



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Established 1979

Abbott To Restructure Diagnostics Division

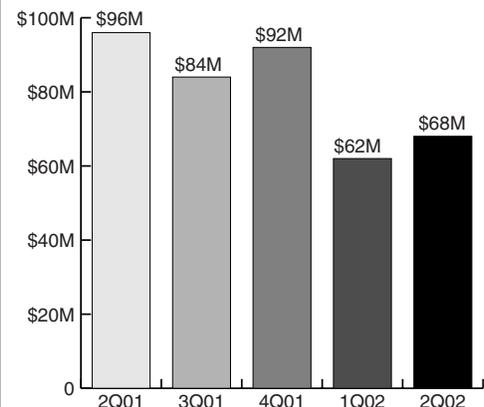
Abbott Laboratories (Abbott Park, IL) has announced plans to restructure its struggling diagnostics division around four business units—immunoassay/clinical chemistry, hematology, molecular diagnostics and blood glucose monitoring. Don Braakman, spokesman for Abbott, tells *Diagnostic Testing & Technology Report (DTTR)* that the restructuring is part of a broader effort to cut costs throughout the company, including at its pharmaceuticals division.

In total, Abbott plans to cut 2,000 jobs, or 3% of its global workforce of 70,000 employees, and close 10 facilities. Braakman says the diagnostics division, which currently employs about 16,500 people worldwide, is targeted for roughly 1,000 job cuts. He declined to disclose the names and locations of specific facilities to be closed.

The restructuring comes as profitability at Abbott's diagnostics division continues to erode. Operating earnings for the division fell to \$68 million in the three months ended June 30, 2002, from \$96 million in the same period a year earlier.

Continued on p. 3

Abbot Diagnostics' Operating Earnings



Source: Abbott

Dade Behring Emerges From Chapter 11, Begins Trading As Public Company

Only two months after filing for a bankruptcy reorganization, Dade Behring (Deerfield, IL) has emerged from Chapter 11 with a debt load cut in half (to approximately \$778 million) and a much brighter future. Dade also is now a publicly traded company that began trading on the over-the-counter market, effective Oct. 3, at \$14.72 per share for a market capitalization of \$695 million (based on 47.2 million fully diluted shares outstanding). Jim Reid-Anderson, Dade's president and CEO, tells *DTTR* that the company was able to navigate its way through the reorganization with nearly no loss of customers.

Continued on p. 2

▲ **Dade Behring**, from page 1

Reid-Anderson says Dade's reorganization might have had a devastating effect on its business by scaring away customers wary of entering into long-term reagent rental contracts with a company in Chapter 11. But Dade's 3,000-person sales and support staff was able to minimize customer concerns, he points out, by contacting every single account in the U.S. and internationally prior to the Chapter 11 filing.

"We explained what we were doing and why," says Reid-Anderson, who personally met with each of Dade's top 10 customers to allay concern. As a result, Dade experienced only a minimal disruption in its business during July and August. Moreover, Dade was recently able to extend its contracts with its two largest customers—group purchasing agents Premier and Novation.

Meanwhile, Reid-Anderson says annual interest savings of more than \$60 million resulting from the reorganization will allow the company to begin paying down its remaining debt and raise investment in research & development. The goal, he says, is to raise R&D spending to 10% of revenue. In 2001, such spending was 7% of revenue.

Among the key new products being developed is Epsilon, a next-generation platform that will consolidate routine chemistry, immunoassay and nephelometry. Reid-Anderson expects an Epsilon system aimed at high-volume labs will be launched in late 2004. He anticipates it will have a menu of 160-180 assays at product launch.

Placing A Value On Dade Behring

Since getting listed on the OTC market on Oct. 3 at \$14.72, Dade's share price has nudged up to \$15 for a market capitalization of \$708 million and an enterprise value of \$1.461 billion. This equates to 1.2 times projected 2002 revenue of \$1.195 billion and 7.2 times projected EBITDA of \$204 million.

Beckman Coulter is the one publicly traded company whose business is probably most similar to Dade's. Following Beckman's big sell-off on Oct. 15 (*see p. 11*), the stock market valuations that investors currently place on Beckman and Dade are also similar. Valuations for Becton Dickinson and Bio-Rad Laboratories are also in the same ballpark, whereas Diagnostic Products Corp. sells at a significant premium to the five IVD companies, compared in the table below. 🏰

Dade Behring Valuation Comparison

	<i>Dade</i>	<i>Beckman</i>	<i>Becton</i>	<i>Bio-Rad</i>	<i>DPC</i>
Enterprise value ¹	\$1,461	\$2,451	\$8,475	\$1,225	\$1,350
Revenue	1,195	1,926	3,942	850	319
EBITDA ²	204	365	944	164	98
Net income	-12	140	465	70	50
EV/revenue	1.2	1.3	2.2	1.4	4.2
EV/EBITDA	7.2	6.7	9.0	7.5	13.8
EV/net income	NA	18	18	18	27

Note: Financial data for Dade come from projections in the reorganization plan filed in U.S. bankruptcy court in August. Financial data for Beckman, Becton, Bio-Rad and DPC are projected, based on reported results as of June 30, 2002.

¹Enterprise value=market capitalization plus net debt.

²EBITDA=earnings before interest, taxes, depreciation and amortization.

Source: *DTTR* from company reports

▲ **Abbott To Restructure**, from page 1

Braakman says the restructuring of Abbott Diagnostics around four separate business units is intended to create more customer-focused divisions. Each business unit will have its own management, sales and support.

Ed Michael has been named vice president of the immunoassay/clinical chemistry unit. He also will serve as interim head of molecular diagnostics while the company searches for a permanent head for this unit. John Schueler has been named vice president of the hematology unit and Ed Fiorentino as vice president of the blood glucose monitoring unit (aka MediSense).

In connection with the restructuring, Abbott expects to incur an after-tax charge of \$100-\$125 million against earnings in the fourth quarter, reflecting the write-down of manufacturing facilities and other assets, along with employee severance charges. The company expects the restructuring to yield after-tax annual savings of \$80-\$100 million.

The latest restructuring charge comes on top of a \$140 million write-off Abbott announced earlier this year after learning that its Lake County (IL) diagnostics operations still failed to comply with quality system regulations of the U.S. Food & Drug Administration (*DTTR*, July 02, pp. 1-2). Abbott initially took a \$168 million charge in 1999 when it signed a consent decree with FDA, forcing the company to suspend sales of roughly 60 immunoassays on the U.S. market.

Meanwhile, overall sales at Abbott Diagnostics continue to deteriorate. Worldwide diagnostics sales edged up 0.8% to \$733 million in the third quarter ended Sept. 30, 2002. U.S. sales fell 9% to \$288 million, while international sales were up 8.4% to \$445 million. Excluding revenue gained from the acquisition of Vysis Inc., *DTTR* estimates that U.S. sales at Abbott Diagnostics declined by some 15% in the third quarter.

Abbott's MediSense blood glucose monitoring unit generated worldwide revenue growth of 6.8% to \$126 million in the third quarter. Abbott plans an international launch of its Precision Easy Meter by year's end, with a U.S. launch expected by mid-2003. This meter performs alternate site testing (*i.e.*, forearm vs. fingertip) with a blood sample size of as little as 1.5 microliters.

During an Oct. 9 conference call, Richard Gonzalez, president and chief operating officer of Abbott's medical products group, confirmed that the company has hired two third-party consultants (Bio-Reg and AccuReg) to help it meet requirements of the FDA consent decree, but he gave no clue as to when FDA's concerns might be satisfied. ▲

Abbott Diagnostics 3Q02 Revenue Summary (\$MM)

	3Q02	3Q01	Change
Worldwide Diagnostics Sales	\$733	\$728	+0.8%
—U.S.	288	317	-9.0%
—International	445	411	+8.4%
Worldwide MediSense	\$126	118	+6.8%
—U.S.	52	54	-4.3%
—International	74	64	+16.2%

Source: Abbott Laboratories

Careside Files For Chapter 11 Bankruptcy

Careside Inc. (Culver City, CA) has filed for Chapter 11 bankruptcy reorganization in the U.S. Bankruptcy Court for the Central District of California. The company says it is now in the process of negotiating with a lender to obtain a loan of up to \$2 million to maintain operations.

“Chapter 11 was not an easy decision for the company to take,” said W. Vickery Stoughton, chief executive officer of Careside, in a press release. “After much consideration, the company determined that this decision was the best opportunity to preserve the going concern value of Careside. Chapter 11 allows time for the company to reorganize and regain financial strength while supporting our existing customers and responding to new customer opportunities. Careside will emerge from Chapter 11 as soon as possible and be in a much stronger position to achieve its full potential.”

Careside received clearance from the U.S. Food & Drug Administration to market its Careside Analyzer—a point-of-care blood testing system that can perform about 60 tests—in December 1999. However, manufacturing glitches hampered the product’s initial launch, and financial difficulties have limited Careside’s marketing efforts. The Careside system, including the H-2000 hematology analyzer, lists for approximately \$30,000; reagent cartridges sell for \$3-5 each.

Careside In Brief (\$000)

	<i>Six months ended</i>	
	<i>6/30/02</i>	<i>6/30/01</i>
Revenue	\$1,010	376
Free cash flow	-3,188	-5,850
Net loss	-7,944	-11,739
Current assets	2,682	8,726
Current liabilities	7,986	4,865

Source: Careside

In the six months ended June 30, 2002, Careside reported a net loss of \$7.9 million vs. a net loss of \$11.7 million for the same period a year earlier; revenue was \$1 million vs. \$376,000. Since its incorporation in July 1996, Careside has accumulated losses of \$68.8 million. At its peak in March 2000, Careside stock, now worthless, had traded as high as \$13 per share for a market capitalization of over \$100 million. 🏠

Abaxis Reports Record 2Qtr Sales Of \$8.7 Million

Abaxis Inc. (Union City, CA) reports record sales of \$8.7 million for the fiscal second quarter ended Sept. 30, 2002, up 30% from \$6.7 million in the same period a year earlier; net income was \$101,000 vs. \$4,000.

Abaxis currently generates more than 85% of its revenue from the sale of point-of-care analyzers and cartridges to the veterinary market, but sales of the company’s portable Piccolo blood chemistry analyzer for human diagnostics are increasing rapidly. Abaxis first entered the human diagnostics market last year and has placed a total of approximately 200 Piccolo instruments as of Sept. 30, 2002.

In the most recent quarter, Abaxis placed 34 Piccolo analyzers vs. 25 in the same period last year. Of the 34 shipped, 18 were sold to the military, 11 were sold in Europe and five were shipped in the U.S. medical market, including three units to wellness centers, one to a small hospital and another to a cruise ship. Piccolo cartridge sales totaled 18,800 units in the most recent quarter, with an average selling price of \$13.64 per cartridge in the U.S. 🏠

inside the diagnostics industry

Leading IVD Vendors Look To New Products For Growth

Highlights

From

UBS Warburg's

Global Life

Sciences

Conference

The stock market may be in a vicious bear market, but that didn't stop more than 2,500 money managers from attending the UBS Warburg Global Life Sciences Conference in New York City on Oct. 7-10. Among the 400+ companies that gave presentations were several notable IVD vendors. For some highlights, read on:

Jack Wareham, chairman and CEO of **Beckman Coulter** (Fullerton, CA), says spending for drug research and testing equipment by big pharmaceutical and biotechnology companies is slowing. He also sees "some hesitancy in the government-funded markets," which are now directing more money toward basic infrastructure and bioterrorism efforts. Beckman, which generates approximately 30% of its total revenue from the life sciences research market, recently warned that a slowdown in this market would hurt its third-quarter financial results (*see p. 11*).

Separately, Wareham says Beckman has begun beta-testing its new Synchron LXi 725, which consolidates 140 immunoassay and routine chemistry tests on a single workstation. This system will go into full launch in early 2003.

Pricing for routine chemistry remains under pressure, according to Wareham, who says improvements in testing utility are being used to maintain pricing. "That's why we are investing more in immunoassay. It's easier to improve clinical utility for immunoassay and hold prices." And he adds, "Everybody is feeding off the problems that Abbott has in immunoassay."

Norman Schwartz, vice president and group manager, life science, at **Bio-Rad Laboratories** (Hercules, CA), says the company has developed a new test for chronic wasting disease (CWD), which has been found in the deer and elk populations in eight Midwestern states. Schwartz says the new test was adapted from the company's BSE or "mad cow" test. He notes that several states are preparing to launch CWD screening programs. CWD and "mad cow" are diseases that eat at the brain and nervous system and are always fatal.

Worldwide, the market for "mad cow" testing now totals \$100-\$150 million, Schwartz estimates, noting that this market essentially did not exist prior to the year 2000. Bio-Rad has a 70% share. "Mad cow" testing represents approximately 10% of Bio-Rad's total annual revenue of \$850 million, *DTTR* estimates.

Peter Meldrum, president and CEO of **Myriad Genetics** (Salt Lake City, UT), says controversy in Europe over Myriad's breast cancer gene patents is generating interest among potential patients. Legal costs to defend the patents against a challenge from Institut Curie (Paris) are not significant, he contends (*DTTR*, Sept. 02, p. 1).

Separately, Meldrum notes that Myriad has successfully raised prices for its tests by an average 3%-7% annually and collects an average 94% of its list prices. Even managed care giant Aetna Inc. (Hartford, CT) gets only a 9% discount, he points out.

Myriad has begun a direct-to-consumer marketing campaign in Denver and Atlanta for its BracAnalysis test, which sells for about \$2,580 and is used to help determine

hereditary risk of breast and ovarian cancer. Advertising will be targeted to women ages 25 to 54. TV ads will be aired on such programs as *Providence*, *ER*, *The Oprah Winfrey Show*, *Regis and Kelly* and *The Today Show*. Print ads will run in *Better Homes and Gardens*, *Ladies Home Journal* and *Women's Health Monitor*, according to Myriad.

The campaign will run through Jan. 31, 2003, and the goal is to reach each member of the target audience an average 16.5 times, according to Myriad. The ads were developed by The Quantum Group, a healthcare advertising agency that also has developed, for example, ads for Schering-Plough's Claritin allergy drug. Meldrum says Myriad is now considering a national ad campaign for the BracAnalysis test.

In the fiscal year ended June 30, 2002, Myriad reported genetic testing revenue of \$26.8 million, up from \$17.1 million in the prior year.

Henry Nordhoff, president of **Gen-Probe** (San Diego, CA), notes that his company—after being spun-off from Chugai Pharmaceuticals (Tokyo, Japan) on Sept. 9, 2002—had a balance sheet with \$100 million in cash and no debt. As an independent company, Gen-Probe is listed on the Nasdaq with a current market capitalization of approximately \$380 million. This is equal to 2.8 times its annual revenue of \$137 million and 52 times its net income of \$7.3 million (based on annualized results for the six months ended June 30, 2002).

According to Nordhoff, Gen-Probe has plowed as much as 49% of its annual revenue into research & development over the past few years—a luxury it could afford as part of a larger pharmaceutical company. This heavy investment will come to fruition in the form of new products over the next few years, he says, even as overall R&D falls to 15%-20% of sales. R&D for the first six months of this year was equal to 34% of revenue.

Patrick Sullivan, chairman and CEO of **Cytec Corp.** (Boxborough, MA) boasts: "We've got a 110-person salesforce that acts like a pharmaceutical salesforce." As of June 30, 2002, Cytec had installed more than 1,700 of its ThinPrep Pap analyzers in the U.S., up from 1,600 at year-end 2001 and 1,250 at year-end 2000. The company recently won a sole-source contract, he notes, to provide ThinPrep to U.S. Navy cervical cancer screening centers, which currently process roughly 263,000 tests annually.

Cytec has a market share of nearly 65% of the 50 million Pap tests performed each year in the U.S. According to Sullivan, the company is positioning itself for future growth in three key areas:

- (1) Adjunctive tests from the ThinPrep vial, including human papillomavirus (HPV) and chlamydia/gonorrhea testing.
- (2) Expansion in Europe, particularly in England and Germany.
- (3) Ductal lavage (Cytec's FDA-approved method for detecting early signs of breast cancer).

Bill Moffitt, president and CEO of **i-Stat Corp.** (East Windsor, NJ), says i-Stat has enough cash on hand (\$28.5 million as of June 30) to hold it over until the company reaches profitability. He expects the first full year of positive cash flow will be 2004, assuming the company can sell approximately 19.3 million test cartridges in that year.

This might be a tough goal to achieve, since test cartridge sales for this year are only expected to grow 11% to 13.1 million. To reach the 19.3 million mark, growth will need to accelerate to better than 20% annually for each of the next two years.

i-Stat recently announced plans to terminate its distribution agreement with Abbott Laboratories, effective Jan. 1, 2004 (*DTTR*, Sept. 02, p. 10). This will require i-Stat to pay Abbott roughly \$65 million in residual payments between 2003 and 2008.

Edward Gallup, chairman and CEO of **Immucor** (Norcross, GA), anticipates continued strong pricing in the blood banking market as a result of industry consolidation, which has eliminated price wars, and the introduction of higher-priced automated products. Twenty years ago, Gallup notes, there were more than a dozen IVD companies competing in blood banking. Today, Immucor and Ortho-Clinical Diagnostics (Raritan, NJ) are the only U.S. vendors. A third company—DiaMed of Switzerland—competes internationally.

New entrants into this market are unlikely, Gallup believes, since it would probably take more than three years to gain the necessary licenses from the U.S. Food & Drug Administration. He anticipates that Immucor will enjoy continued strong price increases for its blood banking products and tests for at least the next few years.

Worldwide, the market for blood banking reagents is \$380 million, including about \$120 million for the U.S., according to Gallup. He says Immucor has 300 blood banking analyzers placed worldwide and a market share of approximately 25%.

Michael Gausling, president and CEO of **OraSure Technologies** (Bethlehem, PA), says OraSure has received an approvable letter from FDA for its OraQuick Rapid HIV-1 Antibody Test. He says the company has responded to FDA's concerns and anticipates final clearance and product launch by year's end. The OraQuick test detects HIV-1 antibodies in fingerstick whole blood within 20 minutes and is likely to become the first rapid HIV test on the U.S. market.

In addition, Gausling notes, OraSure recently signed a U.S. distribution agreement with Abbott Laboratories for the OraQuick test. Under the terms, Abbott is required to meet certain minimum purchase commitments. OraSure expects to receive product revenue of approximately \$4 million from Abbott over the next 12 months, subject to final FDA approval of the OraQuick test.

Paul Sohmer, MD, chairman and CEO of **TriPath Imaging** (Burlington, NC), anticipates that the company's commercial operations, which are focused around the sale of monolayer Pap testing supplies and instruments, will begin operating on a break-even basis in the fourth quarter. Meanwhile, the company's TriPath Oncology unit continues to lose approximately \$1 million per month.

TriPath Oncology is a venture among TriPath, Millennium Pharmaceuticals and Becton Dickinson. Its goal is to develop an assay for staging malignant melanoma as well as detection of cancers of the cervix, breast, ovary, colon and prostate. The venture is not expected to begin generating revenue until 2004.

In the six months ended June 30, 2002, TriPath Imaging reported a net loss of \$10.7 million vs. a net loss of \$7.4 million in the same period a year earlier; revenue was \$16.7 million vs. \$15.4 million. Cash holdings as of June 30 were \$40 million. ■

New Study Supports Use Of HPV Test As Cervical Cancer Screen

A new study published in the Oct. 8 issue of *The Journal of the American Medical Association* shows that the Hybrid Capture 2 HPV DNA Test, made by Digene Corp. (Gaithersburg, MD), may be useful as a primary screening method for cervical cancer.

The study showed a 90.8% sensitivity for HPV testing to detect high-grade cervical disease and cervical cancer and a negative predictive value of 99.6%, compared to a liquid-based Pap test which had a sensitivity of 61.3% and a negative predictive value of 98.5%. The study involved 4,075 women, ages 18 to 50, who attended Planned Parenthood clinics in Washington state for routine cervical cancer screening. It was conducted between December 1997 and October 2000.

Digene's HPV test is the only one approved by the U.S. Food & Drug Administration for human papillomavirus (HPV), the primary causal factor in the development of cervical cancer. The test is currently approved for use as an adjunct to the Pap test for women with abnormal Pap results.

Digene charges laboratories about \$20 per specimen tested using its HPV test. Medicare reimbursement is capped at \$48.50 (high-risk only) and \$97 (high- and low-risk). 🏠

Ventana Acquires HPV Business Assets From Beckman Coulter

Ventana Medical Systems (Tucson, AZ) has purchased Beckman Coulter's human papillomavirus (HPV) business and all corresponding assets for an undisclosed amount. The acquisition includes assignment of the HPV intellectual property portfolio acquired by Beckman from Institut Pasteur (Paris, France) via a 1991 sub-license agreement. Institut Pasteur recently sold its remaining HPV rights to Roche Diagnostics (*DTTR, July 02, p. 8*).

Christopher Gleason, president and CEO of Ventana, says the acquisition provides Ventana with direct access to the necessary portfolio of HPV sub-type patent rights for its Inform HPV test. Ventana launched the Inform HPV test in a tissue-based method in the fourth quarter of 2001. A liquid-based method was launched in May of this year. Gleason says the company is in the process of preparing an application to have the U.S. Food & Drug Administration clear the test for sale in kit form. Inform HPV is currently used by about 50 labs as a "home-brew" test.

Many pathologists will choose the Inform HPV test method over Digene's test, Gleason believes, because Ventana's test requires a direct visual interpretation of a slide. Ventana sells reagents for the Inform HPV test at an average price of \$40-\$45 per high-risk probe. The average global reimbursement to labs is \$110, according to Gleason.

Separately, Ventana recently announced an agreement with ChromaVision Medical Systems (San Juan Capistrano, CA) to jointly market an automated staining and imaging method of testing for HPV. The two companies plan to market a newly developed test combining ChromaVision's ACIS image analysis systems with

Ventana reagents and automated staining platforms. Gleason says the agreement will open new customer prospects for both companies, as the integrated testing system will be actively marketed to the firms' current common customers and new laboratory customers.

In a question and answer session at the recent UBS Warburg Global Life Sciences Conference (*see pp. 5-7*), Gleason said he is "extremely confident" about Ventana's litigation with CytoLogix (*DTTR, Oct. 02, p. 10*), which is set to go to trial in a matter of weeks. "My biggest concern is the amount of money we're paying in legal fees, which is taking away from the bottom-line....We are reasonable people and we should be able to get together and talk about this [out of court]." 🏠

DeCode Genetics To Cut 200 Jobs

Decode Genetics (Reykjavik, Iceland) is laying off 200 employees, or 30% of its workforce, as part of an effort to reach profitability. Following the cutbacks, the company expects to achieve positive cash flow in its research and service operations in 2003. Kari Stefansson, chairman and CEO of DeCode, says the cutbacks should also mean break-even at the overall company, unless DeCode's in-house research & development department finds a drug candidate for clinical trials next year, in which case there would be additional costs.

In the six months ended June 30, 2002, DeCode reported a net loss of \$28.36 million vs. a net loss of \$28.378 million in the same period a year earlier; revenue increased to \$22.9 million from \$11.231 million. Since being formed in 1996, DeCode has accumulated losses of \$186.6 million.

DeCode Genetics In Brief (\$000)

	Six months ended	
	6/30/02	6/30/01
Revenue	\$22,896	\$11,231
Free cash flow*	-41,206	-38,919
Net income	-28,360	-28,378
Cash holdings	115,430	154,593
Long-term debt	49,062	1,892

* Free cash flow=cash flow from operations, minus capital expenditures.
Source: DeCode Genetics

DeCode, which has mapped genes associated with a range of diseases, including schizophrenia, osteoporosis and asthma, is working with Roche Holding on a number of potential drugs and diagnostic tests. DeCode also recently announced a drug research deal with Merck and Co. Under the agreement, the two will work together to identify obesity drug targets, with DeCode eligible to receive up to \$90 million if Merck is able to bring to market more than one product. 🏠

Bayer Diagnostics Completes Acquisition of Visible Genetics

Bayer Diagnostics (Tarrytown, NY) has completed its acquisition of Visible Genetics (Toronto, Ontario, Canada) in a cash deal valued at approximately \$61.4 million. The purchase price is equal to roughly three times VGI's annual revenue of approximately \$18.6 million (based on annualized second-quarter results). VGI generates most of its revenue from sales of its Trugene HIV-1 Genotyping Assay, the only HIV sequencing resistance test approved by the U.S. Food & Drug Administration. 🏠

Diabetes Monitoring Reaches \$4.5 Billion In 2002

The whole-blood glucose self-testing market is on track to reach \$4.535 billion in worldwide revenue for 2002, according to a *DTTR* analysis of year-to-date sales trends of the five largest vendors. The overall market is targeted to grow 15% this year and has a compounded annual growth rate of 12% over 1999-2002.

The market should continue to post annual double-digit growth for the next five years, driven by increased testing among the largely unpenetrated Type II diabetes population. In addition, the frequency of testing in both Type I and Type II diabetes markets should increase because of an onslaught of new products designed to make frequent testing easier, faster and less painful. Highlights of several leading companies follow:

Roche Diagnostics (Basel, Switzerland) is the market leader with an estimated 37% global market share. Based on reported results of 1.858 billion Swiss francs (US \$1.24B) for the nine months ended Sept. 30, 2002—up 8% from the same period last year—*DTTR* estimates that full-year 2002 revenue will reach 2.52 billion Swiss francs (US \$1.66B). Roche says its Accu-Chek product line continues to drive growth. Key drivers include the Accu-Chek Compact, capable of performing 12 separate glucose measurements in a single test cartridge, and the Accu-Chek Active, which requires the smallest sample size of the Accu-Chek line at 1.5 microliters. Both of these products were rolled out in the U.S. last year.

Lifescan (Milpitas, CA), a unit of Johnson & Johnson, is projected to post revenue of \$1.35 billion for full-year 2002, up 23% from \$1.095 billion in 2001. Revenue has been bolstered by acquisition of the glucose test strip manufacturing business of Inverness Medical Technologies in late 2001.

Among the smaller and faster-growing glucose test makers is **TheraSense** (Alameda, CA), which markets the Freestyle self-test system. The company is on track to reach revenue of approximately \$180 million this year, up from \$72 million in 2001. Growth has been fueled by a heavy marketing campaign that includes TV ads plus coupons which give customers who buy 500 test strips a free testing meter.

Home Diagnostics Inc. (HDI-Fort Lauderdale, FL) is currently growing roughly 20%-25% per year and should exceed \$100 million in revenue this year, according to Greg Johnson, vice president for consumer health. The company sells low-priced meters and test strips under co-branding agreements with national drug store chains, including Eckerd, CVS and Duane-Read.

Estimated Worldwide Whole-Blood Glucose Test Revenue (\$MM)

	1999	2000	2001	2002	3-yr Chg.
Roche ¹	\$1,234	\$1,357	\$1,562	\$1,685	11%
Lifescan	1,043	987	1,095	1,350	9%
Bayer ²	560	610	652	700	8%
MediSense	357	418	450	500	12%
TheraSense	1	6	72	180	NM
Home Diagnostics	45	85	100	120	39%
Total	\$3,240	\$3,463	\$3,931	\$4,535	12%

¹ Based on constant exchange rate of 1 Swiss franc = \$0.6697 USD

² Based on constant exchange rate of 1 euro = \$0.9816 USD

Source: *DTTR* estimates and company reports

IVD Stocks Tumble 16% In Latest Five Weeks

Roche non-voting equity shares, which trade on the Zurich stock exchange, are down 13% to 103 Swiss francs year-to-date. Shares of **Bayer**, which trade on the German stock exchanges, are down 42% at 20.58 euros per share year-to-date

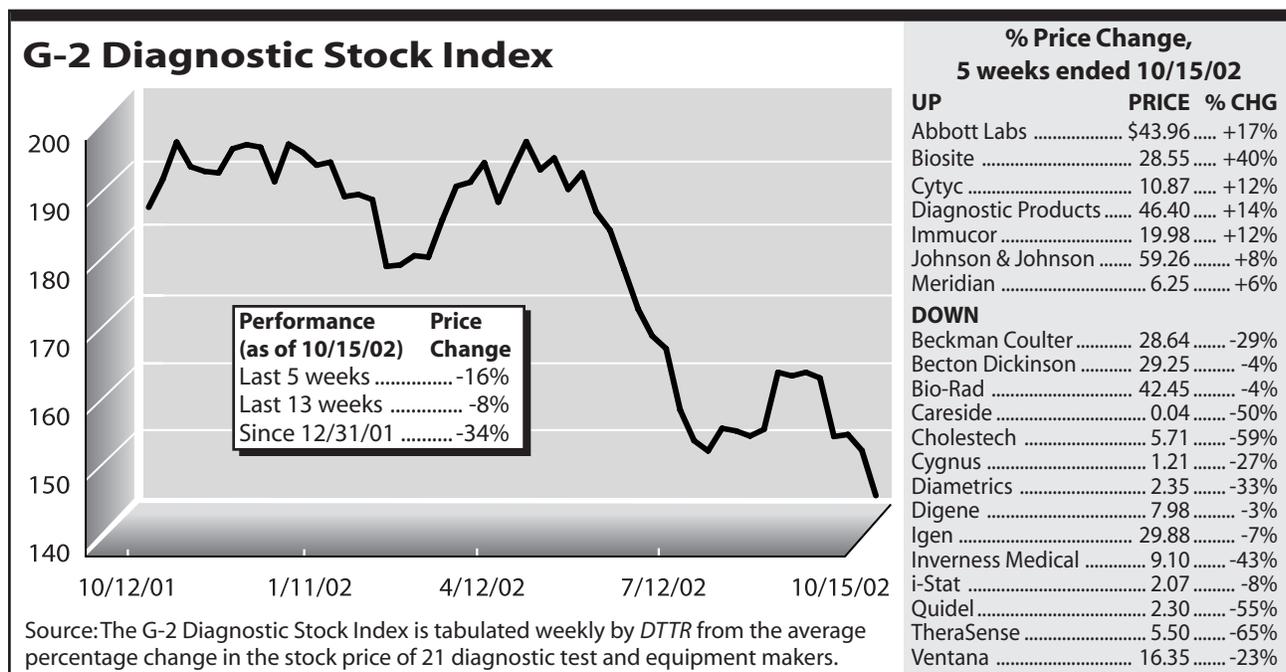
The 21 stocks in the G-2 Diagnostic Stock Index dropped an unweighted average of 16% in the five weeks ended Oct. 15, 2002, with 14 stocks falling in price and seven rising. Year-to-date, the G-2 Index has fallen 34%, compared with a 25% decline for the S&P 500 and a 36% drop for the Nasdaq.

Shares of **Beckman Coulter** (Fullerton, CA) fell 29% to \$28.64 for a market capitalization of \$1.8 billion. The company recently announced that third-quarter sales and earnings would fall short of its forecasts, as cuts in development spending by drug companies hurt demand for equipment for Beckman's life sciences products. In the third quarter, overall sales grew just 5% (to \$501 million) above sales for the same quarter a year ago—well short of the 10% growth expected. Net earnings dropped 2%-3% from the \$33 million reported for last year's third quarter.

TheraSense (Alameda, CA) plunged 65% to \$5.50 per share for a market cap of \$225 million. The company recently warned that sales for the third quarter would be below its previous forecasts.

Cholestech (Hayward, CA) was down 59% to \$5.71 per share for a market cap of \$80 million. The company said sales for the quarter ended Sept. 30 would come in at \$12-\$12.2 million vs. previous expectations of about \$13 million. Sales were hurt by a reduction in pharmaceutical companies' sponsorship of its cholesterol analyzers, the company said.

Biosite (San Diego, CA) was up 40% to \$28.55 per share for a market cap of \$425 million. The company recently resolved its patent and licensing disputes with biotech firm Xoma Ltd. (Berkeley, CA). The resolution means that Biosite will no longer have to spend about \$1.3 million per quarter in legal fees related to the dispute, which started early last year. ▲



G-2 Insider

Is there room for more consolidation among the top 10 IVD vendors? "Yes," say two leading CEOs.

"There are some large companies that are not doing too well" and this could lead to some significant merger activity, **Jack Wareham**, chairman and CEO of **Beckman Coulter**, told investors at the recent UBS Warburg Global Life Sciences Conference (*see pp. 5-7*). Wareham noted Bayer's troubles and added that "J&J has a questionable franchise in terms of sustainability." Wareham did not mention whether Beckman might consider a major merger or acquisition, but did say his company continues to look for strategic acquisitions in the areas of life sciences research, nucleic acid testing and proteomics.

Similarly, **Jim Reid-Anderson**, president and CEO of **Dade Behring**, told the UBS Warburg crowd, "In the coming 12 to 18 months, there will be tremendous opportunities for consolidation in this industry and we believe we need to be involved....There are several competitors that are hurting and may pop in the next year or two." In the meantime, Reid-Anderson says Dade will continue to focus on its day-to-day operations.

These comments fly in the face of the conventional wisdom among most IVD analysts who believe that significant product overlap will prevent consolidation among the largest IVD companies. Time will tell who's right and who's wrong.

Note: *Diagnostic Testing & Technology Report* welcomes subscriber comments and opinions. You can contact us at labreporter@aol.com. 🏠

Company References

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