Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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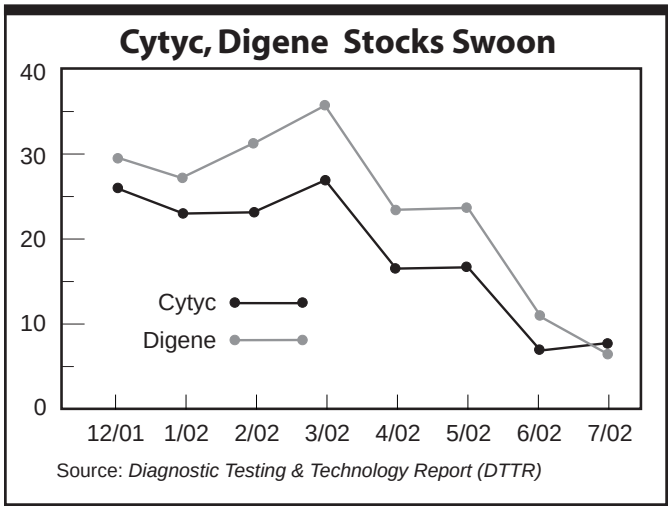
WASHINGTON G-2 REPORTS

Established 1979

Cytyc, Digene Dive On Terminated Merger

The Federal Trade Commission's decision to oppose the merger of Cytyc Corp. and Digene Corp. on anti-competitive grounds—plus news that Roche Diagnostics (Basel, Switzerland) is working to develop a human papillomavirus (HPV) test—have caused investors to flee Cytyc and Digene stocks. Since plans for the ill-fated merger were announced in mid-February, shares of Cytyc ((Boxborough, MA) have plunged 64% to $8.32 per share, wiping out nearly $2 billion of market value. Shares of Digene (Gaithersburg, MD) have plummeted by more than 75% to $7.30, erasing some $400 million of market value.

Some Wall Street analysts speculate that the depressed stock market valuations for each company may attract buyout offers from the likes of Johnson & Johnson, Abbott Laboratories or even Roche.



Meanwhile, TriPath Imaging (Burlington, NC) continues to fly under the radar screen of most investors with a share price of $2.74, or $103 million, down 64% so far this year. For more on the outlook for the cervical cancer testing market, see *Inside The Diagnostics Industry*, pp. 5-7.

Igen Hires Goldman As Roche Spat Heats Up

In an apparent effort to increase pressure on Roche Diagnostics to settle a legal dispute, Igen International Inc. (Gaithersburg, MD) has hired Goldman Sachs to help it find alternative business partners for its "Origen" technology for immunoassays. Earlier this year, a Maryland district court judge confirmed a jury verdict that Roche had breached its licensing agreement and ordered it to pay Igen $505 million in damages (*DTTR, March '02,*

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A final decision regarding the Igen-Roche litigation is expected from the U.S. Court of Appeals for the Fourth Circuit by mid-2003

p. 3). The ruling also allows Igen to terminate its licensing agreement with Roche, which is appealing the decision. In the meantime, the two companies have been trying to negotiate a settlement, but it's been rocky.

The latest flare-up between Igen and Roche was sparked by a July 9 Igen press release in which Sam Wohlstadter, Igen's chairman and CEO, said, "We have made progress in bridging our differences with Roche on several important issues, and we are growing increasingly confident that we will be able to bring this to a satisfactory conclusion….This appears to be an opportune time for the parties to resolve this litigation as it will set the stage for Roche's successful commercialization of its Modular system during the American Association for Clinical Chemistry meeting later this month." Roche's Modular system integrates the Elecsys E170, which is based on Igen's Origen technology, with Roche's Modular automation.

Evidently, Roche interpreted the press release as an attempt to pressure it into an agreement. Roche said the release may have violated a confidentiality agreement the two companies had signed prior to beginning settlement negotiations. In addition, Roche spokesman Daniel Piller said the two sides are still far from an agreement.

Following Roche's statements, Igen announced it had hired Goldman Sachs to help it evaluate a "potential settlement with Roche and also pursue competitive and complimentary business arrangements with multiple third parties."

Igen At A Glance *($000)*

	Three months ended	
	3/31/02	***3/31/01***
Total revenue	$13,969	$8,718
Operating loss	-4,117	-11,929
Net loss	-9,502	-13,720
Cash holdings	74,819	15,089
Long-term debt	51,397	56,821

Source: Igen

Some analysts have speculated that Igen might be a takeover candidate for either Roche or another major diagnostic or pharmaceutical firm. At its current share price of $30.71, Igen has a market capitalization of approximately $681 million. However, Roche says it is not considering acquiring Igen.

Separately, Igen has reported a net loss of $9.502 million in the three months ended March 31, 2002 vs. a net loss of $13.72 million in the same period a year earlier; revenue increased 60% to $13.969 million. Igen says the net loss for the March 2002 quarter included $2.481 million in legal expenses; revenue was up due to increased licensing fees from Roche.

Novartis Chairman Sparks Roche Merger Speculation

Comments by Daniel Vasella, chairman of Novartis (Basel, Switzerland) to German magazine *WirtschaftsWoche* have revived speculation that Novartis may seek a takeover of Roche Holding (Basel, Switzerland). Talk of a combination initially was sparked last year when Novartis acquired a 21% voting stake in Roche. "Roche and Novartis together would be a great company without a doubt," Vasella was quoted as saying. "There are lots of synergies….But Mr. Humer, Roche's chief executive, has unfortunately declared that he does not welcome such a combining of forces." Vasella added that Novartis was prepared to wait "years" for Roche to change its mind.

Gen-Probe Spin-Off Approved By Chugai Shareholders

Gen-Probe Inc. (San Diego, CA) reports that shareholders of its parent company, Chugai Pharmaceutical Co. (Tokyo, Japan), approved the spin-off of Gen-Probe at Chugai's annual shareholder meeting on June 27. The spin-off is planned for September 2002, in connection with Roche Holding's acquisition of Chugai (*DTTR, Jan. '02, p. 1*).

Gen-Probe is being launched as a separate company to avoid potential antitrust concerns. Gen-Probe makes molecular diagnostics for clinical laboratories and blood screening centers that compete with Roche's PCR (polymerase chain reaction) technology business. To accomplish the spin-off, Chugai will distribute its total shareholdings in Gen-Probe to Chugai shareholders. Gen-Probe will then trade as an independent company on the Nasdaq. The transaction will not involve an initial public offering or the raising of any new funds.

In the three months ended March 31, 2002, Gen-Probe reported net income of $3.084 million vs. a net loss of $620,000 in the same period a year earlier; revenue was up 9% to $33.783 million.

Abbott Diagnostics' 2nd-Quarter Sales Edge Up 1.9%

Abbott Laboratories (Abbott Park, IL) reports that its worldwide diagnostics sales increased 1.9% to $735 million in the second quarter ended June 30, 2002. Its U.S. diagnostics sales fell 1.3% to $295 million; international sales were up 4.1% to $440 million. Second-quarter revenue growth at Abbott's diagnostics division was led by the MediSense glucose monitoring unit whose worldwide revenue increased 18% to $125 million.

Abbott Diagnostics 2Q02 Revenue Summary *($MM)*

	2Q02	*2Q01*	*% Chg*
Worldwide Diagnostics Sales	$735	$721	+1.9%
U.S.	295	299	-1.3%
International	440	422	+4.1%
Worldwide MediSense Sales	125	106	+17.9%
U.S.	51	40	+27.0%
International	74	66	+12.2%

Source: Abbott Laboratories

Company-wide, Abbott reported second-quarter 2002 net income of $592.265 million vs. $529.048 million in the same period a year earlier; revenue increased 5% to $4.315 billion. Net income was hurt by a $129 million pretax charge related to the recent decision by the U.S. Food & Drug Administration that Abbott's immunoassay diagnostics operations at its Lake County, Illinois facilities still fail to comply with FDA's quality system regulations. Abbott says it will take another $11 million charge related to FDA's decision in the second half of 2002.

During a July 11 conference call, John Thomas, division vice president for investor relations, said Abbott is in the process of selecting a third-party consultant to help it review findings from FDA's recent inspections of the Lake County facilities. Abbott had previously used Quintiles Consulting (Durham, NC).Thomas also noted that implementation of Abbott's recently announced five-year contract with the American Red Cross (*DTTR, May '02, p. 4*) will be delayed until Abbott receives clearance for its Prism blood banking system, which is contingent upon resolution of the Lake County facility problems with FDA.

Abbott Forms Alliance With Celera Diagnostics

Abbott Laboratories (Abbott Park, IL) has formed a strategic alliance with Celera Diagnostics (Alameda, CA) to develop, manufacture and market molecular tests. A joint review board, composed of three executives from each company, will manage the alliance.

Under the agreement, Celera Diagnostics—itself a 50/50 joint venture between Applied Biosystems Group (Foster City, CA) and Celera Genomics Group (Rockville, MD)—will focus primarily on genetic marker discovery and validation. Abbott will focus on product development, sales and marketing—serving as the worldwide distributor for most products developed by the alliance.

Under terms of the agreement, Abbott and Celera Diagnostics will share expenditures and profits from research, development, manufacture and marketing of any new molecular tests. The companies say they will make all relevant technologies and patents available to the alliance. Approximately 250 scientists and engineers from the two companies will initially be dedicated to the effort.

Current products of Celera Diagnostics—the ViroSeq system for genotyping the HIV virus, cystic fibrosis analyte-specific reagents, and reagents for HLA testing for tissue and organ transplantation—will become part of the alliance and will begin to be sold by Abbott's sales force on Oct. 1 of this year. Sales for these products in the 12 months ended June 30, 2002 were about $10.5 million and are growing rapidly, according to Kathy Ordonez, president of Celera Diagnostics.

Revenue generated through sales of Abbott's virology products—LCx viral load tests for HIV and hepatitis—became part of the alliance this July 1. Other Abbott tests, including their market-leading LCx assays for sexually transmitted disease, will become part of the alliance on July 1, 2003. The alliance will not include Abbott products acquired through its recent purchase of Vysis.

Nanogen Licenses Bio-Rad's Genes For Iron Overload Disease

Bio-Rad Laboratories (Hercules, CA) has granted Nanogen Inc. (San Diego, CA) a non-exclusive license to the C282Y and H63D mutations of the hereditary hemochromatosis HFE gene for use on Nanogen's NanoChip molecular testing system. Bio-Rad purchased patents to the HFE gene and its mutations in 1999 from now-defunct Progenitor Inc.

Hereditary hemochromatosis (HH) is a disorder that results in excessive iron build-up in tissues and major organs of the body. HH, or iron overload, affects more than one million Americans, according to the American Hemochromatosis Society (Lake Mary, FL). However, only about 2% of those with iron overload are ever diagnosed due to vague symptoms and lack of awareness.

Historically, most cases remain undiagnosed until late in the course of the disease after irreversible damage has occurred. Once diagnosed, HH can be treated by phlebotomy in order to lower the level of iron.

What's Next For Cytyc, Digene Now That The Marriage is Off?

An estimated 55 million Pap tests are performed in the U.S. each year

The planned merger of Cytyc Corp. and Digene Corp. had promised to fill gaps in the business operations of each company. For Cytyc, the addition of Digene would have broadened its limited product portfolio and boosted top-line growth. "Cytyc has always been more of a sales and marketing organization than a scientific one," observes Gary Gill, senior science advisor at Diagnostic Cytology Laboratories Inc. (Indianapolis, IN). Digene would have gained deeper access to Cytyc's sales staff, he adds. Cytyc employs more than 100 salespeople; Digene employs only 20 in the U.S. and another 10 in Europe.

Approximately 4,100 women in the U.S. will die from cervical cancer this year, estimates the American Cancer Society

But on June 24, the U.S. Federal Trade Commission announced it had voted 5-0 to authorize its staff to seek a preliminary injunction to block the merger. According to the FTC, the Cytyc-Digene combination would lead to reduced competition and higher consumer prices, both now and in the future, within the highly concentrated market for primary cervical cancer screening tests. Cytyc's ThinPrep product accounts for 93% of all liquid-based Pap tests in the U.S., the Commission noted. The only other company now producing and selling an FDA-approved liquid-based Pap test is TriPath Imaging.

By purchasing Digene, the FTC contended, Cytyc would be in a position to eliminate its sole competitor (TriPath) by limiting access to Digene's test for human papillomavirus (HPV). Similarly, Cytyc could thwart entry to the market by other firms that have planned to start selling liquid-based Pap tests in the U.S.

The Commission further alleged that, absent the acquisition, Cytyc faces future competition from Digene's HPV test in its own right. While Digene's HPV test is currently FDA-approved for use only as a follow-up to equivocal Pap test results, the role of HPV testing is rapidly expanding into the much larger arena of primary screening, the FTC noted.

Faced with FTC opposition, Digene announced on July 1 that it had terminated its plans to be acquired by Cytyc. For both companies, it means that six months of planning and millions of dollars in legal and investment advisor fees have gone down the drain. The termination also has raised competitors' hopes that they can break into cervical cancer and HPV testing markets with their new products. Below are updates on Cytyc, Digene and other key players.

Cytyc has no interest in being taken over, its chairman and CEO, Patrick Sullivan, tells *DTTR*. "There are no discussions underway. And no one has approached the company." In terms of the FTC decision, he says, "I really believe they came to the wrong conclusion. [They] said that thin-layer testing and HPV testing are competing technologies, but I'll argue that they are compatible."

Contrary to the FTC's conclusion, Sullivan contends that "HPV testing won't replace the Pap test as the primary method for cervical cancer screening in the

U.S. for at least 10 to 20 years, if ever at all." HPV testing is not appropriate as a screening tool for women under age 35, he says, because of too many false positives. Using it as a follow-up to, or in conjunction with, Pap testing makes the most sense, in his view. Had the merger been allowed to proceed, Cytyc would not have prevented competing firms from gaining access to Digene's HPV test, he adds.

On top of the negative news from the FTC, Cytyc recently announced that its U.S. customers had built up excess inventory for ThinPrep Pap tests, totaling roughly $50 million as of March 31, 2002. This equates to roughly 90 days of demand. Based on a one-month inventory goal, Cytyc estimates that inventory at its customers needs to be worked down by $35 million.

Moreover, sales have been slower than anticipated for Cytyc's new ductal lavage product, FirstCyte, to evaluate the risk of breast cancer. The company added the product through its recent acquisition of Pro-Duct Health (Menlo Park, CA). Cytyc had hoped to generate $9-$15 million in revenue this year from ductal lavage. Sullivan now expects significantly lower revenue because physicians have been slow to adopt the new technology.

Because of ThinPrep inventory problems and reduced expectations for ductal lavage, Cytyc has lowered its revenue forecast for 2002 to $230-$245 million from $300 million. In 2001, the company reported revenue of $219 million.

Despite the setbacks, Sullivan sees plenty of opportunities for Cytyc to get back on the growth track. The company has an estimated 50+% share of the overall U.S. Pap testing market, and he anticipates that thin-layer testing could reach more than 90% penetration over the next few years.

Pap Testing At The Largest U.S. Lab Companies

According to a *DTTR* survey of five of the largest U.S. clinical laboratories, the Cytyc ThinPrep commands an overall 64% market share for the 23 million Pap tests these labs perform annually. At the largest U.S. lab company, Quest Diagnostics (Teterboro, NJ), Cytyc has 70% penetration.

Company	*Annual Pap Volume*	*Thin-Layer Conversion*	*Primary Vendor*
Quest Diagnostics	10.8M	70%	Cytyc
LabCorp	8.0M	60%	Cytyc
AmeriPath	2.2M	60%	Cytyc
Unilab	1.5M	50%	Cytyc
Dianon	0.5M	60%	Cytyc
Total	23.0M	64%	

Note: Data as of March 31, 2002
Source: *DTTR* from companies

Sullivan also sees international growth opportunities. ThinPrep has about a 35% share of the roughly five million Pap tests performed in Australia, he notes. Cytyc also is working to introduce ThinPrep in Western Europe where an estimated 35 million Pap tests are performed annually. The company's greatest progress to date has been in Switzerland and the United Kingdom, he says.

Cytyc charges a list price of $11.25 per ThinPrep kit, with an estimated average selling price of $7-$9 per kit. The company, which has implemented regular pricing increases, has been criticized by many lab customers for its pricing policy. Sullivan counters that Cytyc's lobbying of Congress was instrumental in raising Medicare reimbursement for Pap testing from $7.15 (prior to Jan. 1, 2000) for traditional tests to $28 per test for thin-layer methods (effective Apr. 1, 2001). "His-

torically, labs had lost $2-$3 for every traditional Pap test they did. Today, they can earn $5-$10 per ThinPrep test," Sullivan says.

Digene says it must bolster its salesforce, given the expected termination of European distribution agreements with Roche Diagnostics and Abbott Laboratories. Roche has an agreement to market and distribute Digene's Hybrid Capture 2 HPV test in Europe, but this deal is winding down and will be terminated on Dec. 31, 2002, according to Evan Jones, Digene chairman and CEO. During a July 10 conference call, he observed that following Roche's June 6 announcement of plans to develop its own HPV test, it became apparent that "Roche did not have Digene's interest paramount for our products in Europe."

Digene is working to submit additional data to FDA to gain approval of combined HPV-Pap testing as a primary cervical cancer screen for women aged 30 and older

Digene must invest roughly $8-$10 million over the next 12 months to boost its sales force in Europe from 10 people to 50, according to Jones. In the U.S., Digene will continue to market its HPV test through its own 20-member salesforce, he said, plus the company has a co-promotion agreement with Cytyc for reflex HPV testing directly from the ThinPrep test vial.

For the fiscal year ended June 30, 2002, Jones anticipates that Digene will report a net loss of $9.5-$10 million and a revenue increase of about 42% to $48.5-$49 million. He had aimed for Digene to turn profitable at the end of fiscal 2002, but now looks for profitability in the second half of fiscal 2003.

Roche Diagnostics recently announced it had acquired, for an undisclosed sum, a broad portfolio of patents pertaining to HPV from the Institut Pasteur (Paris, France). Roche is expected to launch an HPV test in the European market sometime next year, putting it in direct competition with Digene. Roche also has eyed the potential for HPV molecular tests as the primary screen for cervical cancer detection, replacing the traditional Pap smear as well as thin-layer techniques. Given Roche's sheer size ($4.7 billion in annual diagnostic testing revenue and 16,345 employees in diagnostics), it has the potential to become a dominant force in the cervical cancer testing market. It should be noted too that Roche's pharmaceutical division recently announced an agreement with Stressgen Biotechnologies (Victoria, British Columbia, Canada) to co-develop a drug (HspE7) to treat diseases linked to HPV.

TriPath Imaging has struggled to gain market share against Cytyc with its SurePath Test for thin-layer testing, but despite significantly lower pricing, TriPath has been unable to make inroads yet. One major drawback is that the U.S. Food & DrugAdministration has yet to approve the SurePath Test pack as a sample collection medium for Digene's HPV test. Executives from TriPath were not available to be interviewed for this article.

Cervical Cancer/HPV Testing: Sizing Up The Competition *($MM)*

	Roche Diagnostics	Cytyc	Digene	TriPath
Annual revenue	$4,763.5	$272.1	$56.9	$30.3
Operating income	685.5	109.7	-14.2	-21.9
Net income	NA	70.4	-13.3	-21.2
Cash & securities	NA	178.3	45.0	47.9
Employees	16,345	554	193	200

Note: Data for Roche are from reported 2001 results and current exchange rates. Data for Cytyc, Digene and TriPath are based on annualized results for the three months ended March 31, 2002.
Source: *DTTR* from company reports

DAKO Acquires Cytomation In Stock Transaction

DAKO A/S (Copenhagen, Denmark), which specializes in cancer diagnostic reagents, has acquired Cytomation Inc. (Fort Collins, CO), which specializes in flow cytometry. The transaction was completed July 1 through the exchange of shares held by DAKO and Cytomation stockholders for shares in a new combined company—DakoCytomation. The merged company has 1,350 employees and roughly $175 million in annual revenue.

Niels Harboe, MD, who founded DAKO in 1966, will maintain a majority ownership in DakoCytomation with a 61% stake. Novo Nordisk (Novo Alle, Denmark), which had held a minority stake in DAKO, now owns 26% of DakoCytomation. The remaining 13% interest is held by other management and investors from DAKO and Cytomation.

Jes Ostergaard, president and CEO of DAKO, will remain as head of the combined company. Nigel Ferrey, president and CEO of Cytomation, is now president of DakoCytomation's U.S. operations and has joined the corporate management group. The merged company remains privately held, but Ostergaard has announced his intention to seek an initial public offering in 2003.

Founded in 1988, Cytomation designs and manufactures MoFlo cytometers and high-speed cell sorters. Originally developed to sort chromosomes for the Human Genome Project, Cytomation's instruments are now installed at 250 sites worldwide for drug discovery, cancer and HIV research, stem cell and gene therapy, livestock sex selection and DNA diagnostics. In calendar year 2001, the company increased its revenue by 35% to an estimated $25-$30 million. Cytomation employs 150 people and has sales and service offices in the U.S., Germany and Australia.

DAKO At A Glance *(in Danish kroner, 000)*

	For fiscal years ended June 30		
	1999	***2000***	***2001***
Revenue	721,656	870,211	1,044,769
Oper. income	77,917	53,137	83,908
Net income	35,729	42,402	45,949
Employees	777	816	956

Source: DAKO

DAKO, which today employs 1,200 people, reported a net profit of 45.9 million Danish kroner (US $6.1 million) in the 12 months ended June 30, 2001 vs. 42.4 million kroner (US $5.7 million) in the prior year; revenue increased 20% to 1.045 billion (US $139 million). Key products include the DAKO HercepTest, which helps physicians determine appropriate drug therapies for breast cancer patients.

IMI International Gets FDA Okay For Cholesterol Skin Test

The Cholesterol 1,2,3 test, made by IMI International Medical Innovations (Toronto, Ontario, Canada), has been cleared for sale by the U.S. Food & Drug Administration. The test uses a Band-Aid-like applicator pad to check the amount of cholesterol in skin on the palm of the hand. Andrew Weir, spokesman for IMI, says the test will be sold for use in physician offices. The test is not subject to CLIA regulations because no specimen is involved. Anticipated cost per test is $10-$15, according to Weir. He says the test is not meant to replace standard blood cholesterol tests, but can be used with them to help identify patients with severe heart disease.

Ortho-Clinical's 2nd-Quarter Sales Up 6%, Lifescan Up 34%

Johnson & Johnson (New Brunswick, NJ) reports that worldwide sales at its Ortho-Clinical Diagnostics division increased 6% to $269 million in the second quarter ended June 30, 2002; worldwide sales at Lifescan were up 34% to $353 million.

Diagnostics Revenue At J&J *($MM)*

	2Q02	2Q01	% Chg
Lifescan			
U.S.	$236	$180	31%
International	117	84	39%
Worldwide	353	264	34%
Ortho-Clinical Diagnostics			
U.S.	138	132	4%
International	131	122	8%
Worldwide	269	253	6%

Source: J&J

J&J said sales at Lifescan were bolstered by the acquisition of Inverness' glucose unit last year, which added 7% to Lifescan's year-over-year sales growth. Lifescan also noted the recent launch of the InDuo system, a combined blood glucose monitoring and insulin pen dosing system jointly developed with Novo Nordisk (Novo Alle, Denmark).

Company-wide, J&J reported second-quarter net income of $1.654 billion vs. $1.482 billion in the comparable prior-year period; revenue was up 11% to $9.073 billion.

SYNX Pharma Gets U.S. Patent For Heart Failure Test

SYNX Pharma Inc. (Mississauga, Ontario, Canada) has received a U.S. patent for a diagnostic test that can determine congestive heart failure (CHF) within 15 minutes. The test also can be used to screen patients with diseases such as diabetes, hypertension, coronary and renal failure that put them at greater risk for heart failure, the company said in a press release.

The CHF test is unique, SYNX claims, in that it combines two unknown methods for diagnosing CHF that predict patient outcome. The test combines a marker for myocardial cell injury and a marker for left ventricular overload. Combining the indicators, SYNX says, provides more accurate patient prognosis, reduces costs for hospitalization and also could cut costs for pharmaceutical companies that could use the test in clinical trials to identify early warning signs of drugs that may cause heart failure.

SYNX also is developing tests for Alzheimer's disease and stroke. Product launches in Europe are scheduled to begin within the next 12 months and in the U.S. by the end of 2004. In the three months ended March 31, 2002, SYNX reported a net loss of $2.106 million (Canadian $$) vs. a net loss of $1.78 million in the same period a year earlier; revenue totaled $849,000 vs. $365,000.

Wolfgang Hartwig To Be New Head Of Bayer Diagnostics

Bayer Group (Leverkusen, Germany) says Wolfgang Hartwig, PhD, will become head of Bayer Diagnostics on Jan. 1, 2003. Hartwig, who has been with Bayer since 1982, was most recently global head of pharmaceutical research at Bayer's Pharmaceuticals Business Group. He succeeds Rolf Classon, who will become head of strategy and business development at Bayer Healthcare.

Bio-Rad Buys Virtek's Microarray Instrument Business

Bio-Rad Laboratories (Hercules, CA) has acquired the microarray instrument business of Virtek Vision International Inc. (Waterloo, Ontario, Canada). Sales for this Virtek Vision subsidiary were approximately $5.5 million for the fiscal year ended Jan. 31, 2002. Bio-Rad paid about $7 million to acquire the assets.

Products acquired by Bio-Rad include the Virtek ChipReader high-sensitivity microarray scanner, the Virtek ChipWriter Pro high-throughput microarray spotter, the Virtek ChipWriter Compact bench-top microarrayer and the Virtek Colony Arraying and Picking System. In conjunction with the deal, Bio-Rad has acquired space in Virtek's operations facility in Waterloo to establish a new microarray and automation business unit. Bio-Rad also has hired the related Virtek employees to further develop and produce the instruments.

"We are very excited about this acquisition," says Norman Schwartz, Bio-Rad vice president and group manager of life science. "The instruments are a natural extension of our DNA- and proteome-based product lines, and we believe they will soon be standard tools in the DNA and proteome research laboratory."

Trinity Biotech To Acquire Sigma's Coagulation Unit

Trinity Biotech (Dublin, Ireland) has signed a letter of intent with Sigma-Aldrich (St. Louis, MO) to purchase the coagulation division of Sigma Diagnostics. The all-cash deal is expected to close by Sept. 30; the purchase price was not disclosed. Sigma says its coagulation business generated roughly $16 million in revenue last year and was unprofitable.

The Sigma Diagnostics coagulation business comprises more than 50 routine and specialty coagulation tests manufactured in St. Louis and the Amelung range of automated and semi-automated instruments made in Lemgo, Germany. The Amelung range of instruments has a worldwide installed base of 800 instruments and includes the smaller KC1 and KC4 products, the mid-size Amax 200 and the large throughput Amax 400. In addition, a new coagulation analyzer, the Destiny, is scheduled to be launched shortly, according to Trinity.

Trinity initially entered the coagulation business when it acquired the Biopool hemostasis division of Xtrana Inc. (Broomfield, CO) in December 2001 for $6.25 million. Trinity estimates that annual revenue from its coagulation business will now total approximately $19 million, including $11 million from the Sigma Diagnostics products and $8 million from the Biopool products.

Trinity at a Glance *($000)*

	1Q02	*1Q01*	*% Chg*
Revenue	$11,414	$8,299	+38
Oper. income	1,549	1,160	+34
Net income	1,231	984	+25
Cash holdings	6,206	3,843	+61
Long-term debt	20,528	2,170	+846

Source: Trinity Biotech

Separately, Trinity reported net income of $1.231 million for the three months ended March 31, 2002 vs. net income of $984,000 for the same period a year earlier; revenue was up 38% to $11.414 million.

IVD Stocks Drop 15% In Latest Four Weeks

Roche non-voting equity shares, which trade on the Zurich stock exchange, are down 3% year-to-date to 115 Swiss francs. Shares of Bayer, which trade on the German stock exchanges, are down 14% year-to-date at 30.77 euros per share

The 21 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 15% in the four weeks ended July 12, 2002, with 18 stocks moving down in price and only three rising. Year-to-date, the G-2 Index has fallen 29%, compared with a 20% decline for the S&P 500 and a 30% drop for the Nasdaq.

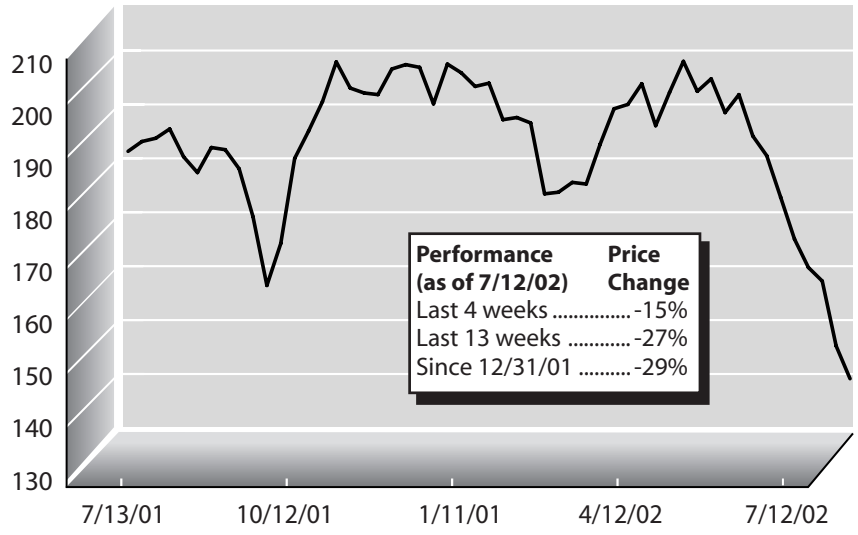
Digene (Gaithersburg, MD) fell by 53% to $7.30 per share for a market capitalization of $129 million. Digene shares have been hurt by a failed merger attempt with **Cytyc Corp.** (Boxborough, MA) and news that Roche Diagnostics is developing a competing test for human papillomavirus (HPV). Cytyc was off 25% to $8.32 per share for a market cap of $1 billion. (*For more on Cytyc and Digene, see pp. 1, 5-7.*)

Shares of **Cholestech** (Hayward, CA) dropped 44% to $9.72 per share, lowering the company's market cap to $140 million. **i-Stat Corp.** (East Windsor, NJ) fell 37% to $2.91 per share for a market cap of $58 million. **TheraSense** (Alameda, CA) was down 27% to $15.19 per share for a market cap of about $600 million.

Immucor (Norcross, GA) rose 26% in the four-week period to $23.08 per share for a market cap of $169 million. The company reported a net profit of $2.801 million for the three months ended May 31, 2002 vs. a net loss of $1.388 million for the same period a year earlier; revenue was up 26% to $23.461 million.

Other gainers included **Careside** (Culver City, CA), which inched up 13% to $0.09 per share for a market cap of $2 million, and **Cygnus** (Redwood City, CA), up 8% to $2.25 per share for a market cap of $86 million.

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 7/12/02

	Price ($)	% Chg
UP		
Careside	0.09	+13
Cygnus	2.25	+8
Immucor	23.08	+26
DOWN		
Abbott Labs	33.15	-10
Beckman Coulter	44.56	-9
Becton Dickinson	29.93	-14
Bio-Rad	38.98	-20
Biosite	20.65	-18
Cholestech	9.72	-44
Cytyc	8.32	-25
Diagnostic Products	34.48	-23
Diametrics	3.00	-26
Digene	7.30	-53
Igen	30.89	-13
Inverness Medical	16.23	-7
i-Stat	2.91	-37
Johnson & Johnson	50.50	-11
Meridian	5.81	-9
Quidel	5.46	-12
TheraSense	15.19	-27
Ventana	19.05	-8

G-2 Insider

Will HPV testing replace the Pap test as the standard of care for cervical cancer screening in the U.S.? Maybe, but it could take 5-10 years and by that time a vaccine for human papillomavirus (HPV) may have been developed, says Gary Gill, senior science advisor at Diagnostic Cytology Laboratories in Indianapolis, IN.

Though HPV is the cause of virtually all cervical cancer cases, Gill believes that physicians, laboratories and patients may be reluctant to use it as a primary screening tool. Doctors and labs have been using the Pap test for more than 50 years, he points out, and changing practice patterns could prove to be difficult. Gill also thinks HPV testing could encounter resistance from patients who might be apprehensive about being tested for a sexually transmitted disease.

For a revealing look at the hurdles to introducing a new testing technology, consider Cytyc's FirstCyte Ductal Lavage procedure. Cytyc acquired the technology through its $184 million purchase of Pro-Duct Health (Menlo Park, CA) last November. The ductal lavage procedure takes about 30 minutes in a physician's office and uses a proprietary hair-thin catheter developed by Pro-Duct to collect cells from the lining of breast milk ducts. Specimens are sent to a lab for analysis to help determine a woman's predisposition for developing breast cancer.

Cytyc began marketing FirstCyte this year and had hoped to generate $9-$15 million this year in revenue from the product. But expectations have been scaled down because physicians have been slow to adopt it.

Company References

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Celera Diagnostics
510-749-4200
Cytomation
970-226-2200
Cytyc Corp.
978-263-8000
DAKO
45-44-85-95-00
Diagnostic Cytology Labs
317-876-7680
Digene
301-944-7000
Gen-Probe
858-410-8000
Igen
301-869-9800
IMI International
416-222-3449
Johnson & Johnson
732-524-0400
Nanogen
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