Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

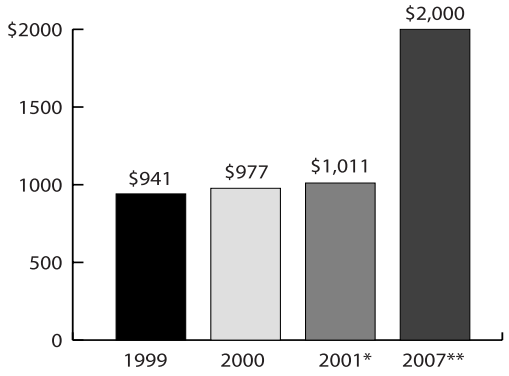
Ortho-Clinical Seeks To Double Sales By 2007

Ortho-Clinical Diagnostics (OCD—Raritan, NJ), a unit of Johnson & Johnson (New Brunswick, NJ), aims to double its revenue to $2 billion by 2007, according to Gerrard Vaillant, company group chairman/diagnostics worldwide.

To reach this ambitious goal, OCD will need to grow its revenue by a double-digit annual growth rate over the next six years—a sharp acceleration compared with the 3.5% growth rate (or 7.8% excluding foreign exchange) that the unit is on track to record this year. Anticipated drivers of this expansion include the company's new Vitros Fusion system and new cellular and molecular diagnostics.

Valliant and Catherine Burzik, president of OCD, detailed their plans for growth at a recent analysts' meeting in New York City. For an outline of their presentations, see *Inside The Diagnostics Industry*, pp. 5-7.

OCD Revenue *($MM)*



*Projected from reported first-half 2001 results
**OCD management's goal
Source: *Diagnostic Testing & Technology Report* from OCD

Carter-Wallace Executives Lining Pockets At Expense Of Shareholders, Says Gabelli

Fund manager Mario Gabelli says shareholders are being shortchanged under the planned $1.1 billion sale of pharmaceuticals, diagnostics, and OTC products company Carter-Wallace (New York City; see *DTTR, June '01, p. 10*). At the same time, Gabelli says that completion of the transaction, which at press time is on track to close by the end of September, will result in a windfall to Carter-Wallace's top executives. Documents filed with the Securities & Exchange Commission (SEC) show that Ralph Levine, chairman and chief executive of Carter-Wallace, will get more than $28 million in lump-sum cash payments if the deal closes, including $8.775 million from severance, $11.391 million from the cash out of his pension plan, and $5.126 million from the cash out of stock options and deferred stock awards.

Continued on p. 2

▲ **Carter-Wallace Executives,** *from page 1*

Paul Veteri, president and chief operations officer of Carter-Wallace, stands to gain a lump sum cash payment of $18.628 million from severance, pension, stock option and deferred stock cash outs.

In a letter to Carter-Wallace shareholders dated Sept. 7, Gabelli stated that he would vote against the proposed transaction at Carter-Wallace's upcoming special meeting of shareholders on Sept. 20. According to a recent SEC filing, Gabelli Asset Management (Rye, NY) and its clients own 9.1 million Carter-Wallace shares, or 20% of the total outstanding.

CPI Development Corp., a private holding company that owns 23.508 million shares of Carter-Wallace for a 51% stake, has declared it will vote in favor of the planned sale. The directors of CPI are Henry Hoyt Jr., Richard Cruess, MD, and Suzanne Garcia—all three also sit on the board of Carter-Wallace

Gabelli asserted in the letter: "We believe that the management of Carter-Wallace, Inc. is selling the company out from under the shareholders at a price that is substantially below its intrinsic value. To add insult to injury, the proposed sale incurs as much as $160 million in unnecessary taxes that directly reduce the proceeds available for the shareholders. We believe that management focused more on their excessive 'Platinum Parachutes' than maximizing shareholder value."

In May, Carter-Wallace announced an agreement to sell its consumer products business to Armkel LLC, a partnership of consumer goods company Church & Dwight Co. (Princeton, NJ) and the private investment firm Kelso & Co. (New York City). Carter-Wallace's consumer business includes Trojan condoms, Arrid deodorant, and Nair hair remover as well as the First Response brand of at-home pregnancy and ovulation test kits.

Under a separate agreement, Carter-Wallace will sell its healthcare business to MedPointe Capital Partners (Short Hills, NJ). MedPointe is a new specialty healthcare business being formed by former executives of Warner-Lambert and Becton Dickinson, with financial backing from the investment firms of Carlyle Group and the Cypress Group, both in New York City. Carter-Wallace's healthcare business includes diagnostic unit Wampole Laboratories (Cranbury, NJ) and pharmaceuticals unit Wallace Laboratories (also in Cranbury). Wampole makes enzyme and fluorescent immunoassay tests to detect infectious and autoimmune diseases. The company also makes the Clearview product line of rapid tests for determination of pregnancy, group A strep, chlamydia, and C. difficile.

The aggregate consideration from both transactions to be paid to Carter-Wallace shareholders is approximately $1.121 billion, less $160 million in corporate taxes to be paid on the sale of the consumer products business and the cost of cashing out executive stock options. This will leave shareholders with approximately $928 million, or $20.30 per share. This is 31% below Carter-Wallace's stock price of $29.50 per share at year-end 2000.

Earlier this year, Gabelli had suggested that Carter-Wallace split into two publicly traded companies and begin an aggressive share repurchase program, but the board struck down his proposal.

In the fiscal year ended March 31, 2001, Carter-Wallace reported company-wide net income of $40.949 million (up 3% from the previous year) on revenue of $781.392 million (up 5%).

ABX Planning Major U.S. Expansion

Jim Mulry, director of marketing for ABX Inc. (Irvine, CA) tells *DTTR* that ABX is preparing for a major marketing effort in the U.S. As part of the effort, ABX has signed a distribution agreement with Fisher HealthCare, a division of Fisher Scientific Inc. (Hampton, NH). Under the agreement, ABX has given Fisher exclusive rights to sell ABX's hematology analyzers to all hospital laboratories and clinical laboratories servicing more than 25 physicians in the U.S. The agreement became effective July 26, 2001 and is non-exclusive in the primary care market.

In addition, Mulry says ABX will double its U.S. sales force to 16 people by year's end. ABX currently employs a total of 85 people and generates about $18 million in annual revenue in the U.S., out of a worldwide total of more than 600 employees and about $80 million in annual revenue. Mulry says ABX will begin to market diagnostic products made by its parent company, Horiba Ltd. (Kyoto, Japan). The first such product is expected to be Horiba's LT-120 bedside analyzer, which measures C-reactive protein from whole blood. Horiba/ABX is waiting for U.S. Food & Drug Administration 510k clearance for LT-120 and expects to begin marketing the product in the U.S. in early 2002, according to Mulry. Other Horiba products likely to be introduced in the U.S. include blood glucose meters.

In July 2001, Horiba dismissed Jean-Edouard Robert as managing director of ABX Diagnostics in Montpelier, France (*DTTR, Sept. '01, p. 1*). Mulry says the dismissal resulted from differences in opinion over strategy in the U.S. market. Robert had wanted ABX to market in the U.S. using primarily an OEM (Original Equipment Manufacturer) strategy. Horiba wanted ABX to introduce Horiba-made products in the U.S.

Avocet Medical Goes Out Of Business

Avocet Medical Inc. (San Jose, CA) ceased operations effective July 27. The company had received FDA clearance to market its AvoSure PT System for prothrombin time (PT) testing in professional office use in late 1998 and for at-home self-testing with a physician's prescription in late 1999.

The AvoSure PT was aimed at the 2.5 million people in the U.S. (four million worldwide) on long-term oral anticoagulation medicine (*i.e.*, Coumadin). Patients on Coumadin are advised to monitor their dosage with a PT blood test once per week. This frequency of testing helps physicians maintain appropriate dosage levels and reduce the risk of stroke. But the testing requires patients to travel to a physician office or laboratory to have blood drawn.

Avocet's AvoSure PT System had promised more convenience to patients on Coumadin. The hand-held instrument required only a single drop of blood from a fingerstick and had been marketed for a list price of approximately $750 per device. However, sales of the instrument and its disposable strips never took off, in part because national Medicare coverage has not been established for home-use PT tests.

Given Imaging Seeks $60+ Million From IPO

Given Imaging Ltd. (Yoqneam, Israel) has registered with the Securities & Exchange Commission to raise $60-$70 million from the sale of five million shares priced at $12 to $14 per share. Lehman Brothers is acting as lead manager for the offering. Assuming its completion at a share price of $13, Given would have a total of 25.1 million shares outstanding and a stock market capitalization of $326 million.

The company has developed the Given System, a wireless imaging system for visual examination of the gastrointestinal tract. The system uses a miniaturized video camera contained in a capsule that is about the same size as a lima bean. The capsule is swallowed by the patient and delivers high-quality color images in a painless and non-invasive manner to a portable data recorder (about the size of a Sony Walkman) worn on the patient's hip.

During a typical seven-hour test, the capsule transmits 50,000 images to the data recorder as the patient continues normal daily activities. The patient returns the recorder at his or her convenience to the physician who uses a computer workstation with proprietary software to process the images into a high-quality video for review. In August 2001, the company received FDA clearance for the system for adjunctive use in the detection of abnormalities of the small intestine.

The sales price of the computer workstation is $14,500; the portable data recorder sells for $5,450; and each disposable capsule sells for $450.

In the six months ended June 30, 2001, Given reported a net loss of $7.394 million vs. a net loss of $2.574 million in the same period a year ago. The company has not generated any revenue to date. Proceeds from the IPO will be used to expand the company's sales force, to purchase inventories, and for operating expenses. Since inception in January 1998, Given has incurred $19.453 million in net losses.

Signature BioScience Raises $43 Million

Privately held Signature BioScience (San Francisco, CA) has raised $43 million from a group of venture funds led by SG Capital Partners and including Vulcan Ventures Inc., MDS Capital Corp., China Development Industrial Bank, and Lehman Brothers Holdings Inc. The company has now raised a total of more than $64 million since its inception in late 1998, according to Mark McDade, chief executive of Signature.

Signature's multipole coupling spectroscopy (MCS) technology uses microwave and radio frequencies to measure the interaction of drugs and cells and proteins. Unlike current assays, MCS does not employ tags or markers (such as fluorescent dyes or radiolabels) and may be performed in virtually any range of environments, from simple aqueous solutions to whole cells.

The company currently provides fee-based services to pharmaceutical companies searching for lead compounds. In addition, Signature says it is in partnership discussions to incorporate its MCS technology into a benchtop research instrument.

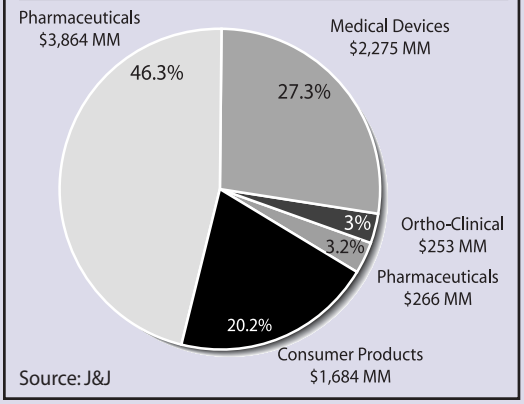
Ortho-Clinical Details Plans To Outpace Industry Growth

Gerrard Valliant
Ortho-Clinical Diagnostics Company Group Chairman, Diagnostics Worldwide

The outlook for growth in the IVD industry has improved and Ortho-Clinical Diagnostics (OCD, a Johnson & Johnson unit based in Raritan, NJ) plans to take full advantage of new market opportunities, Gerrard Valliant, company group chairman, told analysts at J&J's Medical Devices & Diagnostics Business Review meeting in New York City on Sept. 5. Valliant expects the $20 billion worldwide IVD market to grow by 4-6% over the next five years, and he is planning for OCD to grow at roughly double that rate.

Valliant said laboratory staffing shortages and decreasing skill levels are driving the need for instruments that are easier to use and that are better integrated with information systems. He also believes there are increasing opportunities to develop new diagnostic tests for use in selecting and managing drug therapies. Until recently, diagnostics were used primarily to confirm a physician's diagnosis. Today, however, diagnostics are increasingly being used to determine therapies and triage, according to Valliant. As a result, he believes IVD companies are gaining more leverage to raise prices.

J&J's Revenue, 2Q01



Source: J&J

In the three months ended June 30, 2001, OCD reported a 1% increase in revenue to $253 million—representing 3% of J&J's company-wide revenue of $8.342 billion. Valliant is seeking to double OCD's annual revenue to $2 billion by 2007. Outlined below are the five growth areas that Valliant and Catherine Burzik, president of OCD, have targeted.

Vitros Fusion Series

OCD is developing a new series of diagnostic instruments under the brand Vitros Fusion. The first is the Vitros 5,1 FS System, which integrates special chemistry and general chemistry on a single platform. The system "fuses" OCD's current dry-slide technology with the company's new "MicroTip" technology. MicroTip enables special chemistry tests to be performed without plumbing, drains, or fixed probes. Consequently, the system will offer a menu of 90 chemistries, including tests for therapeutic drug monitoring, proteins, and drugs of abuse. The new system is designed to do 1.5 million tests per year, a 30% improvement over OCD's current systems. The Vitros 5,1 FS System, which was on demonstration in Chicago at the recent American Association for Clinical Chemistry annual meeting, is expected to be on the U.S. market in early 2003, according to Burzik.

New Hepatitis Tests On Vitros ECi Immunoassay System

Burzik announced that OCD received premarket approval from the U.S. Food & Drug Administration on Aug. 30 for hepatitis C (HCV) antibody testing using its Vitros ECi instrument. Earlier this year, the company received FDA approval for hepatitis B surface antigen (HBsAg) and anti-hepatitis B surface anti-

Catherine Burzik
President
Ortho-Clinical Diagnostics

gen (anti-HBs) assays. The Vitros ECi, launched in 1998, is an automated and continuous random access analyzer for immunoassay testing. Its menu in the U.S. now includes assays for more than 27 analytes. The Vitros ECi currently has more than 1,200 worldwide installations, according to Burzik. In addition, OCD recently announced that Tenet Healthcare (Santa Barbara, CA) has purchased 250 ECi instruments, which are now in the process of being installed.

New Hepatitis Test For Drug Therapy Monitoring

OCD is developing a test to monitor interferon drug treatment for people with HCV and hopes to have it on the U.S. market for research use only (RUO) by the end of this year, according to Burzik. She estimated that the worldwide market opportunity for HCV diagnostics for interferon therapy could be as high as $1 billion per year. Burzik noted that 170 million people in the world are estimated to be infected with HCV. Interferon drug therapy is effective in treating approximately 50-60% of people with HCV. Patients on interferon are tested every four weeks to monitor dosage over the course of a typical 6-9 month therapy.

With approximately 50 million units of whole blood plasma collected and tested worldwide each year, Burzik estimates that a vCJD blood screening test could generate $500 million in revenue annually

Human Blood Test For "Mad Cow" Disease

OCD announced in April a research collaboration with Caprion Pharmaceuticals (Montreal, Canada) to develop a human blood test for new variant Creutzfeldt-Jacob Disease (vCJD). OCD has taken an option to license Caprion's prion technologies, including Caprion's unique monoclonal antibodies for the agent behind vCJD, the human equivalent of Mad Cow Disease, for human diagnostic applications. vCJD is a fatal neurodegenerative condition which has caused more than 90 deaths in Europe. Currently, definitive diagnosis can only be made post-mortem through a brain biopsy. Burzik said the goal of the OCD/Caprion collaboration is to develop a vCJD test that can be used in existing blood screening systems.

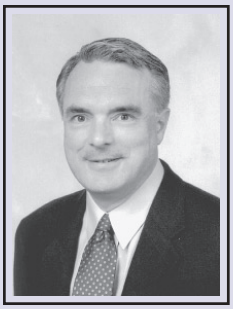
Cellular & Molecular Diagnostics

Late last year, OCD signed a development, license, and supply agreement with Immunicon Corp. (Huntingdon, PA). Privately held Immunicon has developed a technology which can detect and extract from blood samples individual cancer cells (out of a background of more than 100 million cells).

Under the agreement, Immunicon is responsible for product development, bulk reagent supply, and manufacture of instrumentation systems. OCD is responsible for product finishing, sales, distribution, and service. OCD has formed a separate business division named Advanced Diagnostic and Cellular Systems to focus on bringing products developed from this agreement to market.

Valliant said the focus of development efforts is on cancer diagnostics for the detection and staging of breast, ovarian, colorectal, and prostate cancer. He noted that clinical trials for diagnostics developed by Immunicon/OCD are currently underway at prestigious cancer centers such as MD Anderson and Sloan Kettering. Valliant said Immunicon/OCD could have a diagnostic instrument for detecting and staging cancer on the market by mid-2003.

Lifescan Seeks To Regain Top Position In Glucose Market



Eric Milledge
Company Group Chairman
Lifescan

"We're totally committed to getting Lifescan back into a global leadership position," its chairman Eric Milledge told analysts at J&J's recent Medical Devices & Diagnostics Business Review meeting. Lifescan (Milpitas, CA) lost its position as the top provider of meters and strips for self-monitoring of blood glucose (SMBG) in 1997 to Roche Diagnostics. The worldwide market for SMBG is approximately $4 billion and Roche is the current leader with a 32% share, followed by Lifescan with a 26% share, according to Milledge.

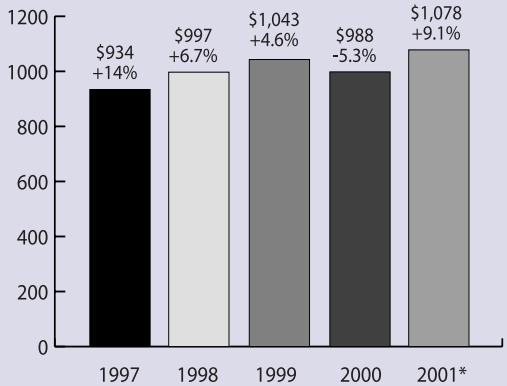
However, Milledge said Lifescan is beginning to see signs of a turnaround, including a 9.1% increase in sales in the first six months of 2001 to $529 million. Driving growth, according to Milledge, is the launch of Lifescan's One Touch Ultra, an SMBG system that requires only a 1.0 uL sample of blood from either the fingertip or arm. The meter provides results in about five seconds compared with 40-45 seconds for most competing brands. Milledge noted that less painful SMBG systems such as One Touch Ultra are leading users to increase the number of tests they perform each day.

Milledge also cited Lifescan's efforts to get on the formularies of managed care plans. He noted that managed care plans account for 45% of all sales of SMBG products in the U.S. Lifescan now has access to 93% of all managed care lives in the U.S., he said, and is a preferred provider to the three top pharmacy benefit management companies: Merck-Medco, AdvancePCS, and Express Scripts.

Milledge said Lifescan has begun test-marketing TV commercials for One Touch Ultra, marking the first time an SMBG system has been marketed on TV. The commercial features blues musician BB King (who has diabetes) and is currently being piloted in Minneapolis, MN and Tampa, FL.

New products include the InDuo system, the world's first combined blood glucose monitoring and insulin pen dosing system. The hand-held product combines Lifescan's One Touch Ultra meter with Novo Nordisk's Innovo pen and cartridge for patient self-dosing of insulin. The combined product will retail for $99 and be launched in the U.S., Canada, and Germany by year's end, according to Milledge.

Lifescan Revenue *($MM)*



*Projected from reported first-half 2001 results
Source: *DTTR* from Lifescan

Lifescan has also received FDA clearance to market its Harmony INR Monitoring System for prothrombin time (PT) testing in doctor's offices and patient home use (physician's prescription required) for management of oral anticoagulation therapy (*i.e.*, Coumadin). National Medicare coverage has not been established for home-use PT tests, but Milledge expects a coverage decision to be announced within the next few months. Lifescan will introduce Harmony by mid-2002, he said.

Bayer To Keep Pharmaceutical Business

Bayer (Leverkusen, Germany) has announced that it will retain its pharmaceuticals business, ending weeks of speculation that it might sell the troubled unit. Bayer was forced to review its pharmaceuticals strategy following last month's withdrawal of its cholesterol-lowering drug Baycol/Lipobay, which has been linked to more than 50 deaths (*DTTR, Sept. '01, p. 1*).

"The supervisory board and the board of management agree that, despite the major setback, these [pharmaceutical] activities remain a core business of the Bayer Group," said management board chairman Manfred Schneider in a Sept. 13 press release.

But Bayer also announced new plans to make its healthcare unit (includes pharmaceuticals, consumer products, and diagnostics) a separate legal entity within the Bayer Group. The move will give Bayer "greater flexibility for necessary strategic partnerships," said Schneider. He said Bayer is open to joint ventures for its healthcare unit, as long as it retains majority control.

Bayer's healthcare unit had revenue of 10.028 billion euros (US $9.3 billion) last year, including 1.965 billion euros (US $1.8 billion) from diagnostics

In addition, Bayer announced that Werner Wenning, the company's head of finance, will become Bayer's next chairman, replacing Schneider, who is scheduled to step down in April 2002. Wenning has been a Bayer employee since 1966 and a management board member since 1997.

Bayer's decision to retain its "four pillar" operating structure (healthcare, agrochemicals, polymers, and chemicals) has disappointed many investors. They believe the value of the company's healthcare business is not fully recognized within Bayer's conglomerate structure. "Bayer management's stubbornness stands in the way of doing what's best for the shareholders," says Thomas Shrager, managing director at the investment firm Tweedy, Browne Co. (New York City), which owns 4.5 million shares (valued at about $129 million) of Bayer. Shares of Bayer have fallen 47% so far this year to 29.35 euros per share.

Medtronic Completes Acquisitions Of MiniMed/MRG

Medtronic Inc. (Minneapolis, MN) completed its $3.6 billion acquisitions of MiniMed Inc. (Northridge, CA) and Medical Research Group (MRG-Sylmar, CA) on Aug. 28. The acquisitions include a cash price of $3.2 billion for MiniMed and $400 million for MRG. The acquisitions were first announced on May 30 and put Medtronic into the self-monitoring blood glucose market (*DTTR, July '01, p. 1*).

MiniMed, which reported $176.311 million of revenue for the six months ended June 30, 2001, derives most of its revenue from the sale of insulin delivery pumps. However, the company is working with MRG to develop an implantable "artificial pancreas" that monitors blood glucose levels, then automatically delivers the appropriate amount of insulin.

MiniMed and MRG will be combined to create Medtronic MiniMed, with headquarters in Northridge, CA. Terry Gregg, former president and chief operating officer of MiniMed, will be president of the new unit.

Abaxis Wins Contracts With Holland America, Princess Cruises

Abaxis Inc. (Union City, CA) has announced the sale of 14 Piccolo point-of-care blood chemistry analyzers to the Holland America Cruise Line, a subsidiary of Carnival Corp. (Miami, FL), the largest cruise company in the world. Separately, Abaxis has announced the sale of 12 Piccolo systems to Princess Cruises, part of P&O Princess Cruises (London, England). In both sales, the Piccolo systems replaced slide-based products, which failed to meet the needs of the cruise lines, according to Abaxis.

The company's Piccolo system consists of a 6.9 kilogram, portable analyzer and a series of 8 cm diameter single-use reagent cartridges. The system performs multiple tests on whole blood using either venous or fingerstick samples. Abaxis markets five multi-test reagent panels covering a total of 19 different tests. Results are provided in 14 minutes.

The human diagnostics market is relatively new to Abaxis. The company has been focused on and derives most of its revenue from the sale of diagnostic equipment to the veterinary market under the brands Vetscan (for blood chemistry) and Vetscan HMT (for hematology). Clint Severson, chairman of Abaxis, says that early data from the company's human market customers indicate use of approximately three reagent discs per day, an increase compared to the 1.9 reagent discs used daily on average in the veterinary market.

In the three months ended June 30, 2001, Abaxis reported net income of $217,000 vs. $425,000 in the same period a year ago; revenue was up 6% to $7.539 million. Abaxis sold 394,000 discs (average revenue of $11.08 per disc) during the quarter vs. 313,000 discs (average revenue of $10.58) in the same period a year ago. The company sold a total of 354 analyzers (including 22 Piccolos sold domestically) at an average revenue of $8,059 per machine during the quarter vs. 467 analyzers (including eight Piccolos sold domestically) at $7,923 per machine in the same year-ago period.

Careside Posts $7.5 Million Loss

Careside Inc. (Culver City, CA) has reported a net loss of $7.482 million for the second quarter of 2001 vs. a net loss of $3.858 million in the same quarter a year ago; revenue fell to $192,000 from $245,000. Since its inception in November 1996, Careside has accumulated $52.2 million in losses on negligible sales. As of June 30, 2001, the company's balance sheet showed $5.624 million in cash holdings.

The company's Careside System is a point-of-care blood analyzer with a menu of 59 tests in clinical chemistry, electrochemistry, coagulation and hematology. Careside reports that it has placed 40 Careside Analyzers through mid-July. The company also reports that its sales and marketing personnel have trained more than 400 distributor representatives from Fisher Scientific, Labsco, and several local distributors. As a result, the company expects its sales to increase in the third and fourth quarters.

Myriad's Breast Cancer Gene Patents Under Fire

Researchers, physicians, and politicians in France, Canada, and England are seeking to overturn patents held by Myriad Genetics (Salt Lake City, UT) that they claim give Myriad a monopoly on tests to screen for breast and ovarian cancer. The outcome of these disagreements, which may take years to resolve, could determine whether or not patents on specific genes can be upheld. The outcome could also have significant consequences for the dozens of diagnostic and pharmaceutical companies that are investing hundreds of millions of dollars to discover and patent disease-related genes for use in genetic tests and drug therapies.

Executives at Myriad Genetics could not be reached for direct comment. However, the company has stated that it intends to protect its commercial rights and will exercise its exclusive rights to perform diagnostic testing on BRCA1 and BRCA2 genes

On Sept. 12, the Paris-based cancer research group Institut Curie announced it would fight Myriad's European patents on two breast-cancer susceptibility genes, BRCA1 and BRCA2. Myriad discovered the genes in the early 1990s and began marketing a predictive test (named BRACAnalysis) for hereditary breast cancer in late 1996. Myriad got U.S. patents for the genes in 1996 and received patents in Canada and from the European Patent Organization earlier this year.

Hereditary breast cancer is believed to account for approximately 10% of all cases of breast cancer. Myriad's patents give it exclusive rights to perform diagnostic testing on BRCA1 and BRCA2. That means that full DNA sequencing of the genes must be done using Myriad's proprietary BRACAnalysis test at its laboratory in Salt Lake City at a price of $2,600 per test.

Institut Curie, which is developing new diagnostics and treatments for cancer, says the patents jeopardize cancer research in Europe and force hospitals to pay three times as much for the Myriad technique as for cheaper methods of testing that could be carried out if the patents did not exist. It plans to file an opposition procedure with the European Patent Office in Munich to have the patents annulled.

Separately, Mike Harris, the Ontario Premier, announced on Sept. 19 that his government will ignore Myriad's patents and continue to perform other genetic screening tests for breast cancer. In a major speech to the Ontario Advisory Committee on Predictive Genetic Technology, Harris said Canadian law should be amended to prevent private firms from patenting genes. "Unlike new drugs, genes aren't invented—they are discovered. They have always existed ... The benefits of a worldwide effort such as the Human Genome Project should not be the property of a handful of people or of companies." Harris said his administration continues to pay for lower-cost predictive breast and ovarian cancer tests despite Myriad Genetic's patents. The most frequently used alternative to Myriad's test is the PTT test, which analyzes protein changes in the breast-cancer genes and costs about $800 to perform.

In addition, Britain's department of health is trying to negotiate a price reduction while permitting National Health Service doctors to continue their own breast cancer testing. And, the Cancer Research Campaign (CRG), a British charity group, has blocked a bid by Myriad to patent the BRCA2 gene in Britain. James Davidson, managing director of CRG, says CRG blocked the patent on grounds that it funded the British research that led to BRCA2's identification.

IVD Stocks Drop 5% In Latest Four Weeks

The G-2 Diagnostic Stock Index fell 5% in the four weeks ended Sept. 17. Five stocks in our index went up in price, 15 fell. Since the start of the year, the index has risen 5%, while the S&P 500 is down 21% and the Nasdaq is down 36%.

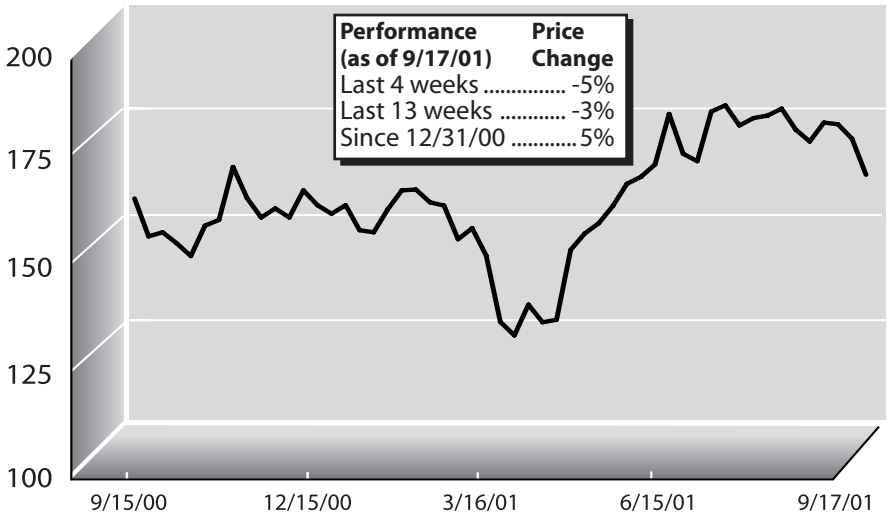
Cholestech Corp. (Hayward, CA) jumped 41% to $12.37 per share for a market capitalization of $159 million. The company has issued no press releases and made no announcements over the past several weeks, indicating that investors may be speculating that the company is a takeover candidate. Cholestech reported net income of 1.245 million in this year's second quarter vs. $949,000 million in the same period a year ago; revenue was up 35% to $12.378 million. Cholestech makes the Cholestech LDX System, a portable CLIA-waived analyzer that measures total cholesterol, LDL ("bad" cholesterol), HDL ("good" cholesterol), and alanine aminotransferase (ALT). Cholestech also manages promotional corporate wellness programs for pharmaceutical companies marketing lipid-lowering statin drugs.

Affymetrix (Santa Clara, CA) fell 25% to $16.49 per share for a market cap of $1 billion. Year-to-date, shares of Affymetrix have dropped 78%. The company has suffered as sales of its GeneChip product line (primarily used by pharmaceutical companies) have slowed. In the three months ended June 30, 2001, the company reported a net loss of $10.156 million vs. a net loss of $6.092 million in the same period last year; revenue edged up 3% to $46.684 million.

Other IVD stocks declining in price included **i-Stat** (East Windsor, NJ), which fell 21% to $6.75 per share, and **Cytyc** (Boxborough, MA), which fell 17% to $21.40 per share.

Shares of **Bayer**, which trade on the German stock exchanges, have fallen 47% so far this year to 29.35 euros per share; **Roche** non-voting equity shares, which trade on the Zurich Stock Exchange, are down 36% year-to-date to 105.25 Swiss francs per share.

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 20 diagnostic test and equipment makers.

% price change, 4 weeks ended 9/17/01

	Price	Chg
UP		
Calypte	$0.29	12%
Cholestech	12.37	41%
Diametrics	4.04	5%
Diagnostic Products	40.50	9%
Johnson & Johnson	55.82	4%
DOWN		
Abbott Labs	50.53	-3%
Affymetrix	16.49	-25%
Bio-Rad	48.80	-5%
Beckman Coulter	43.13	-8%
Becton Dickinson	36.15	-1%
Biosite	23.77	-15%
Careside	2.55	-11%
Cygnus	7.70	-17%
Cytyc	21.40	-17%
Digene	25.51	-13%
Inverness Medical	37.00	-1%
i-Stat	6.75	-21%
Meridian	4.80	-5%
Quidel	4.12	-13%
Ventana	24.91	-11%

G-2 Insider

We at Washington G-2 Reports join in the Nation's mourning for the innocent lives lost in the senseless, despicable terrorist attacks of Sept. 11. Our thoughts and prayers go out to those who have lost loved ones.

If there is any bright spot that can be recognized in the face of this tragedy, it is in the way the Nation has rallied to help those in need. Acts of charity from IVD companies have included:

Johnson & Johnson (New Brunswick, NJ), which through the charity organization AmeriCares, delivered a half-ton of medical and other relief supplies by helicopter the afternoon of Sept. 11 to St. Vincent's Hospital in New York City, the hospital located closest to the World Trade Center Towers disaster. J&J also used its own corporate airplanes to deliver blood screening kits to blood centers in the Southwest and the West Coast, to meet a critical shortage of these vital blood system components.

J&J, which is a leading supplier of blood screening instruments and reagents, says it is working with the American Red Cross and America's Blood Centers across the country to help ensure an ongoing supply of blood. Overall, J&J has pledged $10 million in financial and product aid to help meet the needs of those affected by the terrorist attacks.

Abbott Laboratories (Abbott Park, IL) has donated $2 million to the September 11th Fund, an agency created by the United Way and the New York Community Trust, which will forward the money to the American Red Cross and AmeriCares. Becton Dickinson (Franklin Lakes, NJ) has also pledged $1 million to the September 11th Fund.

Company References

Abaxis 510-675-6500

Abbott Labs 847-937-6100

ABX (Irvine, CA) 888-903-5001

Avocet 888-286-2381

Bayer Diagnostics 914-631-8000

Becton Dickinson 201-847-6800

Careside 310-338-6767

Carter-Wallace 212-339-5000

Cholestech 510-732-7200

Johnson & Johnson 732-524-0400

Lifescan 800-227-8862

Given Imaging (011) 972-4-909-7777

Medtronic 763-514-4000

Myriad Genetics 801-584-3600

Ortho-Clinical Diagnostics 908-218-1300

Signature BioScience 510-576-2426

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