second test is a supplemental test used to confirm positive results. Both are conducted on brain tissue and spinal cord samples from dead cattle. There currently is no test on the market that can detect the disease in live animals. 🏠

J&J's Ralph Larsen Gets Compensation Of \$27M In 2000

Ralph Larsen, chairman and chief executive of Johnson & Johnson (New Brunswick, NJ), received total compensation of \$27.044 million last year, according to the company's latest shareholder proxy statement. Larsen's compensation included 10-year options to purchase 750,000 shares of J&J stock at a base price of \$101.38 per share. These options have an estimated present value of \$22.34 million. Larsen also got a salary of \$1.435 million, plus a bonus of \$1.55 million and other compensation totaling \$1.718 million (primarily from J&J's long-term incentive plan for executives). Larsen, 62, joined J&J in 1962 as a manufacturing trainee and became chairman and chief executive in 1999, the proxy statement says.

For full-year 2000, J&J reported net income of \$4.8 billion, up 15% from \$4.167 billion in 1999; revenue rose 6% to \$29.139 billion. The company's stock price rose 13% last year to \$105.06 per share.

James Lenehan, worldwide chairman of J&J's Medical Devices and Diagnostics Group, received total compensation in 2000 of \$5.403 million, including \$730,000 in salary; a bonus of \$625,385; \$473,321 in other compensation; and 120,000 stock options with a present value of \$3.574 million.

Diagnostics Revenue At J&J (\$MM)

	2000	1999	% Chg
Lifescan			
US	\$662	\$721	-8%
International	325	322	+1%
Worldwide	988	1,043	-5%
Ortho-Clinical Diagnostics			
US	497	457	+9%
International	481	484	-1%
Worldwide	977	941	+4%

Source: J&J

J&J generated total worldwide IVD revenue of \$1.965 billion in 2000 vs. \$1.984 billion in 1999. Its IVD business consists of its blood glucose monitoring subsidiary Lifescan (Milpitas, CA) and its Ortho-Clinical Diagnostics (Raritan, NJ) unit, which manufactures clinical chemistry and immunoassay analyzers for traditional laboratories, and blood screening and typing systems for blood banks. In 2000, Lifescan, which employs more than 2,000 workers, saw its worldwide revenue decline by 5% to \$988 million; Ortho-Clinical Diagnostics, which has approximately 4,000 employees, increased its worldwide revenue by 4% to \$977 million. 🏠

Ortho-Clinical Wins Catholic Healthcare West Contract

Ortho-Clinical Diagnostics has signed a southern California regional contract to deliver chemistry and immunodiagnostic laboratory testing systems to Catholic Healthcare West (San Francisco, CA). CHW is the largest Catholic health-care system in the West, with 48 hospitals and seven medical practice groups in California, Arizona, and Nevada.

The contract includes nine Vitros 950 and four Vitros 250 Chemistry Systems and five Vitros ECi Immunodiagnostic Systems. CHW currently uses Vitros Chemistry and ECi Immunodiagnostic Systems in five of its facilities in southern California. CHW will now expand the use of these instruments to all facilities within its network. 🏠

Axis-Shield Reports Full-Year 2000 Loss Of 8.2M Pounds

Axis-Shield (Dundee, Scotland) recorded a net loss of 8.457 million pounds (US \$12.1 million) for the year ended Dec. 31, 2000 vs. a net loss of 10.05 million pounds in 1999; revenue increased to 35.184 million pounds (US \$50.331 million) from 14.662 million pounds. The company's largest business segment is point-of-care test kits, which accounted for 38% of total revenue in 2000. Axis-Shield's top-selling test is its NycoCard C-Reactive Protein (CRP) Test, a point-of-care test used to differentiate between bacterial and viral infection to determine whether antibiotics should be prescribed for a patient.

Axis-Shield was formed in May 1999 by the merger of Axis Biochemicals (Oslo, Norway) and Dundee-based Shield Diagnostics. The company's distribution capabilities were augmented in November 1999 by the acquisition of Medinor ASA (Oslo). In addition, Axis-Shield acquired Nycomed Diagnostics (Oslo) in February 2000 for 22 million pounds. Axis-Shield currently has roughly 400 employees, most of them in Norway and Scotland.

Axis-Shield won clearance from the U.S. Food & Drug Administration last year to sell its Carbohydrate Deficient Transferrin (%CDT) assay, which can detect whether an individual has consumed heavy amounts of alcohol over the past two to three weeks. Most alcohol tests in use today can only measure the presence of alcohol in

the body at the time the test is administered. The Axis-Shield test will be marketed in the U.S. by Bio Rad Laboratories Inc. (Hercules, CA) and Roche Diagnostics (Indianapolis, IN).

The %CDT test is expected to be given by physicians as part of medical exams. Axis-Shield says the test identifies alcohol abuse substantially earlier than conventional markers, which are focused on identifying the development of cirrhosis and liver damage seen in the latter stages of alcoholism. The test has been used in parts of Europe for four years to help physicians determine if alcoholic patients are adhering to their treatment program. ▲

Axis-Shield At A Glance

12 months ended Dec.31 (in thousands of pounds)

	2000	1999
Revenue	35,184	14,662
EBITDA ¹	-2,073	-4,140
Net income	-8,457	-10,050
Working capital ²	15,246	11,629

¹EBITDA=earnings before interest, taxes, depreciation, and amortization

²Working capital=current assets minus current liabilities

Source: Axis-Shield

Careside Records 4Q00 Loss of \$4.7M

Careside At A Glance (\$000)

	4Q00	4Q99
Revenue	\$105	\$61
Net income	-4,674	-3,185
Cash and equivalents	1,789	4,905

Source: Careside

Careside Inc. (Culver City, CA) recorded a net loss of \$4.674 million in the fourth quarter of 2000 vs. a net loss of \$3.185 million in fourth-quarter 1999; revenue totaled \$105,000 vs. \$61,000. Manufacturing glitches hampered the company's launch of its desktop blood analyzer last year (*DTTR*, Oct. '00, p. 4). Chairman W. Vickery Stoughton says commercial shipments resumed in December. As of Dec. 31, 2000, Careside had \$1.789 million in cash, current liabilities of \$4.744 million, and long-term debt of \$1.215 million. ▲

IVD Stocks Tumble In Latest 5 Weeks

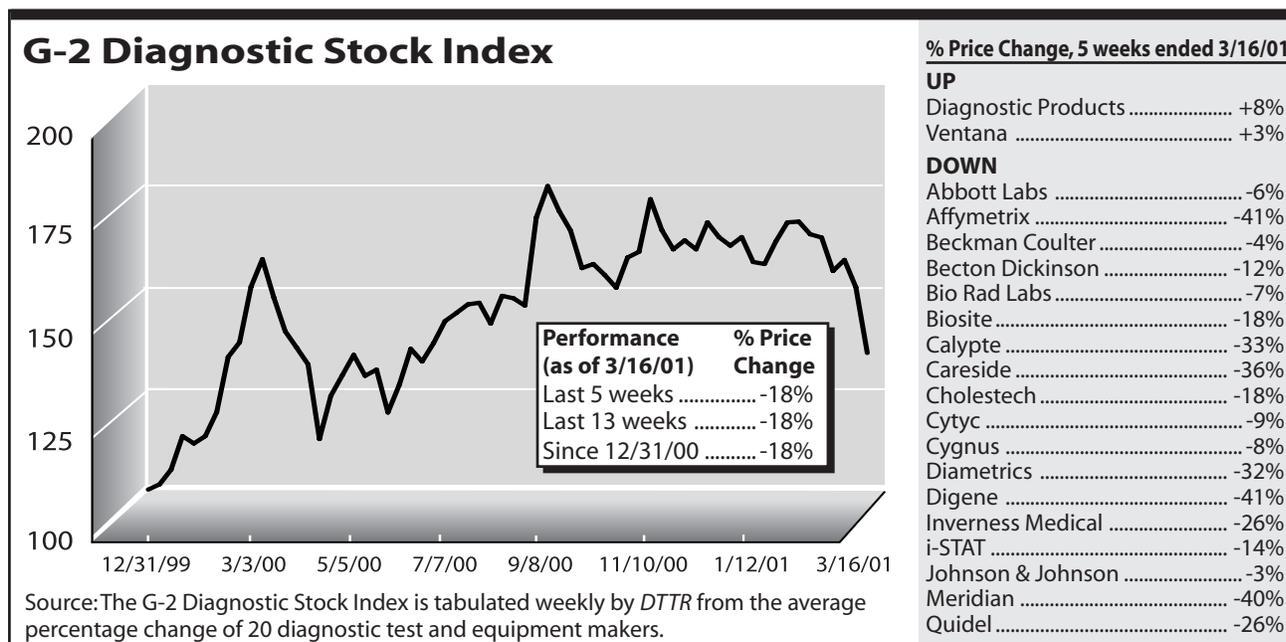
The G-2 Diagnostic Stock Index declined 18% in the five weeks ended March 16. Eighteen stocks in our index fell in price, two rose. Since the start of the year, the index has dropped 18%, while the S&P 500 is down 13% and the Nasdaq is down 23%.

Shares of **Affymetrix Inc.** (Santa Clara, CA) dropped by 41% to \$37 per share, giving the company a market capitalization of \$2.1 billion. The company says it recently found errors in data taken from mouse genes used to design one type of its gene chips. Affymetrix plans to offer replacement chips to its customers at a cost to the company of up to \$4 million.

Digene Corp. (Gaithersburg, MD), which makes the Hybrid Capture2 HPV Test for detecting human papillomavirus, saw its stock drop 41% to \$15.75 per share for a market capitalization of \$281 million. The company reported a higher-than-expected net loss of \$1.578 million in the three months ended Dec. 31, 2000 (*DTTR, March '01, p. 11*).

Shares of **Meridian Bioscience** (Cincinnati, OH) fell 40% to \$3 per share for a market capitalization of \$43 million. In response to an FDA inspection of its manufacturing and quality procedures, Meridian 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 (*DTTR, March '01, p. 11*).

The only two stocks in the G-2 Index to increase in price were **Diagnostic Products** (Los Angeles, CA), up 8% to \$53.50 per share, and **Ventana Medical Systems** (Tucson, AZ), up 3% to \$21.13 per share. Ventana, which makes automated equipment for tissue preparation and slide staining at histology labs, is a new addition to our index. ▲



G-2 Insider

Many industry pundits are predicting that a "tidal wave" of new genetics-based diagnostic testing technologies will result in increased utilization of, and reliance on, clinical laboratory testing. However, the scientific and regulatory hurdles in bringing a new test to market should not be overlooked. Not to mention the stinginess that managed care companies and Medicare have historically shown toward reimbursing new diagnostic technologies (*DTTR*, Dec. '00, p. 12).

Timetable For OSDI HER-2/Neu Assay

- 1986:** Oncogene begins work to develop antibodies for HER-2/neu
- 1989:** First abstract for "Oncoprotein" antibody presented at San Antonio Breast Cancer Symposium
- 1990:** Oncoprotein offered to research market
- 1995:** Oncogene Science gets patent for method of finding Oncoprotein in blood serum
- 2000:** FDA clears OSDI HER-2/Neu Assay

Source: Oncogene Science

The long road that Oncogene Science (Cambridge, MA), part of Bayer Diagnostics, had to travel in order to bring its HER-2/neu serum test to market is a case in point. Walter Carney, PhD, head of Oncogene Science, says he first began working to develop antibodies for HER-2/neu in June 1986. Fourteen years later Oncogene received FDA clearance (Sept. 29, 2000) to sell the resulting diagnostic test: the OSDI HER-2/Neu Assay for quantitative determination of serum HER-2/neu in women with metastatic breast cancer. Jeff Whitaker, manager of sales and marketing for Oncogene, says the company is hoping to receive a CPT code for the test by January 2002.

If Oncogene's timetable is any indication of the time it takes to bring a new diagnostic test to market, the genomics revolution will have to wait. Think I'm all wet? Write me at labreporter@aol.com. Jondavid Klipp, managing editor 🏠

Company References

- Abbott Labs 847-937-6100
- Affymetrix 408-731-5000
- Axis-Shield
+44 (0) 1382 422 000
- Careside 310-338-6767
- Digene 301-944-7000
- Johnson & Johnson
732-524-0400
- Meridian Bioscience
513-271-3700
- Oncogene Science
888-674-3424
- Ortho-Clinical Diagnostics
908-218-1300
- Quest Diagnostics
201-393-5000
- Roche Diagnostics
317-849-9350
- Sequenom 858-350-0345
- Tweedy, Browne Co.
212-916-0600
- Visible Genetics
416-813-3240
- Vysis 630-271-7000

Correction: In our February issue (p. 2), we said Roche Diagnostics was the exclusive U.S. distributor of Sysmex Corp.'s coagulation products. In fact, Dade Behring is the exclusive distributor of Sysmex coagulation instrumentation in the U.S.

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